

Cross-Border Impact Assessment 2021

Dossier 4: Is the EU Patient's Rights Directive fit for providing well-functioning healthcare in cross-border regions? An ex-post assessment



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Maastricht University

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Dossier 4: Is the EU Patient's Rights Directive fit for providing well-functioning healthcare in cross-border regions? An ex-post assessment

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Abbreviations

APR-DRG	All Patient Refined Diagnosis Related Group
BE	Belgium
DBC	Diagnose Behandelcombinatie
DE	Germany
DRG	Diagnosis Related Group
EC	European Commission
EHIC	European Health Insurance Card
EU	European Union
EUCFR	The Charter of Fundamental Rights of the European Union
EMR	Euregio Meuse-Rhine
GDP	Gross Domestic Product
G-DRG	German Diagnosis Related Group
NL	Netherlands
OECD	Organisation for Economic Cooperation and Development
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

1. Introduction & Method

Although cross-border healthcare is essential especially for border regions, the differences among Member States and, in particular, among their health systems, may cause barriers to its citizens in accessing healthcare in a cross-border setting. In the light of the objectives of Socio-economic/Sustainable Development, European Integration and Euregional Cohesion, this dossier examines the current challenges on the access to cross-border healthcare in the (cross-)border regions of Belgium, the Netherlands and Germany. Since the Patients' Rights Directive 2011/24/EU provides legislation on the access to cross-border healthcare in the European Union, the analysis focuses on an ex-post assessment of this law's cross-border effects. This research is timely because the Directive is currently under evaluation by the European Commission.¹

The underlying assumption is that cross-border healthcare is an essential element in cross-border regions to provide adequate living conditions for its citizens, since otherwise the individual national border regions would suffer from shortcomings due to their remote geographical situation from national centres. From this perspective, this dossier is an exploratory study that seeks to examine various obstacles arising in cross-border healthcare based on the benchmark of what amounts to well-functioning healthcare in cross-border regions. Under the objective of Socio-Economic Development, the dossier presents several examples of obstacles that have an effect on the mobility of citizens of (cross-)border regions. In relation to the European Integration objective, this dossier examines the state of play of the EU-level framework on cross-border healthcare. The dossier will analyse whether Directive 2011/24 [hereinafter, the Directive] is fit for purpose in light of the special characteristics and needs of cross-border regions. Considering the Directive's potential for providing solutions to the border obstacles arising from the peculiar needs of patients' mobility in cross-border regions, the dossier will conclude with a discussion on cross-border cooperation under the objective of Euregional cohesion. It will thus identify best practises of organising healthcare in a cross-border context.

1.1 Method and demarcation

Ex-post evaluation

This dossier will contribute to the 'ex-post' mapping of negative cross-border effects of existing policies and legislation, mainly that of the Directive 2011/24 on patients' rights. The Directive cannot however be evaluated in isolation: it functions as part of a complementary system of cross-border healthcare next to Regulation 883/2004² [hereinafter, the Regulation] on the coordination of social security benefits. Nevertheless, for the feasibility and focus of this research, reference to the Regulation is only made to a limited extent, i.e. where necessary.

¹ The evaluation is planned to be completed in the second quarter of 2022. European Commission, 'Cross-border healthcare – evaluation of patients' rights' https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights_en.

² Regulation (EC) no 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Geographical demarcation

As regards the geographical delimitation of the analysis, it is relevant that healthcare is a national prerogative. Therefore, examples of obstacles were collected only from selected areas: the border regions shared between Belgium, the Netherlands and Germany. Nevertheless, as the dossier focuses on the suitability of the Patients' Rights Directive from the perspective of cross-border regions, arguably some of the aspects of the dossier could also be applicable to other regions in the EU.

Definitions

The dossier uses the term **border region**. By this, reference is made, by implication, also to **cross-border regions** – i.e. seen from a 360 degrees/cross-border view instead of a purely national view.

It is furthermore necessary to define what is meant by **cross-border healthcare** in this dossier. Cross-border healthcare encompasses not only the mobility of patients, but also the free movement of services and providers (either institutional, such as hospitals or clinics, or individual doctors)³, as well as the mobility of medical personnel.⁴ For the purposes of this dossier, the term 'cross-border healthcare' will take a narrower scope, focusing particularly on the **access to cross-border planned medical care of inhabitants of (cross-)border regions** within the scope of the EU Patients' Rights Directive, in the framework of the ongoing evaluation of that law. Complementary to that, Annex I will describe further examples of obstacles from a wider scale of services, which demonstrate the diversity of healthcare systems and the numerous challenges that can arise from this diversity in a cross-border setting. Note that the dossier will not analyse each obstacle in detail; that would exceed its exploratory nature. While aiming to provide a general overview and typification of existing barriers, this study also examines best practices of cross-border healthcare in border regions to develop recommendations on overcoming such obstacles when organising healthcare in a cross-border context.

Methodology

The dossier studies obstacles arising from the relevant border regions shared between Belgium, the Netherlands and Germany by means of anecdotal evidence. Obstacles were retrieved from ITEM's own as well as the GIPs' (Cross-Border Information Points) casuistry and from the Dutch insurers' dispute settlement database (*Geschillencommissie Zorgverzekeringen*⁵). Enquiries were also made to national insurers and organizations dealing with cross-border healthcare.

³ M. Wismar, W. Palm, J. Figueras, K. Ernst, E. Ginneken, 'Cross-border health care in the European Union Mapping and analysing practices and policies' Observatory Studies Series, No. 22. World Health Organisation 2011, p. 219.

⁴ *Ibid*, p. 2.

⁵ The Dutch Health Insurance Disputes Committee is part of the Health Insurance Complaints and Disputes Foundation (SKGZ). The SKGZ handles complaints from consumers about their health insurer. The SKGZ has been appointed by the Ministers of Health, Welfare and Sport (VWS) and Finance as the extrajudicial dispute settler for health insurance and supplementary health insurance, <https://www.kpzv.nl/>.

1.2 The Research Themes, Principles, Benchmarks and Indicators of the Dossier

Table 1: Research themes, principles, benchmarks, and indicators for assessing the cross-border effects of the EU Patients' Rights Directive and whether it is fit for providing well-functioning healthcare in cross-border regions

Theme	Principles	Benchmarks	Indicator
Sustainable Development/Socio-Economic Development	<p>Sustainable development Art. 3(3) TEU</p> <p>Internal market Art. 114 TFEU</p> <p>Free movement of persons and services Art. 21 TFEU Art. 56 TFEU</p>	Well-functioning healthcare in border regions from the aspects of economic, social, and territorial development and sustainability	<p>What are the special characteristics of cross-border regions and their inhabitants in terms of healthcare?</p> <p>Which type of mismatches exists between the public health systems of BE-DE-NL that commonly cause obstacles to cross-border healthcare provision?</p> <p>Which are the most common obstacles of cross-border healthcare in border regions?</p>
European Integration	<p>Public health Art. 168 TFEU Art. 35 EUCFR</p> <p>Free movement of patients Regulation 883/2004 Regulation 987/2009 Directive 2011/24</p>	Citizens of border regions have access to (cross-border) healthcare	<p>When are persons entitled to receiving healthcare in another Member State?</p> <p>Are the obstacles identified under the theme Socio-economic development a result of shortcomings of the EU legal framework?</p>
Euregional Cohesion	<p>Strengthening economic, social, and territorial cohesion Art. 174 TFEU</p> <p>Mutual assistance and cooperation between Member States Art. 4(3) TEU Art. 10 Directive 2011/24 Rec. 50 Directive 2011/24 Art. 76 Regulation 883/2004</p>	Organisation of well-functioning healthcare provision in border regions supported by cooperation of the regional authorities	<p>Is the Directive fit for purpose in light of the special characteristics of cross-border regions?</p> <p>What are the best practises of organising healthcare in a cross-border context? What are the factors of their success?</p> <p>Could the obstacles identified in the themes above be overcome by cooperation of the relevant authorities?</p>

