# European Paediatric Cancer Community Recommendations for Improvement of Rules on Cross-border Access to Healthcare

## Proposals for the European Parliament Report on Modernised rules for patients' rights in cross-border healthcare 2025/2206 (INL)

## INTRODUCTION AND BACKGROUND

**Childhood Cancer International – Europe (CCI-E)** and **the European Society for Paediatric Oncology (SIOPE)** welcome the European Parliament's ongoing review of the rules on cross-border access to healthcare through the Report 2025/2206 (INL). Our community has examined the implementation of the EU cross-border healthcare rules and the implications for children and young people with cancer through the CATCH-Europe project, conducted jointly with the European Reference Network on Paediatric Cancer (ERN PaedCan) and the academic clinical trial network Innovative Therapies for Children with Cancer (ITCC). The main conclusions and recommendations of the project are set out in this present joint position paper and have informed our present recommendations to the European Parliament Report, including its Annex.

Each year, more than 35,000 children and young people in Europe are diagnosed with cancer, and more than 6,000 young patients die of cancer[1]. Inequalities in access to treatment, care and research across Europe contribute to an estimated 20% gap in survival rates, with Eastern Europe countries facing the greatest challenges[2].

**Because childhood cancers are rare and complex diseases, cross-border access to care, clinical trials and innovation is essential – not optional - to ensuring that all children and young people have the best possible chance of survival and quality of life.**

Yet evidence from the CATCH-Europe project shows that families still face slow, unclear and non-uniform procedures when accessing care and research abroad: unsuccessful attempts to access specialist care in another Member State are reported in up to four countries, and half of all cross-border requests to join potentially life-enhancing early-phase clinical trials end in failure.

SIOPE and CCI-E have identified **seven priority areas** which require focused consideration during the revision of the current rules on cross-border healthcare. We detail below the rationale for each along with:

1. **Articles to maintain** in the current Draft Report 2025/2206 (INL) that are strongly aligned with the evidence-based needs in childhood cancer as identified in the CATCH Europe project.

2. **Proposed amendments for inclusion in the Annex** of the Draft Report 2025/2206 (INL) in view of a potential revision of the EU Cross-Border Healthcare Directive itself.

[1] Cancer Today, 2023 Nov 30, https://gco.iarc.who.int/today/home
[2] Gatta G, Botta L, Rossi S, Aareleid T, Bielska-Lasota M, Clavel J, et al. Childhood cancer survival in Europe 1999-2007: results of EUROCARE-5--a population-based study. Lancet Oncol. 2014 Jan;15(1):35–47.


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## PRIORITY AREAS FOR PAEDIATRIC CANCER COMMUNITY

### 1. Guarantee fast, transparent authorisation and reimbursement

Prior authorisation and reimbursement timelines under the current legislative set-up vary hugely between Member States - some decide within weeks, others within months - leaving families in financial uncertainty during a time-critical illness. A child's medical condition can change faster than administrative procedures, so delayed referrals reduce the chances of successful treatment.

**Recommendation**: Make cross-border referral and authorisation processes clear, fast, and transparent, with guaranteed timelines and reduced administrative burden - such as by setting maximum timelines for prior authorisation and reimbursement decisions.

### 2. Extend cross-border healthcare rules to clinical trials and innovation

In paediatric oncology, clinical trials are part of standard care. More than 40% of children and adolescents with cancer in some western European countries are treated within a trial. In addition, for patients who no longer have access to curative standard treatments (those with refractory or relapsed malignancies), participation in early-phase clinical trials is the international standard of care. These trials can provide access to novel medicines which may prolong survival and improve quality of life when no other therapeutic options remain. Because these trials are rare and resource-intensive, they are organised in only a handful of European countries to centralise expertise and recruit enough patients, forcing families to travel abroad at great expense. Clinical trials covering innovative therapies, such as CAR-T cell treatments and precision medicines, are similarly restricted to select centres[3], and patients who need them require access and reimbursement of treatment in another Member State.

