# Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare

Abstract

Executive Summary

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# Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare (SANTE/2021/B2/01)

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## ABSTRACT

The present study supports the European Commission in its ex-post evaluation of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare to take stock on its achievements and shortcomings ten years after its adoption. Relying on an extensive review of the literarure, a public consultation and targeted consultation activities, the study has found mixed results in the implementation of the Directive in terms of its provisions on patients' rights and cooperation between Member States in rare and low prevalence diseases and the establishment of the European Reference Networks (ERN), virtual networks involving healthcare providers across Europe. The Directive is a valuable legal instrument that has brought certainty and a clear legal framework for EU citizens to exercise their rights to cross-border healthcare and the free movement of services. It responds to current needs of patients and provides EU added value. However, in spite of removing some obstacles, some important barriers to cross-border care persist, such as a general lack of awareness of patients of their rights and entitlements, issues regarding information provision by Member States, as well as problems with the national implementation of some of its provisions that have led to complicated administrative procedures. While increasing patients flow across border is not an objective, these have been low under the Directive. This has meant that the impact of the Directive has been minor for national health systems, but also has limited the benefits for patients in general. In terms of cooperation in rare diseases and the ERNs, the study shows promising results in terms of of their relevance to address current and future patient needs as well as their effectiveness in meeting their objectives, their coherence with the wider EU policy and activities in the field of rare diseases and their clear EU added value. However, there are some issues affecting the effectivess of the networks, the most important being the weak integration of the networks in national health systems and the absence of reimbursement mechanisms for the time spent by healthcare professionals in virtual consultations.

## EXECUTIVE SUMMARY

The current legal framework for cross-border patient mobility in the EU rests on three legislative instruments: the Social Security Coordination Regulations, the Treaty on the Functioning of the European Union's (TFEU) provisions, as interpreted in case law of the Court of Justice of the European Union (CJEU), and the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

The Directive was adopted on 9 March 2011 and came into force on 24 April 2011 after several initiatives from the European Parliament (EP) on the matter[1]. The deadline for the transposition of the Directive was 25 October 2013; however, this was not completed in the Member States until late 2015.

The Directive has the following general objectives:

- **General Objective 1:** Setting out the rights for patients seeking healthcare abroad within a legal framework for cross-border healthcare in the EU.
- **General Objective 2:** To promote voluntary cooperation on healthcare between Member States, specifically in border regions, recognition of prescriptions issued in other countries, data collection on cross-border healthcare[2].
- **General Objective 3**: To create European Reference Networks (ERNs) on rare and low prevalence diseases that are fully operational including their organisational structure, to carry out their clinical, knowledge sharing, research, and other activities.
- **General Objective 4**: To give healthcare providers across the EU access to the best expertise and timely exchange of life-saving knowledge by combining skills of healthcare professionals involved and resources used.
- **General Objective 5**: To ensure that EU patients have better access to high quality healthcare services for rare or low prevalence complex disease

The Directive aims to provide a legal framework for cross-border healthcare in the EU. It sets out the rights and entitlements of patients seeking healthcare abroad. It also establishes the responsibilities of the Member States of affiliation and treatment in relation to provision of information to patients by National Contact Points (NCPs), prior authorisation, reimbursement, follow-up treatment, etc.

The 24 ERNs were established in 2017 as cross-Europe virtual healthcare provider networks to facilitate collaboration on rare or low prevalence complex diseases that require highly specialised knowledge or treatment. The Directive envisages them as a means of sharing knowledge and expertise, concentrating resources and

[1] The EP adopted in April 2005 a report on patient mobility and healthcare developments in the EU; in March 2007, it adopted a resolution on Community action on the provision of cross-border healthcare and in May 2007, a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market.