The dossier covers the evaluation of the three research themes in the following order: In the assessment of the theme of **Socio-Economic Development**, the dossier describes the special characteristics of cross-border regions and their inhabitants in terms of healthcare and assesses which type of mismatches and obstacles commonly arise in cross-border healthcare provision. For this purpose, several sample cases were gathered in the cross-border regions between Belgium, the Netherlands and Germany. Under the theme **European Integration**, the dossier studies the EU legislation on cross-border healthcare – particularly Directive 2011/24 on Patients’ Rights – and evaluates whether the obstacles experienced in the cross-border regions are a result of any shortcomings of this framework. Finally, in the assessment of **Euregional Cohesion**, the Directive will be evaluated in light of the previously defined special characteristics of cross-border regions and their inhabitants, revealing possibilities for cooperation and opportunities for overcoming obstacles when organising healthcare in a cross-border context.

2. Cross-border healthcare in border regions: challenges and peculiarities

Cross-border regions have special characteristics when compared to the national centres. Due to the high mobility of persons and services in these regions, daily life is frequently more integrated between two national systems. As described by the recently published report of the European Commission on cross-border regions: “[...] they are hot spots of intense cross-border interaction, where many people carry out daily activities on both sides of the border.”⁶

Access to well-functioning healthcare in a cross-border region not only contributes to the well-being of its population, but is also essential from the perspective of economic, social, and territorial development and sustainability of these regions. Due to their peripheral location and growing difficulties such as aging population, cross-border regions may be more vulnerable than non-border areas and face additional obstacles. Economically, border regions perform less well, and access to public services is generally lower in border regions than in other regions within a Member State.⁷ Also, cross-border regions may have different demographics than national centres, which may result in different healthcare demands. These weaknesses and vulnerabilities were reaffirmed by the COVID-19 crisis⁸, which also revealed the importance of cross-border healthcare cooperation, particularly in border regions.⁹

In border regions, citizens often seek healthcare services across the border due to their geographical proximity.¹⁰ What is more, from the border regions’ inhabitants’ perspective, and given the peripheral

⁶ European Commission, ‘EU Border Regions: Living labs of European integration’ COM(2021) 393 final, p. 1.

⁷ European Commission, ‘Boosting growth and cohesion in EU border regions’ (SWD(2017) 307 final, p. 4.

⁸ European Commission, ‘EU Border Regions: Living labs of European integration’ COM(2021) 393 final, p. 8. See also Dossier 3 of *ITEM Cross-Border Impact Assessment 2021*.

⁹ European Commission, ‘Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis’ C/2020/2153.

¹⁰ Proximity may also relate to the inhabitants’ perception of familiarity: “Where there is a shared feeling of closeness people will prefer to cross the border to receive health care not just because it is geographically closer but also because they feel more familiar with the setting. The alternative is often travelling longer distances within the country of residence to providers and facilities which they perceive as more foreign e.g. due to cultural and linguistic differences. In this sense, distance and proximity should not merely be measured in kilometres; they also depend on people’s perceptions and the

location of these regions, healthcare services may not always be timely available within the domestic borders. Also, people generally prefer to receive healthcare close to their home and family. Better quality of healthcare, linguistic issues or the unavailability of certain treatments or healthcare services in one's home country, may be further reasons to seek treatment in a neighbouring state.¹¹

Consequently, from a market perspective, i.e. when viewed as a “**healthcare user**”, the inhabitant of a (cross-)border region reveals special characteristics. What is distinctive is that these healthcare users are not necessarily medical tourists¹², nor is their need for cross-border healthcare (necessarily only) on an occasional or temporary basis. This means that they may have a **structural need for healthcare services across the border**, including both regular medical care as well as specialised care.¹³ Furthermore, other cross-border links or elements, other than the fact of living in a cross-border region, may be absent in the case of these healthcare users. This means that the (cross-)border region inhabitants are not necessarily only frontier workers, or they (or their family members) may not have a history of employment or residence in the neighbouring Member State. They are persons who may *only* be exercising their rights to free movement in their capacity as EU citizens in their immediate surroundings – i.e. in a *cross-border region as an integral living space without physical borders*. The distinction of this type of healthcare users becomes especially relevant when evaluating the EU legislative framework and the suitability of Directive 2011/24 from a cross-border regional perspective.

Given these special characteristics, a well-functioning cross-border healthcare provision is, therefore, vital to the sustainability and development of these regions. However, this is not always without problems because healthcare is mainly organised nationally. The high mobility of citizens in (cross-)border regions, combined with the differences in health systems, therefore results in obstacles. The following section will illustrate some of the peculiar challenges regarding access to healthcare in the (cross-)border regions between the Netherlands, Belgium, and Germany.

2.1 Obstacles in cross-border healthcare provision

Although this dossier focuses on obstacles specifically relating to the access to healthcare, it is valuable to note that various other obstacles arise in health-related service provision in a cross-border context. Under Annex I, several examples collected from the casuistry of ITEM and the Cross-Border

value attached to them”, see I. A. Glinos, R. Baete ‘A Literature Review of Cross-Border Patient Mobility in the European Union’ Observatoire social européen 2006, p. 6.

¹¹ European Commission, ‘Evaluation of patient rights in cross-border healthcare: Public Consultation Factual Report’ Ref. Ares(2021)6103901 - 07/10/2021, p. 3.

¹² I. A. Glinos, R. Baeten, M. Helble, H. Maarse also suggest not to define the typology of cross-border patient mobility as medical tourism, but as the movement of a patient travelling to another country to seek planned health care, see ‘A typology of cross-border patient mobility’ Health Place 2010.

¹³ “If care facilities get centralized and thus moved away from the EMR, this might result in an underserved population which currently already experiences a lower health standard in parts of the EMR compared to the people in other parts of their countries. To be more specific, if the children with chronic, long-term and often rare diseases have to be treated far away, parents are sometimes forced to leave the region and move to a city closer to the hospital. Otherwise, it can lead to a significant financial and emotional burden for the parents; not being able to work while traveling to distant locations for specialized care creates undesirable situations for parents taking care of their chronically ill child” See M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, ‘Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery’ PREMIUM-project (unpublished), pp. 10-11. See more in Section 4.

Information Points (GIPs) illustrate the types of mismatches between those public health systems adjacent to the Dutch border that are likely to cause obstacles to cross-border use of healthcare.