Despite this evidence, cross-border participation in clinical trials is not addressed by EU legislation, and trials remain excluded from reimbursable care under the Directive - leaving sick children without a clear path to potentially life-saving treatment abroad.

**Recommendation**: Integrate clinical trials and access to innovative therapies in the application of EU cross-border healthcare legislation.

### 3. Ensure predictable funding, including travel and living costs

Even when treatment itself is covered, families report having to pay upfront for travel, accommodation and lost income - costs that can determine whether a child receives life-saving treatment abroad at all. In practice, many families end up relying on charity funding to cover these costs, and sometimes even medical costs when these are not covered by reimbursement insurance. Cross-border care can mean uprooting family life for months: when siblings cannot accompany a sick child abroad, the separation causes significant emotional distress and family disruption that compounds an already devastating situation.

**Recommendation:** Ensure sustainable resourcing and insurance continuity through consistent authorisation processes, dedicated funding schemes, coverage of associated travel and accommodation costs, and families' protection against socio-economic disruptions in the lead-up to, during and after treatment.

[3] Teodora Lalova et al., 'Cross-Border Access to Clinical Trials in the EU: Exploratory Study on Needs and Reality', Frontiers in Medicine 7 (22 October 2020): 585722, https://doi.org/10.3389/fmed.2020.585722.

### 4. Protection of social rights for families of patients receiving cross-border care

Parents of children with cancer are frequently required to relocate, sometimes for extended periods, to access specialised treatment or clinical trials only available in another Member State. Where this relocation requires establishing formal domiciliation abroad, it can trigger the loss of home-country social security coverage, unemployment benefits, or other residence-linked entitlements. This creates a serious disincentive for families to seek life-saving care abroad and effectively penalises them for exercising the very rights this Directive is meant to guarantee. Article 5 of the Directive currently sets out the responsibilities of the Member State of affiliation towards patients receiving cross-border healthcare (i.e., reimbursement, information, medical follow-up and access to medical records) but is silent on the preservation of patients' and accompanying family members' social security status at home.

**Recommendation**: Amend the Directive to ensure that patients, and where relevant their accompanying family members or caregivers, do not lose their social security entitlements, residence-based rights or benefits in the Member State of affiliation as a result of a temporary stay or change of residence in another Member State in the framework of this Directive. This amendment ensures that necessary cross-border treatment does not come at the cost of a family's social protection at home.

### 5. Guarantee early, accessible, multilingual information

Language barriers were reported by families attempting cross-border care in the CATCH project. For instance, very few national websites offer clear, up-to-date guidance on rights and procedures.

**Recommendation:** Encourage Member States to provide accessible, multilingual and regularly updated information on specialised centres, networks, open clinical trials and reimbursement rights for both families and health professionals.

### 6. Create national cross-border care navigator services for families with allocated financing

National Contact Points, intended to guide families, may lack the resources, training and coordination to do so effectively. Patient organisations play an indispensable role by filling this gap informally (e.g., translating documents, coordinating logistics) many of them without proper funding or formal recognition.

**Recommendation**: Set up national cross-border 'navigators' formally integrating patient organisations as partners in guiding families through medical, legal and logistical steps. In addition, strengthen the role and expert staffing of National Contact Points, especially for all paediatric rare diseases.

### 7. Ensure the sustainability of cross-border networks, European organisations and research platforms in paediatric oncology

ERN PaedCan aims to reduce inequalities in childhood cancer survival by providing equal access to high quality, accessible, and cost-effective cross-border healthcare for children and young people with cancer. This network brings together 90 hospital institutions. Other networks and European organisations are active in paediatric cancers such as SIOPE, CCI Europe and ITCC; they also play a key role and collaborate with ERN PaedCan.

**Recommendation:** Secure long-term, dedicated funding for paediatric cancer networks – an area where cross-border aspect is central and exchange of expertise is required for access to specialist care, clinical trials, and effective advocacy.