[2] Cooperation in the area of rare diseases is addressed in a separate intervention logic. E-health and health technology assessment are out of the scope of this assignment.

patients, and thereby improving diagnosis and treatment for those with rare conditions.[3] ERNs are expected to benefit patients in two main ways: by pooling of expertise for the diagnosis and treatment of patients and by generating and increasing the knowledge and expertise of the medical community in treating these diseases. The latter is to be achieved by increasing the number of known cases and thus enabling, among others, the development of registries and research collaboration.[4]

### *Objectives and scope of the study*

The objective of the study was to support DG SANTE in conducting an ex-post evaluation of the Directive 2011/24/EU, in accordance with the Better Regulation Guidelines (BRG). The study focused on the following areas:

- responsibilities of the Member State of treatment;
- responsibilities of the Member State where the patient is insured (reimbursement of costs for cross-border healthcare and the use of prior authorisation for reimbursement);
- provision of information to patients by the National Contact Points (NCPs);
- administrative procedures for cross-border healthcare;
- recognition of prescriptions issued in other Member States;
- mutual assistance and cooperation in healthcare in the border regions; and
- development of the European Reference Networks (ERNs) and cooperation in rare diseases.

The study included 42 evaluation questions structured around five overarching questions on the performance of the Directive following the evaluation criteria set out by the Commission's better regulation guidelines:

- **Effectiveness:** how effectively does the Directive operate in practice and what barriers remain to patients seeking cross-border healthcare?
- **Efficiency:** to what extent has the Directive delivered the expected benefits at proportionate costs, and what have been the administrative burdens for patients seeking healthcare in another Member State?
- **Relevance**: to what extent is the Directive relevant for meeting patients' needs to cross-border healthcare and what is the patients' awareness of their rights to cross-border healthcare?
- **Coherence:** how does the Directive interact with other legislation, such as the Regulation on the coordination of social security systems?
- **EU added-value:** in what ways has the Directive provided EU added value in terms of patient rights to cross-border healthcare and patient choice of healthcare services in the EU?

The main scope of the study was the ex-post evaluation of the Directive, since the deadline for its transposition in 2013 until the end of 2020 and covering Articles 1

[3] European Commission (2015). 'Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare'.
[4] European Commission (2018). 'Rare diseases 2008-2016'.

to 13[5]. However, it also included a forward-looking reflection and an assessment of its alignment with the future needs of patients in cross-border healthcare. In terms of geographical scope, the study covered EU-27 and EEA EFTA countries Norway, Iceland, and Liechtenstein.

### *Methodological approach and limitations*

The study was delivered over a period of eight (8) months. It was executed in three main phases: inception, data collection and analysis and synthesis, and divided in eight tasks.[6] The main tasks carried out involved:

- **Desk-based research**, including a literature review which rinvolved the revision and extraction of evidence from EU legislation, Staff Working Documents; reports and documents produced by and for the European Commission; additional academic papers, articles, theses and chapters. Through the different sources consulted, 236 documents were identified for abstract and/or full text screening, with a total of 121 academic papers and reports included in the analysis. The desk research also included a web-analysis of the information provided by the NCPs.

- **Public consultation** organised by the Commission between May and July 2021, obtaining 193 responses.

- **Field research**, including the following consultation activities with more than 285 stakeholders:

    - **interviews at EU and national level;**

    - **targeted surveys, questionnaires or information requests** to healthcare providers, patient ombudsmen, pharmacists and ERNs;

    - **case study on the recognition of medical prescriptions in four countries**, and

    - a **virtual workshop with stakeholders**, held on 9 November 2021.

- **Analysis of quantitative and qualitative data**, from which conclusions and recommendations were formulated.

The evidence collected and analysed through the methods explained above were triangulated at three different levels:

- **Triangulation of data**: primary data from stakeholder consultation activities and secondary data derived from the desk research.

[5] The provisions on cooperation in e-health (Article 14) and cooperation on Health Technology Assessment (Article 15) were excluded from the study as there were other parallel studies being conducted which addressed these topics.
[6] Originally the study covered nine tasks, but it was decided to cancel the

- **Triangulation of respondent groups**: NCPs, patient representatives, national and regional authorities, healthcare providers, the medical community, etc.

- **Triangulation of methods**: desk-based research, surveys, interviews, public consultation, workshops, case studies.

There are several limitations to the study that are important to highlight when considering the findings and conclusions presented in this report. These can be summarised as follows:

- **Stakeholder engagement**: Substantial efforts were made to engage stakeholders from all the groups identified in the Commission's stakeholder consultation strategy and across countries. While overall this objective was achieved, some groups were less engaged in the consultation activities.