The Dutch health insurers' dispute settlement database (*De Geschillencommissie Zorgverzekeringen*¹⁴), abounds with examples where patients seeking care in Germany or Belgium have been refused reimbursement.¹⁵ One illustrative example concerns a case where an applicant from Limburg (the Netherlands) would have been required to travel all the way to the other end of the Netherlands, Haarlem, for his treatment of severe osteoarthritis. Therefore, he chose to seek treatment closer to his home, across the border in Aachen (Germany). However, his health insurance company refused to cover the treatment, since the therapy in question did not comply with the standards 'state of the art and practice' and was therefore excluded from the healthcare benefits covered by the insurer.¹⁶

Cases regarding access to cross-border healthcare have also reached national courts, as well as the EU Court of Justice. One such case involved a patient who resided in Belgium and was insured in the Netherlands. After a medical investigation, her Belgian general practitioner sent her to a hospital in Maastricht, the Netherlands, for a radiological examination, where she was diagnosed with cancer. The patient wanted a second opinion and decided to consult a doctor in Germany, who found that the situation was worse than initially diagnosed. Consequently, the patient was operated and further treated in the German hospital. However, the health insurer refused to cover this treatment as the patient had not obtained prior authorisation from her insurance company.¹⁷

In the region Zeeuws-Vlaanderen, too, Belgian residents habitually seek care across the border in the Netherlands. However, it was reported that residents of Belgium who were also insured there often failed to receive reimbursement for their planned medical care, for which they need a permission from their Belgian health insurance company. Furthermore, it was stated that the differences in the invoicing systems between the Netherlands and Belgium often cause difficulties.¹⁸ As a result, the

¹⁴ The Health Insurance Disputes Committee is part of the Health Insurance Complaints and Disputes Foundation (SKGZ). The SKGZ handles complaints from consumers about their health insurer. The SKGZ has been appointed by the Ministers of Health, Welfare and Sport (VWS) and Finance as the extrajudicial dispute settler for health insurance and supplementary health insurance, <https://www.kpzv.nl/>.

¹⁵ See for instance a case from 2020 where a patient was not fully reimbursed for care received in Hasselt (Belgium) <https://www.kpzv.nl/document/fcd628c8-7212-4a13-ba0f-92947f96d453>, and a case from 2012, where the patient received treatment in Kleve (Germany) due to long waiting lists of the treatment in his local hospital, but the care was only partially reimbursed, <https://www.kpzv.nl/document/e9b479ff-b946-4938-ab09-ebe41949abe5>.

¹⁶ The SKGZ, Bindend advies 22 juli 2020, <https://www.kpzv.nl/document/b55cbe9d-2be3-49b0-9e3a-de3e0e4c0180>.

¹⁷ C-636/19 Y v CAK. As the applicant (Y) was living as a pensioner in Belgium, he was not covered as a 'non-resident' by the Netherlands compulsory healthcare insurance scheme. It was unclear for the referring court whether the Directive would be applicable to a pensioner, such as Y, who tried to rely on the Directive under which no prior authorisation should be required for the post-operative treatments. In the final judgment of the European Court of Justice, delivered on 28 October 2021, the Court responded in the affirmative. Y should receive reimbursement for that care even when prior authorisation had not been requested. In the judgment, however, the Court did not refer to the reimbursement of the surgical operations.

¹⁸ Also noted in Rijksoverheid, 'Niet aanpassen, maar afwijken - Verslag van de bestuurlijke werkgroep grensbelemmeringen' 20 October 2020. Another research also points out a situation where the patient, insured in the Netherlands, sought treatment in Belgium due to the long waiting times. She experiences issues with the insurer, as the Dutch health insurance asked for an overview of costs that the Belgian hospital would incur, but the Belgian hospital could not produce one. See J. Beuken, M. Bouwmans, D. Versteegen, D. Dolmans, 'Out of sight, out of mind? A qualitative study of patients' perspectives on cross-border healthcare in a European border region', Patient Education and Counseling, Volume 104, Issue 10, 2021, pp. 2559-2564.

cross-border access to healthcare for residents of the border region is limited and may further contribute to the deteriorating availability of healthcare on that side.¹⁹

Bottlenecks have also been identified in the field of youth healthcare between Belgium, the Netherlands, and Germany in terms of legislation, procedures, cultural differences, and the use of terminology on specialist healthcare. These impediments are frequently overcome practically rather than structurally. Municipalities in the Netherlands were given final responsibility for youth care following a legislative change that resulted in decentralisation in 2015. With this legislative change, youth (mental) healthcare no longer falls under the scope of EU legislation, making it difficult for families living in border regions to access the necessary care facilities. As a result, families insured in Germany may be eligible for reimbursement of cross-border youth healthcare, while those insured in the Netherlands are not.²⁰

These examples are among many situations that demonstrate the challenges that inhabitants of cross-border regions may face when accessing healthcare in a neighbouring country. Obstacles may also result from differences between healthcare systems, which will be outlined below.

2.2 National incongruences in organising healthcare – a simplified overview

As illustrated above, patient mobility and cross-border healthcare provision are typified by the diversity and differences between the respective health systems and domestic legislations. Meanwhile the EU merely plays a coordinating and supplementary role. Notably, the organisation, provision and financing of healthcare remains the competence of EU Member States.²¹ This legal fact often presents a challenge to cross-border regions that, as described above, often touch upon two (or even three, as in the case of the Euregio Meuse-Rhine) different national health systems, resulting in the intersection of diverging domestic legislations. These differences, incongruences or ‘mismatches’ between the two (or three) systems may then lead to obstacles in cross-border healthcare provision in practice.

This section aims to provide a better understanding of these incongruences. With relevance to the Directive, a simplified overview will be given on the aspects of organisation, financing, and access of healthcare in Belgium, the Netherlands and Germany. A thorough study of these differences could easily fill a dissertation and would, of course, exceed the scope of this research. Nonetheless, the insights gained through this exploratory overview already point towards intriguing potential avenues for future research on establishing functioning healthcare in cross-border regions.

¹⁹ B-solutions: Final Report by the Expert, ‘Cross-border healthcare and the reimbursement of cross-border healthcare costs – Provincie Zeeland’ 2021.

²⁰ B-solutions: Final Report by the Expert (S. Adamsky), ‘Improvement of cross-border communication and care for cross-border children and young people’, 2019; en Dossier 6 of *ITEM Cross-Border Impact Assessment 2020*, ‘The cross-border effects of decentralisation in social security: case study on Dutch youth care’.

²¹ Article 168 TFEU. The Patients’ Rights Directive also notes that its rules are provided “*in full respect of national competencies in organising and delivering healthcare*” and it applies to the provision of healthcare to patients “*regardless of how it is organised, delivered and financed*”. See Article 1(1)-(2) Directive 2011/24.

Overview of healthcare financing and health insurance

In the **Netherlands**, all residents are obliged to take out a health insurance. The compulsory insurance scheme is regulated by the government, on the basis of which insurance companies offer a standardised health insurance package (*basisverzekering*).²² There are two types of insurance policies: policies based on benefits in kind and policies based on reimbursements of medical costs. The insured person under the ‘benefits-in-kind’ policy may make use of the healthcare providers that the insurer has concluded agreements with (*gecontracteerde zorgverlener*), and payment is settled between the insurer and healthcare provider. The reimbursement policies are usually more expensive for the insured persons. Under these schemes, the patient may freely choose a healthcare provider and declare these costs with the insurer. In practice, it means that citizens under both types of insurance policies may seek treatment abroad.²³ However, those insured under the ‘benefits-in-kind’ policy are entitled to full reimbursement only if the health insurer has a contract with the foreign hospital; they receive limited reimbursement when a non-contracted care provider is involved.²⁴

The financing of the health insurance is regulated by the Health Insurance Act (*Zorgverzekeringswet*). Citizens pay nominal premiums directly to the health insurer²⁵. Contributions to the health insurance scheme is also made via income-dependent premiums, paid by the employers. Furthermore, insured persons over 18 years old pay annual obligatory deductible excess (*verplicht eigen risico*).²⁶ Additional healthcare, such as physiotherapy, which is not included in the statutory coverage, is covered under complementary (voluntary) insurance packages.