## ABOUT EUROPEAN CHILDHOOD CANCER ORGANISATIONS

**Childhood Cancer International - Europe (CCI-E, or CCI Europe)** represents childhood cancer parent and survivor groups as well as other childhood cancer organisations in Europe: more than 60 organisations in over 30 European countries are members of CCI-E. CCI Europe works together with all relevant stakeholders for the same goal: to help everyone affected by childhood cancer thrive, free from lasting impact. **(www.ccieurope.eu)**

**The European Society for Paediatric Oncology (SIOPE, or SIOP Europe)** is the single united European organisation representing all professionals working in the field of childhood cancers. With more than 2,500 members across 35 countries, SIOP Europe is leading the way to ensure the best possible care and outcomes for all children and adolescents with cancer in Europe. **(www.siope.eu)**

## 1. ARTICLES TO MAINTAIN IN THE REPORT ON MODERNISED RULES FOR PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE 2025/2206 (INL) THAT ARE STRONGLY ALIGNED WITH THE EVIDENCE-BASED NEEDS IN CHILDHOOD CANCER

Please find below the priorities identified by the childhood cancer community, listing the articles that shall be maintained in the Draft Report 2025/2206 (INL).

| Section | Article number & Text from the Report | Rationale |
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| **European Reference Networks: Sustainable Funding** | ***10**. Encourages the reinforcement and sustainable financing of ERNs as central engines of cross-border clinical cooperation; urges the Commission, in this regard, to propose a framework granting ERNs a distinct legal status to enable them to directly apply for EU funding, sign contracts, and effectively working as unified entities within national health systems;* | ERN PaedCan has been a milestone for childhood cancer care networking and coordination in Europe. It aims to reduce inequalities in childhood cancer survival by providing equal access to high quality, accessible, and cost-effective cross-border healthcare. It is essential that it continues this work and is appropriately resourced. |
| **Rights of Persons with Disabilities, Rare and complex diseases** | ***13.** Calls on the Commission and Member States to formally recognise in the revised legislative framework that rare and complex diseases require, by their very nature, highly specialised expertise, multi-disciplinary care coordination, and access to cutting-edge research and innovation that cannot be equitably or consistently delivered within national borders alone; and to formally recognise that, accordingly, access to cross-border healthcare for patients with rare and complex diseases must be treated not as an exception but as a structural feature of the Union's healthcare system, deserving of dedicated legal provisions, guaranteed funding, and proactive facilitation by Member States;* | Because childhood cancers are rare and complex diseases, they require highly specialised, multi-disciplinary care and concentrated expertise. No single country can deliver the full range of optimal care, clinical trials and innovation on its own. |
| | ***14.** Calls on the Commission to extend the scope of EU cross-border healthcare legislation to explicitly cover participation in clinical trials for rare and complex diseases, including early-phase trials, recognising that, for conditions in which low-intervention trials form part of standard treatment and experimental therapies offer a second chance to patients with relapsed or refractory malignancies, access to research conducted in selected centres across Europe is an essential, rather than optional, component of care.* | In paediatric oncology, clinical trials are part of standard care. More than 40% of children and adolescents with cancer in some western European countries are treated within a trial. In addition, for patients who no longer have access to curative standard treatments (those with refractory or relapsed malignancies), participation in early-phase clinical trials is the international standard of care and can provide access to novel medicines potentially prolonging survival and improving quality of life, when no other therapeutic options remain. Because |