- **Analysis of public consultation results**: although the number of responses received (193) was sufficient to conduct a robust analysis of general results, it was not high enough to allow sub-groups analyses. To mitigate this, respondents were (re)grouped in broader categories to allow some comparison (e.g., receivers and organisers/providers/payers of healthcare services). Differences in the views of these broader groups were reported only when they were statistically relevant.

- **Limited evidence to provide complete answers to some evaluation questions:** the literature review and consultation activities produced limited evidence on some issues, for example, the functioning of the system of prior notification; the use of the Directive compared to the Regulations and other parallel instruments in border regions; use of the Directive by different patient groups; reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients' insurance affiliation; coherence of the Directive with the Directive on the recognition of professional qualifications; and the application of the professional rules for the health service provider.

- **Cost-benefit assessment:** the methodology applied in the assessment of the Directive's costs and benefits is largely qualitative due to several limitations with the quantitative data.

In addition to these gaps, a general limitation that can be highlighted is that, despite the Directive's impact on all Member States, little research has been conducted on the topic and there is insufficient comparative research across multiple Member States. Therefore, there are important gaps in the knowledge and evidence available, with most research dating back several years.

To overcome some of the study's limitation, the presentation of the preliminary findings in different fora (virtual workshop, meeting of the ERN coordinators group, meeting of the cross-border healthcare expert group) has allowed to validate some of the main conclusions presented in this report. Stakeholders from all sectors have indicated that the results of the evaluation study are not surprising and in line to what they had expected.

## *Findings*

**Effectiveness:**

The Directive has contributed to removing obstacles to cross-border healthcare and to free movement of healthcare services mainly by:

- **bringing additional legal clarity** in relation to patients' rights to cross-border healthcare and establishing a framework that enables them to exercise these rights;
- **creating NCPs** and establishing clear obligations for Member States and healthcare providers in relation to the provision of information to patients, which has resulted in a gradual improvement of patients' awareness of their rights;
- **enhancing freedom of patients' choice of the healthcare services** in the EU by enabling access to healthcare abroad, for the most part, without prior approval[7], including private care.
- **regulating the recognition of medical prescriptions across the EU,** although there are some persisting issues in relation to the verification of prescriptions from other countries, including language barriers or pharmacists not being able to verify whether the prescription was issued by a doctor legally entitled to do this.

Moreover, there have been some indirect (and maybe unexpected) effects in several Member States where the Directive has acted as a driver for the development of (both domestic and cross-border) patients' rights and greater domestic transparency on treatment prices, rules, procedures and standards.

However, some important obstacles to the access to cross-border healthcare remain. There are still information gaps hindering access to cross-border healthcare and free movement of health services. For instance, patients yet not feel sufficiently informed about their rights and entitlements, indicating that many are not able to make an informed choice about cross-border healthcare. Awareness of the NCPs is low and NCP websites are not always effective in providing information to patients. Although the websites' content has clearly improved between 2015 and 2021, there are persisting gaps across NCPs in relation to the availability, completeness, clarity and accessibility of information. The most significant gaps relate to information related to patients' rights[8], information on entitlement for reimbursement of costs, quality and safety standards, differences between the Directive and the Social Security Coordination Regulations, availability

[7] In 2019, the number of requests for PA received (excluding France and Greece) was 4,649, with requests authorised amounting to 3,953 in 2019. Excluding France, the number of requests for reimbursement received without PA amounts to 112,847, and the requests granted to 90,674.

[8] The assessment of information on patients' rights included the following issues: information on the definition of waiting time; information on rights in case of undue delay and in the event of harm; information on access to hospitals for disabled patients, on how to access electronic medical records, on mechanisms to settle disputes (e.g. reimbursement issues); information on rare diseases and the ERNs; information on complaint procedures in case of follow-up treatment issues.

of information in English and/or minority languages, and coverage of the needs of specific groups (e.g. people with disabilities).

Other important barriers stem from the **practical implementation of the Directive's provisions** by the Member States. The barriers identified include:

- administrative procedures at national level that appear to be disproportionate to the objective of administering prior authorisation and reimbursement procedures[9];
- gaps in relation to awareness of healthcare providers of their obligations under the Directive, especially in relation to prior authorisation and prices;
- lack of clear integrated information and user-friendly procedures on cross-border healthcare treatment pathways under the two mechanisms (Directive and Social Security Regulations).