In **Belgium**, the responsibilities regarding the organisation of healthcare are divided between the federal and regional governments. The federal authorities are responsible for the regulation and financing of the compulsory health insurance. Health insurance in Belgium is compulsory. Citizens enrol in sickness funds (*mutualiteiten*). These are non-profit health insurance funds, funded by the federal government and from mandatory social security contributions. Compared to the Netherlands and Germany, the monthly insurance premiums in Belgium are rather low.²⁷ However, patients may also

²² MISSOC Mutual information System on Social protection, <https://www.missoc.org/missoc-database/comparative-tables/>, European Observatory on Health Systems and Policies, ‘Health systems in Transition: the Netherlands’, vol 12 No 1. 2010, M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, ‘Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery’ PREMIUM-project (unpublished), p. 20.

²³ Here it is important to note that seeking healthcare abroad is generally more feasible for those insured under the ‘reimbursement policy’, as the insured person may seek treatment from healthcare facilities with which the insurer does not have a contract. As these policies are more expensive than the ‘benefits in kind’, a question arises whether seeking healthcare abroad from non-contracted healthcare institutions is only for those who can afford the choice of the reimbursement policy. Nevertheless, the Dutch insurance companies have often contracted with Belgian and German hospitals, through which the inhabitants of these border regions are entitled for reimbursement also under the policy of ‘benefits in kind’.

²⁴ A. P. van der Mei, ‘De patiëntenrichtlijn en het Nederlandse zorgverzekeringsstelsel’ In: SEW: Tijdschrift voor Europees en economisch recht. 64, 2, 1 Feb 2016, p. 53-59.

²⁵ A health insurance policy costs between 110 and 135 euros per month. The price strongly depends on the type of policy. The average premium of a health insurance policy will be 124.80 euros per month in 2021. See more at <https://www.zorgwijzer.nl/>.

²⁶ For a minimum amount per year (€385,- in 2021 or higher by choice) insured persons must pay for certain basic health treatment costs in the Netherlands out of their own pocket.

²⁷ Belgian health insurance will cost approximately € 10.00 per month, find about more at https://www.grensinfo.nl/gip/nl/nlonbe/zorg/zorgverzekerd_in_belgie/index.jsp?situatie=nlonbe.

be required to pay co-payments.²⁸ It is also possible to take out a voluntary private health insurance for services that are not covered by the compulsory health insurance.²⁹

In **Germany**, health insurance is also mandatory for all citizens. It is provided by two systems: non-governmental health insurance funds, '*Krankenkassen*', within the statutory health insurance system, and complementary private health insurance (for example, for self-employed). The sickness funds are financed via contributions paid by the employer and employees: (non-basic) care may be also subject to minor co-payments. Income-related supplementary contributions may also be charged by the health insurance companies.³⁰

Payment mechanisms: Hospital care

In the **Netherlands**, hospital services are paid through a payment model of Diagnosis Treatment Combinations (DBC). This means that all services are not billed separately, but as a combination of treatments relevant for each diagnosis.³¹ In **Germany**, hospital financing follows the DRG (diagnosis-related group) system (also referred as the German DRG, G-DRG), that uses a patient classification system and covers all charges of inpatient stay.³² In **Belgium**, another type of DRG system is used (APR-DRG (All Patient Refined DRG, that classifies categories of patients with the same clinical and care profiles). Furthermore, as delivery of healthcare is mainly private in Belgium, most physicians and specialists working in hospital are paid on a fee-for-service basis, meaning that contributions are made directly to the physician.³³ Next to payment mechanisms, differences also arise regarding the content of the invoices. For example, unlike in the Netherlands, a hospital invoice in Belgium does not include hospital infrastructure costs, thus reducing the total costs of the invoice.

Access to (specialised) healthcare

In the **Netherlands**, specialised care may only be accessed when a referral is obtained from the general practitioner (*huisarts*). In **Belgium**, patients are free to access most specialised care without seeing a general practitioner, but the consultation fee is lower for referred patients. In **Germany**, the patient has freedom of choice among contracted specialists. The costs for non-contracted healthcare

²⁸ Co-payment refers to a fixed amount for a certain health service, that the patient pays directly to the provider.

²⁹ MISSOC: Mutual information System on Social protection, <https://www.missoc.org/missoc-database/comparative-tables/>, European Observatory on Health Systems and Policies, 'Health systems in Transition: Belgium', vol 12 No 5. 2010; and M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, 'Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery' PREMIUM-project (unpublished), p. 23.

³⁰ MISSOC: Mutual information System on Social protection, <https://www.missoc.org/missoc-database/comparative-tables/>, European Observatory on Health Systems and Policies, 'Health systems in Transition: Germany', vol 16 No 2. 2014; and M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, 'Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery' PREMIUM-project (unpublished), p. 21.

³¹ MISSOC: Mutual information System on Social protection, <https://www.missoc.org/missoc-database/comparative-tables/>, European Observatory on Health Systems and Policies, 'Health systems in Transition: the Netherlands', vol 12 No 1. 2010, M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, 'Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery' PREMIUM-project (unpublished), p. 20.

³² European Observatory on Health Systems and Policies, 'Health systems in Transition: Germany', vol 16 No 2. 2014.

³³ European Observatory on Health Systems and Policies, 'Health systems in Transition: Belgium', vol 12 No 5. 2010.

providers have to be paid out of the patients' own pocket and are not reimbursed. However, certain medical specialists (such as radiologist, pathologists) may only be consulted upon referral.³⁴

Healthcare spending

Healthcare expenditures in Belgium, the Netherlands and Germany are similar (Table 2)³⁵, amounting to around 10-11% of the gross domestic product (GDP). Per capita, these expenditures are the highest in Germany and the lowest in Belgium.

Table 2: Simplification of the differences presented

	Belgium	The Netherlands	Germany
Healthcare expenditure (% of GDP)	10.32	9.97	11.47
Healthcare expenditure per capita (EUR)	3679	3908	4504
Health insurance	Compulsory	Compulsory	Compulsory
Payment mechanism: hospital care	Fee-for-service, APR-DRG	DBC	G-DRG
Access to (specialised) healthcare	Free	Only with a referral from GP	Free

The above findings constitute a simplified overview of the differences of the health systems in Belgium, the Netherlands and Germany. The dossier will return to these aspects when assessing the Directive's fitness in providing healthcare in cross-border regions. Before this question can be answered, the dossier will examine the EU framework on cross-border healthcare.

3. EU legislative framework on access to cross-border healthcare

The organisation of healthcare is the competence of the Member States; Article 168 TFEU very much highlights the *complementary* nature of EU action in this field. Nonetheless, there is EU-level legislation that deals with cross-border healthcare.