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| | | these trials are rare and resource-intensive, they are organised in only a handful of European countries to centralise expertise and recruit enough patients, forcing families to travel abroad at great expense. Cross-border participation in clinical trials is not addressed by EU cross-border healthcare Directive, and trials remain excluded from reimbursable care - leaving sick children without a clear path to potentially life-saving treatment abroad. |
| **Special Protection and Prioritisation for Children** | ***15.*** *Calls on the Commission and Member States to establish child-specific provisions within the cross-border healthcare framework guaranteeing priority access to paediatric specialist care and, expedited authorisation procedures, and amending Article 7(4) of Directive 2011/24/EU to ensure the mandatory reimbursement of travel and accommodation costs for both the child and their accompanying parents or guardians, in recognition of children's particular vulnerability and the inseparability of family support from effective paediatric care;* | Even when treatment itself is covered, families report having to pay upfront for travel and accommodation - costs that can determine whether a child receives life-saving treatment abroad at all.<br>In practice, many families end up relying on charity funding to cover these costs. Cross-border care can mean uprooting family life for months: when primary caregivers and siblings cannot accompany a sick child abroad, the separation causes significant emotional distress and family disruption that compounds an already devastating situation. |
| | ***16.*** *Calls on the Commission and Member States to recognise the specific medical, social and emotional needs of children with rare and complex diseases and to require each Member State to establish national cross-border navigator services providing personalised, cost-free guidance for young patients, their families and their caregivers throughout the entire cross-border care pathway, thereby reducing the disproportionate administrative burden placed on families navigating fragmented health systems;* | National Contact Points, intended to guide families, may lack the resources to do so rapidly and effectively particularly for fast-progressing diseases like childhood cancer. Language and other practical barriers were reported by families. Patient organisations play an indispensable role by filling these gaps informally (e.g., translation of documents, coordinating logistics), many without proper funding or formal recognition. |
| | ***17****. Calls on the Commission and Member States to provide dedicated, multi-annual infrastructure funding to strengthen and expand existing cross-border networks in rare and complex disease areas, including the European Reference Networks established under Directive 2011/24/EU, with a view to fostering specialist capacity across the Union and reducing geographic disparities to access to expertise;* | ERN PaedCan and other complementary networks and European organisations are active in paediatric cancer and collaborate with each other. Secure long-term, dedicated funding for paediatric cancer networks – an area where the cross-border aspect is central and exchange of expertise is required for access to specialist care, clinical trials, and effective representation – is essential.<br><br>**NB**: as similar networking may occur in other rare diseases areas including those covered by the other 23 ERNs, **this article may be best placed in section 'Rights of Persons with Disabilities, Rare and complex diseases'.** |

## 2. PROPOSED AMENDMENTS FOR INCLUSION IN THE ANNEX OF THE DRAFT REPORT 2025/2206 (INL) – 'RECOMMENDATIONS FOR DRAWING UP A EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE AMENDING DIRECTIVE 2011/24/EU ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE'

Out of the seven priorities listed above, CCI Europe and SIOPE propose amendments for three of them. Please find below the corresponding articles that we suggest amending. Highlighted in **gold are the amendments** that we would like to see in the revision of the rules on cross-border access to healthcare legislation.

| **Articles of the Directive on the application of patients' rights in cross-border healthcare** | **Suggested amendments from CCI-E & SIOPE** |
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| **PRIORITY 1. Extension of cross-border healthcare rules to clinical trials and innovation** | |
| **Recitals:** | |
| (55) Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (1), and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2). | (55) Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (1), and they are all serious, chronic and often life threatening. Some patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy, difficulties which were also recognised by the Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2).<br><br>**(55a) [NEW] For rare and complex diseases, access to cross-border healthcare includes access to clinical trials, including early-phase trials. Low-intervention trials form part of standard treatment for certain conditions, while experimental therapies offered in selected centres may offer a second chance to patients with relapsed or refractory malignancies. Access to research conducted** |

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| | **in centres across Europe is therefore an essential component of care for these patients.** |
| **Directive Article 12. European Reference Networks** | |
| 1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.<br><br>2. European reference networks shall have at least three of the following objectives:<br><br>[…]<br><br>(c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare; | 1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.<br><br>2. European reference networks shall have at least three of the following objectives:<br><br>[…]<br><br>(c) to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare, **including access to relevant clinical trials**, for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare; |
| **Directive Article 13. Rare diseases** | |
| The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to: | The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to: |