Financial barriers to cross-border healthcare were raised by interviewees across all sectors. While the Directive provides a mechanism by which citizens can seek (at least partial) reimbursement for the healthcare costs accrued, patients must advance treatment costs. To provide more certainty to patients with regards to expected costs and reimbursement, several Member States have put in place a system of voluntary prior notification, which is believed to be a useful system to reduce the financial risk for patients.

In relation to promoting voluntary cooperation on healthcare between Member States, the Commission has encouraged cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships between neighbouring countries and border regions as provided by the Directive. These activities have led to the identification of challenges and issuing of recommendations, and resulted in the sharing of best practices and the exchange of information between Member States, as well as concrete cross-border projects.

As multiple layers of cross-border cooperation mechanisms between Member State exist, some of them pre-dating the Directive, it not possible to ascertain the exact extent of the Directive's impact on cross-border cooperation. Nevertheless, evidence suggests that the Directive strengthened and increased this cooperation by providing an additional framework for operational collaboration and information sharing. It has also provided an additional framework supporting the development of cross-border cooperation mechanisms and agreements.

The Directive and the Implementing Directive 2012/52/EU have been somewhat effective in regulating the recognition of prescriptions, but have not completely solved persisting issues in this area. Patients continue experiencing problems in relation to the verification of prescriptions in another country, including language barriers, pharmacists refusing prescriptions provided by a doctor in another EU

[9] For example, requests for official/certified ('sworn') translation of documents, the costs of which may be higher than the reimbursement of the services themselves.

country, and pharmacists not being able to verify whether the prescription was issued by a doctor legally entitled to do this.

The Directive, through the creation of the ERNs, is effective in supporting the diagnosis and treatment of patients with rare and low prevalence complex diseases, promoting knowledge sharing, and contributing to research. Through training, development and dissemination of guidelines and other materials, operational activities, and scientific and clinical cooperation, ERNs are providing healthcare professionals with access to a cross-border pool of expertise and knowledge. Considering that it has been less than five years since the ERNs have been established, the networks are creating a critical mass of patients' data through the patient registries, which are expected to provide a platform for research and lead to the collection and coordination of experience in treating patients with rare conditions requiring complex treatments.

The establishment of the virtual consultation panels through the Clinical Patient Management System (CPMS), a dedicated IT platform and telemedicine tool developed by the Commission to allow healthcare providers from all over the EU to work together virtually to diagnose and treat patients, was considered a key element for the development and effectiveness of the networks, even though the tool presents some shortcomings. The CPMS is considered by some users as burdensome and not always sufficiently adapted to specificities of some of the rare diseases. Other issues include a weak integration of ERNs into the national health systems of Member States, an absence of clear referral pathways for patients and the absence of payment or reimbursement mechanism for cross-border services of ERNs healthcare providers. All these issues have resulted in the CPMS virtual consultation panels being underused.

The effectiveness of ERNs has also been impacted by the administrative workload related to the complex funding of coordination and project management activities (i.e., identifying and applying for funding from different sources) as the funding for ERNs has been provided from different spending programmes (Health Programme, Connecting Europe Facility (CEF)) and through different mechanisms (grants and tenders).

Efficiency:

Given the low patient flows under the Directive, for Member States, treatment costs, compliance costs and administrative costs are minor. Also, while there is some variance in the patient mobility by country, costs do not appear to be disproportionate across countries. However, for patients opting for the Directive's route, costs can be considerable. Non-reimbursable costs such as travel and accommodation, as well as the administrative burden of accessing reimbursement or authorisation, and having to advance treatment payments, are important cost drivers for patients, especially for patients from lower income countries, patients from a lower socio-economic status or patients who need access to specialist treatments, which are usually expensive and, even if reimbursed, entail a high advanced payment. Patients have tended to travel to neighbouring countries to receive treatment and, based on anecdotal evidence, they areusing the Directive for relatively low costs procedures. Thus, the limited number and the type of cross-border treatments accessed using the Directive are likely the main drivers of low overall treatment benefits too.