One can find, on the one hand, the European social security coordination regulations (Regulation 883/2004 and Implementing Regulation 987/2009) and, on the other hand, the Patients' Rights Directive 2011/24 (based on case law from the Court of Justice of the EU). These instruments both regulate a variety of situations, laying down the rules and conditions under which cross-border

³⁴ MISSOC: Mutual information System on Social protection, <https://www.missoc.org/missoc-database/comparative-tables/>.

³⁵ OECD Health Statistics 2020; Eurostat Database; WHO Global Health Expenditure Database.

healthcare may be sought and must be reimbursed.³⁶ Next to the EU-instruments, the Member States are encouraged to engage in cross-border collaboration to ensure adequate healthcare and to create additional routes for persons to seek treatment across the border based on contractual agreements.³⁷

The Directive functions as complementary system to that of the Regulation; therefore the Directive cannot be evaluated in isolation.³⁸ The Regulation is a longstanding legal framework for the coordination of social security systems in the EU.³⁹ Since the right to access healthcare in another Member State is essential from the point of view of a functioning Internal Market and the promotion of the free movement of persons therein, the Regulation coordinates a number of social security benefits in cross-border situations, including sickness benefits. However, since this dossier focuses on the Directive in light of its current evaluation by the European Commission, we will only discuss those parts of the Regulation relevant to this topic⁴⁰, i.e. those provisions that concern the access to healthcare by inhabitants of (cross-)border regions. The Directive is a much more recent law intended as a complementary system to the social security coordination of the Regulation. The Directive has been adopted with the aim of codifying important new principles and legal developments that had emerged from the European jurisprudence of the Court of Justice, as illustrated below.

3.1 Access to cross-border healthcare under Regulation 883/2004

Who gets access? (Personal scope of application of the Regulation)

Under the Regulation, insured persons⁴¹ are entitled to receive both planned and unforeseen (emergency) cross-border healthcare during their stay in another Member State. The Regulation also coordinates the sickness benefits of persons residing in another state than the Member State where they are insured (the competent Member State), for instance frontier workers. In all of these situations, the costs of healthcare are covered by the competent Member State, which makes its designation essential.

The competent Member State is determined by the rules on applicable legislation. Based on Article 11(1) of the Regulation, the legislation of a single Member State is applicable. Overall, workers are insured in their state of employment (*lex loci laboris*) and inactive citizens in their state of residence (*lex loci domicilii*). In case of pensioners, the Member State of pension covers the costs of the healthcare (*lex loci pensionado*). In some situations, special rules apply, for example in the case of posted workers⁴² or persons pursuing activities in two or more Member States.⁴³

What may they access and how? (Material scope of application of the Regulation)

The Regulation distinguishes between planned and unplanned healthcare services. The Regulation thus provides, on the one hand, for persons who, during their stay in another Member State, require

³⁶ See Chapter 1 Regulation 883/2004, Chapter III Directive 2011/24.

³⁷ These possibilities are further examined under Section 4 when the dossier evaluates the theme of European Cohesion.

³⁸ Article 2 Directive 2011/24.

³⁹ It updated and replaced Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community.

⁴⁰ Whilst also the Regulation 883/2004 is currently under review (and at an advanced stage at that), the scope of that revision exceeds the scope of this research.

⁴¹ Articles 2 and 1(c) Regulation 883/2004.

⁴² Article 12 Regulation 883/2004.

⁴³ Article 13 Regulation 883/2004.

emergency care (i.e. unplanned care).⁴⁴ On the other hand, persons may also intentionally travel to another Member State to receive healthcare within the meaning of Article 20 of the Regulation (i.e. planned healthcare). Specific provisions are applied to the coordination of sickness benefits to frontier workers, pensioners⁴⁵ and their family members. Frontier workers, for instance, may receive healthcare in their Member State of residence and in the competent Member State, eventually providing these workers with a choice.⁴⁶ **Thus, under the Regulation, the conditions on access to healthcare differ depending on which type of cross-border inhabitant is seeking healthcare and under which circumstances.**

Conditions for planned healthcare

For planned care, in order to be eligible for reimbursements, the patient needs to obtain an authorisation from their competent institution prior receiving the treatment in another Member State. The institution is obliged to grant the authorisation if the request concerns healthcare that is covered under the statutory insurance package in the competent Member State and if the treatment cannot be provided in a medically justifiable time in that Member State, considering the current state of health and the course of the illness of the patient.⁴⁷ Authorisation may be refused if the same, or equally effective, treatment can be obtained in the competent Member State. This decision must take into account the individual case of the patient. This includes an objective medical assessment of the patient's condition, history, probable course of illness, the degree of pain and/or the nature of the patient's disability.⁴⁸ In case prior authorisation was obtained, reimbursement must take place according to the rates of the Member State of treatment. In practice, patients must present to the cross-border care provider a document obtained from their competent institution (the S2-form, previously known as E-112).⁴⁹

In situations where the conditions of authorisation are *not* fulfilled, the institution may grant an authorisation at its own discretion. This is in line with EU law, in that the Regulation does not oblige the competent institution to refuse prior authorisation in such situations.

On the basis of the Regulation, patients are, in principle, permitted to obtain planned healthcare in another Member State with prior authorisation. However, the EU's Court of Justice has long considered this system of prior authorisation an obstacle to the free movement of goods and services. In the landmark judgments of *Kohll* and *Decker*⁵⁰, the Court ruled that imposing such rules should, in principle, be prohibited. Accordingly, these rules are now codified into Directive 2011/24/EU.

3.2 The Patients' Rights Directive 2011/24

Putting a stronger emphasis on the free movement of services, the Directive offers the possibility for patients to obtain care in another Member State without prior authorisation.⁵¹ The following section

⁴⁴ Article 19 Regulation 883/2004.

⁴⁵ Section 2 Regulation 883/2004.

⁴⁶ Articles 17-18 Regulation 883/2004.

⁴⁷ Article 20(2) Regulation 883/2004.

⁴⁸ Article 8(5) Directive 2011/24.

⁴⁹ Article 26 Implementing Regulation 987/2009.

⁵⁰ Cases C-158/96 *Kohll* [1998], C-120/95 *Decker* [1998].

⁵¹ Article 56 TFEU.

will examine these possibilities that the Patient Rights Directive 2011/24/EU, adopted on 9 March 2011, provides to patients in cross-border situations.

Who gets access? (Personal scope of application of the Directive)

Under the Patient Rights Directive, all patients who are insured in their home Member State are also eligible to travel across borders to receive treatment in another Member State. Compared to the Regulation, **the Directive thus does not apply special provisions to the type of cross-border inhabitant, for instance, frontier workers.** As its main objective, the Directive aims to ensure patient mobility, facilitate access to safe and high-quality cross-border healthcare, and promote cooperation on healthcare between the Member States.⁵² Notably, the Directive strengthens co-operation in the areas of prescriptions, rare diseases and health technology.⁵³ It, too, provides rules for complaint procedures and sets the rights of patients: the right to receive information and the right to medical follow-up.⁵⁴

The Directive also lays down obligations for the Member States on mutual assistance, specifically on the exchange of information.⁵⁵ To enable patients to exercise their rights on cross-border healthcare in practice, the Member States are required to establish National Contact Points (NCPs) providing information on cross-border healthcare to patients.⁵⁶

What may they access and how? (Material scope of application of the Directive)

In short, the Directive thus applies to:

“health services provided by health professionals to patients to assess, maintain or restore their state of health, including prescription, dispensation and provision of medicinal products and medical devices.”⁵⁷

Importantly, the Directive excludes long-term care, organ transplants and public vaccination programmes from its scope.⁵⁸ Under the Directive, patients may access the abovementioned health services to receive treatment even *without* obtaining a prior authorisation.