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| (a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;<br><br>(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation. | (a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;<br><br>(b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.<br><br>(c) **[NEW] ensure that patients with rare, complex or life-threatening diseases are made aware of, given access to and participation in relevant clinical trials, including early-phase trials, conducted at healthcare providers or centres of expertise in another Member State.** |
| **PRIORITY 2. Social Rights and Reimbursements** | |
| **Recitals:** | |
| (34) Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross- | (34) Member States of affiliation should give patients the right to receive at least the same benefits in another Member State as those provided for by the legislation of the Member State of affiliation. If the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorisation or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation. The fact that the obligation to reimburse cross-border healthcare under this Directive is limited to such healthcare that is among |



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| border healthcare under this Directive is limited to such healthcare that is among the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory. | the benefits to which the patient is entitled within its Member State of affiliation does not preclude Member States from reimbursing the cost of cross-border healthcare beyond those limits. Member States are ~~free, for example,~~ **encouraged**[4] to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory. |
| **Directive Article 5. Responsibilities of the Member State of affiliation** | |
| The Member State of affiliation shall ensure that:<br><br>(a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;<br><br>(b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State…<br><br>[….] | The Member State of affiliation shall ensure that:<br><br>(a) the cost of cross-border healthcare is reimbursed in accordance with Chapter III;<br><br>(b) there are mechanisms in place to provide patients on request with information on their rights and entitlements in that Member State…<br><br>[….]<br><br>**(e) [NEW] patients, and where relevant their accompanying family members or caregivers, do not lose their social security entitlements, residence-based rights or benefits in the Member State of affiliation as a result of a temporary stay in or change of residence to another Member State in the framework of this Directive.** |

[4] This proposed amendment is based on a policy recommendation and proposed amendment from the Policy Department for Transformation, Innovation and Health, DG for Economy, Transformation and Industry; Briefing request by the SANT Committee, "Legal Expertise on modernised rules for patient's rights in cross-border healthcare: the unexploited potential of Directive 2011/24", PE 786.425, June 2026, p. 19 (link: https://www.europarl.europa.eu/RegData/etudes/BRIE/2026/786425/ECTI_BRI(2026)786425_EN.pdf )

| Directive Article 7. General principles for reimbursement of costs | |
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| [….] | [….] |
| 4. The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received. | 4. The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received. |
| Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost. | Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost. |
| The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs. | The Member State of affiliation may decide to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs. **For children receiving cross-border healthcare, the Member State of affiliation shall reimburse the travel and accommodation costs of the child and of one or more accompanying parents, siblings or legal guardians, in recognition of the inseparability of family support from effective paediatric care.** |
| [….] | [….] |

| PRIORITY 3. Navigators | |
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| **Directive Article 6. National contact points for cross-border healthcare** | |
| 1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the national contact points consult with patient organisations, healthcare providers and healthcare insurers.<br><br>[…] | 1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. The Commission and the Member States shall make this information publicly available. Member States shall ensure that the national contact points consult **and cooperate**[5] with patient organisations, healthcare providers and healthcare insurers.<br><br>[…]<br><br>**6. [NEW] Member States should establish national cross-border navigator services to provide personalised, cost-free guidance to children with rare or complex diseases and their families throughout the cross-border care pathway, including administrative, linguistic and logistical support.** |

[5] This proposed amendment is based on a policy recommendation and proposed amendment from the Policy Department for Transformation, Innovation and Health, DG for Economy, Transformation and Industry; Briefing request by the SANT Committee, "Legal Expertise on modernised rules for patient's rights in cross-border healthcare: the unexploited potential of Directive 2011/24", PE 786.425, June 2026, p. 20 (link : https://www.europarl.europa.eu/RegData/etudes/BRIE/2026/786425/ECTI_BRI(2026)786425_EN.pdf).



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