A quantitative assessment of the cost effectiveness of ERNs is challenging as only the EU level funding can be established while the funding from the coordinating centres and the hospitals hosting ERN members can only be estimated. The study found that there are other costs and administrative burdens, such as grant management, for ERN members that affect the efficiency of the networks. Another issue that was considered in the assessment of the ERNs efficiency is that the networks are still very recent and in their initiail stages and therefore significant resources and time have been spent on setting the networks up and operationalise them, limiting at this initial stage the available resources to treat and diagnose patients. Nonetheless, the ERNs are already bringing important changes to the field of rare diseases in terms of diagnosis and treatment, knowledge sharing and training, and research. This means that, in terms of benefits, patients with rare and low prevalences diseases are emerging as a clear stakeholder group benefiting from the Directive.

Overall, even if patient flows have been lower than expected before the adoption of the Directive, limiting its impact, as a legal instrument it has played an important role in providing legal certainty for cross-border healthcare, enhancing cross-border cooperation in healthcare between neighbouring countries and border regions, and bringing benefits to rare disease patients. In addition, it has indirectly acted as a driver for the development of (both domestic and cross-border) patients' rights and greater domestic transparency on treatment prices, rules, procedures and standards. All this considered, the costs are justifiable and proportionate to the benefits achieved.

Relevance:

The Directive continues to be relevant to the needs of EU citizens. A significant proportion of EU citizens are willing to travel abroad for healthcare and they indicate different reasons for this, including to access higher quality or cheaper treatments, with lower waiting times, or treatments that are not available in their home countries. NCPs have also been found to be relevant to meet patients' information needs, although some improvements are still needed.

However, there are some needs that the Directive currently does not address. These are mainly financial[10], mobility[11] and language[12] needs. Adding to this, prior-authorisation for patients with rare diseases may be more difficult to obtain due to the clinical evaluation required. These needs prevent some patients from traveling, ultimately challenging equal access to cross-border healthcare

In relation to future needs of patients seeking cross-border heakthcare, one of the main developments is possibly the digitalisation of healthcare and the increasing use of telemedicine. The use of telemedicine has accelerated during the COVID-19 pandemic and several models for its reimbursement are emerging at national level.

[10] This relates to paying upfront for treatment, limits to reimbursement based on the Member State of affiliation's levels and the travel costs (e.g., trip and accommodation).
[11] The Directive contains no specific provisions addressing the needs of those less able to travel (e.g., elderly people or people with disabilities).
[12] The Directive does not mandate language support for cross-border patients i.e., it does not explicitly mention the right of patients to access information in a language they understand or cross-linguistically (e.g., via translation and/or interpreting)

The Directive is relevant to address this emerging trend as it enables cross-border telemedicine. However, the lack of a clear, EU-level approach towards the reimbursement of cross-border telemedicine services could result in a fragmented and/or restrictive application of the Directive by Member States, which could ultimately hinder the use of this form of healthcare provision.

ERNs are expected to be relevant and benefit patients in two main ways: the pooling of expertise between specialists for the direct treatment of patients, and also increasing the experience of the medical community in treating these diseases by increasing the number of known cases and thus enabling the development of registries and contributing to research.[13] Evidence indicates that the ERNs are being increasingly used by clinicians and are seen as relevant to current and future needs of patients by stakeholders. The focus of the ERNs on low prevalence complex and rare conditions is also considered relevant. ERNs have the potential to further serve patient needs beyond their immediate objectives by improving research collaboration in relation to rare conditions.

Coherence:

The Directive's legal provisions are clear, consistent and internally coherent. However challenges remain in terms of the practical application of the Directive across the EU. Issues around reimbursement of costs, legal certainty and transparency regarding prior authorisatons, burdensome administrative procedures and the lack of comparability of healthcare service costs have created barriers preventing patients from accessing cross-border healthcare.

While the Directive clarifies its relationship with the Regulations (EC) No 883/2004 and (EC) No 987/2009 on the coordination of social security systems, and the Commission further clarified the distinction between both legal instruments, some confusion remains due to the overlap between both legal framework in terms of material[14] and personal scope[15].