Whilst the Directive does not (cannot) prohibit authorisations altogether, it turns them into legal exceptions that require legitimate justification in order to be valid. Member States may introduce systems of prior authorisation for several reasons: to ensure sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to control costs and avoid, as far as possible, any waste of financial, technical, and human resources. This may occur when there is a serious risk of undermining the financial balance of a social security system, or when the objective is to maintain the treatment capacity of a healthcare provider.

In that respect, the Directive specifies that prior authorisation may be required:

⁵² Recital 10 Directive 2011/24.

⁵³ See Chapter IV Directive 2011/24.

⁵⁴ See Chapter II Directive 2011/24.

⁵⁵ Article 10 Directive 2011/24.

⁵⁶ Article 6 Directive 2011/24.

⁵⁷ Article 3(a) Directive 2011/24.

⁵⁸ Article 1(3) Directive 2011/24.

- when the treatment requires in-patient overnight hospital care or highly specialised/costly equipment, or
- when a treatment is particularly high risk for the patient or the population, or
- the healthcare provider abroad raises quality and safety concerns.⁵⁹

Furthermore, when Member States implement systems of prior authorisation, they must be necessary and proportionate to the objective sought (proportionality test). The system must not constitute a means of arbitrary discrimination or unjustifiably restrict the free movement of patients.⁶⁰

Following the provisions of the Directive, the Member States may decide whether they introduce such systems and which healthcare is subject to prior authorisation.⁶¹ Therefore, in fact, the situations in which Belgian, Dutch or and German authorities might require such an authorisation may differ.⁶²

In a similar vein with the Regulation, prior authorisation *cannot* be refused if the treatment is included in the healthcare benefits covered in the competent Member State; and if the competent Member State cannot offer the same treatment within a medically justifiable time limit. At the same time, though, prior authorisation *can* be refused if there are quality and safety concerns, risks to the patient or to the general population, or if the treatment is available in the competent Member State within a justifiable time frame.⁶³

3.3 Do the obstacles to cross-border healthcare in border regions arise from shortcomings in the EU legal framework?

The above section examined under which conditions cross-border healthcare may be sought in another Member State. The practical cases presented in Section 2 provided examples of obstacles to the access of cross-border healthcare that have an effect particularly on cross-border regions. It is important to evaluate whether these obstacles arise from any shortcomings of the EU legal framework in reflecting the needs of border regions and their inhabitants.

⁵⁹ Article 8(2) Directive 2011/24.

⁶⁰ Article 8(1) Directive 2011/24.

⁶¹ Recitals 42-43 Directive 2011/24.

⁶² The Netherlands has not introduced an additional list of treatments subject to prior authorisation. In Belgium, the official list of medical benefits subject to prior authorisation is included in the Ministerial Decree of 24 June 2014, and as stated in Article 294(1)(14) of the Royal Decree, published on the website of the National Institute for Health and Disability Insurance (RIZIV). Next to the overnight stay, prior authorisation is required for outpatient benefits that require heart catheterization, the use of CT/MRI/PET scanner or radiotherapy service. In Germany, prior authorisation is required for hospital care within the meaning of §39 Sozialgesetzbuch (SGB) Fünftes Buch (V).

⁶³ Article 8(5)-(6) Directive 2011/24.

Table 3: Simplification of the EU legal framework on access to cross-border healthcare

	Regulation 883/2004	Directive 2011/24
Covered persons	Insured persons, special provisions for: <ul style="list-style-type: none"> • frontier workers • pensioners • their family members 	Insured persons: Patients
Healthcare provider⁶⁴	Public	Public or private
Access to cross-border healthcare (planned)	Prior authorisation required for all planned care (under Article 20)	<ul style="list-style-type: none"> • Access without authorisation as <i>main rule</i> • Restrictions through authorisation (<i>exception</i>) must be justified/justifiable Only in the event of: <ul style="list-style-type: none"> – Over-night hospital care – Highly specialised or costly equipment – Risks to patient or population – Quality and safety concerns of treatment – Not included in the insurance package
Prior authorisation must be given when	<ul style="list-style-type: none"> • Treatment is included in the insurance package, and • Treatment cannot be given within a medically justified time frame in the home Member State 	
Reimbursement	Based on the tariffs of the Member State of treatment, bill settled between health insurers	Only up to the cost level of the treatment in the home Member State, patient pays in advance
Form of authorisation	S2 form (E-112) for planned care, EHIC (E-111) for emergency care, S1 form ('portability document') e.g. for frontier workers	Ad hoc document

When comparing the Directive to the rules on prior authorisation of planned healthcare under the Regulation, they differ remarkably (Table 3). Although the Directive offers the possibility for patients to seek healthcare in another Member State without requesting a prior permission from their insurer, in certain cases prior authorisation may be required. Under the Regulation, such authorisation is always mandatory. **It is exactly these prior authorisations that may prove difficult in a cross-border setting.**

The rules on prior authorisation may limit the access to cross-border healthcare of inhabitants of these regions considerably as, in the end, the decision on whether authorisation for treatment across the border is granted is in the hands of the insurer. A case in point is the previously mentioned example of inhabitants of cross-border regions who were unable to seek treatment across the border since their requests for prior authorisation were refused. Based on the rules on granting prior authorisations, the insurer may argue that, in these cases, timely similar treatment was available in the Member State of residence, and, therefore, their refusal is justified. Thus, within this framework, it is possible that the

⁶⁴ This distinction requires careful consideration of the applicable health system. For instance, in case of the Dutch healthcare system, reimbursements can be sought under the Regulation from private providers contracted with the public healthcare scheme.

inhabitants of cross-border regions are in a disadvantageous position compared to those residing in the central areas. The rules on prior authorisation only assess whether timely treatment is available within the national borders as a whole. This assessment fails to consider, however, the perspective of the inhabitant of the cross-border region, for whom treatment could be had more conveniently and closer to home just across the border.

The issues of prior authorisation link to the definition of inhabitants of border regions as provided in the beginning of the dossier. These healthcare users are not necessarily medical tourists, and for them it may prove to be administratively and financially burdensome to request prior authorisations for regular treatments or to pay these treatments in advance before reimbursement is granted. While the systems under the Regulation and the Directive do provide a set of rights, they reflect the need for occasional cross-border healthcare, or for instance, for care for specific groups such as pensioners or frontier workers rather than the general healthcare needs of border residents. **There are no explicit provisions for persons living in border regions, whose lives do not contain any cross-border elements (such as work) other than living in the proximity of a national border.**

On a positive note, however, the starting point of the Directive is that prior authorisation is not required. In this sense, the Directive has been a welcome development as it provides more flexibility in accessing healthcare, compared to the Regulation. Especially this framework of planned care could be useful for inhabitants of border regions who are seeking consultations or other ‘regular’ care for which prior authorisation is not mandatory. Nevertheless, the Directive does not solve obstacles arising from the rules on prior authorisation when the cross-border inhabitant is in need of **hospital (overnight) care or other cost-intensive, specialised care**. Also, the absence of prior authorisation **may cause uncertainty among patients**, as they will only receive a decision on reimbursement after their treatment.

A notable difference between the Directive and the Regulations in relation to the reimbursement of planned healthcare points to a further potential obstacle: Under the Directive, the reimbursements are provided only up to the level of the home Member State (“*Member State of affiliation*”) of the patient.⁶⁵ This approach is substantially different from the regime provided under the social security coordination Regulation, under which it is the Member State of treatment whose rates determine the reimbursement. Therefore, **if the patient is receiving care in a Member State where the costs are higher than in the competent Member State, the actual costs may only be partially reimbursed under the Directive**. This might be a less favorable result for the patient and may discourage a cross-border inhabitant from seeking healthcare services in a neighboring country where the costs are higher. Thus, the differences in the costs of healthcare services between the Member States, may also form an obstacle.

The same applies to the different reimbursement mechanisms. Under the Regulation, the payment is often settled between both institutions, and the patient may avoid the initial financial burden of the healthcare costs. **Under the Directive, however, the costs are initially paid out-of-pocket by the patient**. Afterwards, the patient can request reimbursement from the competent institution. This system of reimbursement may lead to inequalities between the inhabitants of cross-border regions: not every citizen necessarily has the financial means to pay their treatment in advance. The post-treatment reimbursement may also cause financial uncertainties. Hence, it does not come as a surprise

⁶⁵ Article 7(4) Directive 2011/24.

that this payment upfront, combined with the financial uncertainty of (in)complete reimbursement, have been among the main barriers identified by the public consultation of the Directive.⁶⁶

Next to the differences in reimbursement and the requirement of prior authorisation, it has to be noted that the Regulation only applies to healthcare sought from public healthcare providers whereas, under the Directive, care from both public and private providers is reimbursable.⁶⁷ **Therefore, the patient has more options to choose from healthcare providers and enjoys more freedom under the Directive, as prior authorisation is not always required.** However, it is critical to emphasize here that the differences between the health systems and their respective private/public divide in healthcare services is once again relevant.⁶⁸

This analysis indeed reveals several important shortcomings of the EU legal framework with regard to organising cross-border healthcare in border regions. Based on these findings, it can be argued that the emergence of obstacles **could be mitigated by an EU legal framework that considers the needs of border regions and promotes the rights to healthcare of their inhabitants in a cross-border setting.** However, as the real-life sample cases under Section 2 reveal, it is also the systemic incongruences and differences in domestic legislations that cause obstacles to a functioning cross-border healthcare in a border region. Examples included the differences in invoicing systems in hospital care, as well as the differences in coverage of insurance policies. In this context, it is essential to note, once more, the limited competencies of the Union in the field of health policy. Whether this is to change anytime soon – even in the light of recent plans of establishing a European Health Union⁶⁹ – is rather doubtful. More precisely, the Directive as an EU legal instrument is not directly applicable. It ‘only’ establishes a common objective that must be met by the Member States but leaves the implementation to the national governments⁷⁰. In light of the limited legal effect of the Directive and the competences of the EU regarding the organization of healthcare (treaty exclusion), harmonisation of healthcare systems or, in this case, of invoicing systems or insurance packages, is legally virtually impossible to achieve. Because of this, **the Directive alone may not be able to provide a sufficient panacea to overcome all obstacles uniquely experienced in border regions.** This means that the establishment of a well-functioning, cross-border healthcare also requires actions and cooperation on the part of the Member States' authorities at national and regional level.

⁶⁶ European Commission, ‘Evaluation of patient rights in cross-border healthcare: Public Consultation Factual Report’ Ref. Ares(2021)6103901 - 07/10/2021, p. 4.

⁶⁷ Article 1(2) Directive 2011/24.

⁶⁸ See footnote 65.

⁶⁹ The COVID-19 pandemic showed the importance of healthcare coordination. The European Commission is building a European Health Union, in which “all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer.” The key initiatives include crisis preparedness, pharmaceutical strategy, and Europe’s Beating Cancer Plan. See more at https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en.

⁷⁰ In this respect it is also important to evaluate whether the Member States have effectively implemented the Directive.

4. Establishing well-functioning healthcare in border regions: overcoming obstacles

Next, the dossier seeks to answer how, in the framework of the Directive, well-functioning healthcare in border regions could be realised. This matter goes hand in hand with the question if and how the border obstacles, mentioned under Section 2, could be solved in a structural manner. More specifically, then, this Section will examine how these obstacles could be overcome by the regional authorities and identifies some best practises of organising healthcare in a cross-border context.

4.1 The EU Patients' Rights Directive in the light of the special characteristics of border regions

Taking the perspective of a *cross-border* region as a starting point to organise healthcare could offer several advantages. Importantly, the Directive does already pay some tribute to the special position of border regions, as it expressly encourages the cooperation between the Member States specifically in these areas.

Also, the European Commission has recognised the necessity of exploring additional avenues towards legal integration. It has included a focus on cross-border mutual assistance and cooperation in its ongoing evaluation, assessing specifically the Directive's impact on these aspects.⁷¹ According to the results of the public consultation, less than half of the respondents believe that the Directive actually supported agreements in cooperation in healthcare provision.⁷² This underlines that the Directive may still have room for improvement in terms of facilitating cross-border cooperation, which could reduce the emergence of barriers and improve healthcare provision in border regions.

Indeed, **cross-border cooperation** in healthcare offers several potential benefits.⁷³ There may be economic advantages, for instance, since cooperation allows for more efficient resource pooling in these regions. One example is when regional authorities cooperate by establishing centres of specialist care, that would otherwise be available only in the proximity of national centres. For instance, the initiative of Euregional Centre for Paediatric Surgery in the Meuse-Rhine Euroregion aims to mitigate the negative effects that arise from the political, medical, and demographic position of the border region. Alongside improving accessibility, this type of cross-border cooperation may also improve the quality of healthcare in the area by uniting the efforts and expertise of healthcare professionals. It has been found that

*"[...] the Netherlands has a number of large paediatric surgical centres spread throughout the country, but in the south of the country such a facility is lacking to a certain extent. In practice, this means that children in the Meuse-Rhine Euroregion that are in need of a surgical procedure often have to travel in order to receive treatment, far away from their homes and families."*⁷⁴

⁷¹ European Commission Roadmap: Evaluation of patients' rights in cross-border healthcare, 14 January 2021.

⁷² European Commission, 'Evaluation of patient rights in cross-border healthcare: Public Consultation Factual Report' Ref. Ares(2021)6103901 - 07/10/2021, p. 5.

⁷³ European Commission, 'EU Border Regions: Living labs of European integration' COM(2021) 393 final, p. 4.