In the area of rare diseases, the Directive creates synergies between the ERNs and other policies and activites in the field such as the Orphanet database and the development of ORPHAcodes, as well as other initiatives such as the European Joint Programme on Rare Diseases, which, with support from the Commission and Member States, aims at creating a rare diseases research eco-system in Europe. Another area of good synergies with the ERNs is the European Health Data Space.

Similarly, the Directive aligns well with the Directive on the recognition of professional qualifications and provides clarity on arrangements for patient mobility across borders, as evidenced during the COVID-19 crisis.

[13] European Commission (2018). 'Rare diseases 2008-2016.'
[14] Both the Regulations and the Directive apply to planned and unplanned healthcare although the Directive does not contain such a distinction. However, the Directive covers all providers, including non-contracted or private providers, while Regulation (EC) 883/2004 does not impose any obligation on the Member States with regards to treatment given by providers who are not part of the social security system of the Member State of treatment, such as non-contracted or private providers.
[15] The Directive applies to all persons covered by Regulation (EC) No 883/2004 as well as to the third country nationals and their family members who are legally resident in the territory of a Member State

EU added-value

The Directive has provided added EU value in cross-border healthcare and the outcomes of its implementation could not reasonably be expected to emerge from Member States acting alone. These include:

- the provision of information on patients' rights to cross-border healthcare;
- providing a mechanism for the reimbursement of costs;
- cross-border cooperation in border regions;
- cross-border recognition of medical prescriptions;
- supporting the diagnosis ans treatment options for patients with rare and low prevalence complex diseases.

However, the implementation issues highlighted in the study mean that the full EU added value is not currently being realised. As discussed above, evidence indicates that key cross-border mechanisms are not currently being used to their full potential, often as a result of low awareness among citizens and practitioners.

Considering the results of the study, repealing the Directive is not an appropriate measure. It would have consequences with regards to the legal certainty the Directive provides in terms of patients' rights to cross-border healthcare. The Directive has also contributed in various ways to removing obstacles to access to cross-border healthcare and the free movement of health services and cooperation in cross-border healthcare, especially in the field of rare diseases. The Directive's transposition has had positive impact in the national legislation by, for example, making it mandatory for medical entities to give very clear and transparent information on prices, which was not the case before. While this type of impacts alone would be a sufficient reason to maintain the national legal framework unchanged in the absence of the Directive according to some stakeholders, it is not possible to make an assumption that, based solely on these reasons, the national legislation across the EU will be maintained in the medium or longer term. In addition, would the Directive repealed, the CJEU case law will become the reference point for policy in this field, creating uncertainty for the patients as they would have to interpret the court judgements, reverting to the situation prior to the adoption of the Directive, which justified its adoption. Thus, repealing the Directive would have an impact in the legal certainty that it provides to patients accessing cross-border healthcare.

## *Conclusions*

The Directive 2011/24/EU has brought legal certainty to the application of patients' rights in cross-border healthcare, setting out the rights and entitlements of patients seeking healthcare abroad, and is relevant to address current patients' needs. While the Directive has removed some obstacles to cross-border healthcare, its effectiveness has proved to be limited as there is limited evidence to show that the Directive has had a major impact in enabling patients to access better quality or cheaper services abroad, with lower waiting times. This may result from persisting barriers and the still relatively low awareness of the Directive.

While the two main instruments for cross-border healthcare, the Directive and the Social Security Regulations, are complementary in some respects, the overlap between them continues to cause confusion for patients and healthcare professionals. Nonetheless, by providing a legal framework to cross-border healthcare that provides clarity and certainty compared to CJEU cases on cross-border healthcare that, in the past, were considered difficult to interpret, covering situations where the Social Security Regulations do not apply (planned care not subject to prior authorisation and access to private healthcare providers), the provisions on patients' rights have a clear EU added value.

The Directive has encouraged cooperation between Member States, especially in the area of rare diseases with the establishment of the ERNs. The objectives of the ERNs are considered relevant to address the current and future needs of patients with rare and low prevalence complex diseases. Considering that the networks have only been established since 2017, they seem to be effective in achieving their goals. The ERNs are largely coherent with EU policies and activities in the field of rare diseases and bring a clear EU added value.

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