⁷⁴ Find more at <https://www.maastrichtuniversity.nl/research/item/research/euregional-centre-for-paediatric-surgery>, Prof. dr. H. Schneider, Dr. N. Büttgen, Dr. L. Kortese R. Tans, LL.M. M. Unfried, M.A., 'De Weg Vrijmaken voor een

Whilst Article 168 TFEU confines the limited competences of the EU concerning the organisation of healthcare, it also explicitly postulates cooperation in cross-border regions.⁷⁵ The preamble of the Directive elaborates on this postulate:

*“Member States should facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level **in order to ensure safe, high-quality and efficient cross-border healthcare**. This could be of **particular importance in border regions**, where cross-border provision of services may be the **most efficient way of organising health services for the local population**, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States.”⁷⁶*

*“[---] the Commission should encourage cooperation in cross-border healthcare provision at regional and local level, particularly by **identifying major obstacles to collaboration between healthcare providers in border regions**, and by making recommendations and disseminating information and best practices on **how to overcome such obstacles**.”⁷⁷*

The Directive does not impose an obligation on the Member States to cooperate but strongly encourages such cooperation – preferably based on (written) agreements – especially with regard to cross-border healthcare in border regions. Accordingly, Article 10 of the Directive provides:

*“The Commission shall encourage Member States, particularly neighbouring countries, **to conclude agreements among themselves**. The Commission shall also encourage the Member States to **cooperate in cross-border healthcare provision in border regions**.”⁷⁸*

In short, the EU legal framework thus expressly invites the Member States to conclude agreements on cross-border healthcare in (cross-)border regions. In concluding those agreements, the governments are not restricted by EU law when it comes to encouraging patient mobility: if they wish, the Member States may provide conditions that are more favourable than those in the Directive. To overcome the obstacles arising from the prior authorisation requirement and discretionary reimbursement systems, several cross-border regions have concluded agreements on the provision of and access to healthcare services. Within the geographical demarcation of this dossier, two agreements and one foundation will be presented shortly hereafter as examples of good practice.

Euregionaal Kinderchirurgisch Centrum Toekomstbestendige Grensoverschrijdende Zorgsamenwerking in de Euregio Maas-Rijn’ October 2020.

⁷⁵ Article 168 (2) TFEU reads: ‘...It [the Union] shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.’

⁷⁶ Recital 50 Directive 2011/24.

⁷⁷ Recital 51 Directive 2011/24.

⁷⁸ Article 10(3) Directive 2011/24.

4.2 Examples of good practice: ZOAST, IZOM and euPrevent

ZOAST

A framework agreement was signed in 2005 along the French-Belgian border, and since then several zones of cross-border healthcare (*Zone organisée d'accès aux soins de santé transfrontaliers*, ZOAST's) have been established there. Seven ZOASTs now cover the entire Franco-Belgian border area, which have become benchmarks for healthcare cooperation in the EU. No prior authorisation is necessary for patients seeking cross-border healthcare services in these zones, and reimbursement is based on the tariffs of the Member State of treatment. From a practical perspective, in ZOAST Ardennes, French social security card readers have been installed in Belgian institutions, avoiding a situation where a patient must pay in advance for medical care. Under the system of Regulation 883/2004, funds paid to the Belgian hospitals are recovered from the French liaison agency. As a result, in addition to solving the issues of prior authorisation, the agreement avoids the pitfalls of the Directive regarding limited reimbursements and upfront payment.⁷⁹ Overall, the cooperation has improved access to high-quality healthcare close to the patient's home in the French-Belgian border regions where healthcare was often scarce. Furthermore, the complementary border hospitals have reduced the costs of healthcare provision.⁸⁰

The IZOM project

The IZOM project ('Integratie Zorg Op Maat') is one example of former cross-border healthcare cooperation between Belgium, the Netherlands, and Germany in the Euregio Meuse-Rhine (EMR), launched as early as 2000 by the health insurers in these areas (the Dutch health insurer CZ in cooperation with the Belgian Mutualité Chrétienne and the German AOK Rheinland). The challenges of organising healthcare in the region led to this cooperation: specialist care was subject to long waiting times and, in some areas, local health services were lacking.⁸¹ The project facilitated patient mobility by allowing its residents to choose in which country to seek healthcare. For this purpose, the health insurer issued a special form of prior authorisation (EE12+ form) to the resident, valid for a period between three and twelve months. Under this scheme, the residents could make use of care provided by specialist doctors, on both therapeutic and diagnostic levels, have medicines prescribed within the framework of treatment and access the relevant hospital care.⁸² However, some healthcare services were excluded from the scheme, for instance physiotherapy and the care of general practitioners. The services were invoiced via the health insurance funds.⁸³

Although the project led to many benefits for both patients and healthcare professionals, some issues were encountered. One related to the imbalances in patient flows: more Belgian patients crossed the border than Dutch or German patients.⁸⁴ This imbalance was especially remarkable in certain specialist

⁷⁹ European Commission, 'European Cross-border Cooperation on Health: Theory and Practice' 2017 https://ec.europa.eu/regional_policy/sources/cooperate/crossborder/cbc_health/cbc_health_en.pdf, p. 11.

⁸⁰ European Commission, 'Enhancing healthcare cooperation in cross-border regions' https://ec.europa.eu/futurium/en/system/files/ged/booklet_enhancing_healthcare_cooperation.pdf.

⁸¹ *Ibid*, p. 60.

⁸² See also A. Coheur, 'Cross border care - New prospects for convergence. European Integration and Health Care Systems: A Challenge for Social Policy' 2001.

⁸³ European Commission, 'European Cross-border Cooperation on Health: Theory and Practice' 2017 https://ec.europa.eu/regional_policy/sources/cooperate/crossborder/cbc_health/cbc_health_en.pdf, pp. 60-63.

⁸⁴ *Ibid*, p. 63. For instance, in 2014, 15 807 S2 forms were issued for healthcare in Germany, representing patients with Belgian social insurance. These were mainly members of the German-speaking community of Belgium. Conversely, there

branches of medicine, such as paediatrics. Furthermore, at the time that the Patients' Rights Directive was adopted, questions were raised about the added value of the IZOM project, given that the Directive also provided the option of receiving care without prior authorisation. The imbalances and the legislative changes led two German contractors to terminate the agreement in 2016. Partly in response to the withdrawal of these two German partners, the Belgian Ministry of Social Affairs and Public Health evaluated the project in 2016, and subsequently the decision was made to terminate the project by the end of 2017. On 1 January 2018, the EMR reverted to the application of EU law, on the basis of the coordination Regulations and the Patients' Rights Directive.⁸⁵

euPrevent

In the same region as the IZOM-project, i.e. the EMR, euPrevent was initiated in 2000 as an Interreg A project. Since 2010, euPrevent functions as a formal non-profit foundation that aims to improve the health situation for citizens in the EMR by facilitating cross-border cooperation. For example, in collaboration with a network of hospitals, nursing homes, out-patient services, doctors, insurance companies, and patient associations, the foundation has addressed issues of patient safety and infection control in cross-border healthcare provision. euPrevent has partnered with regional and local governments, public health authorities, hospitals, mental health institutions, patient organisations, universities, and educational institutions.⁸⁶

4.3 Overcoming obstacles: factors of success for establishing well-functioning healthcare in cross-border regions

ZOAST and IZOM are examples of good practise in overcoming obstacles to the provision of cross-border healthcare. Under both agreements, the most prevailing obstacles – mandatory prior authorisation and the burden of the reimbursement system – had been resolved. The establishment of euPrevent and the IZOM-project show that this type of cooperation, specifically in the Euregio Meuse-Rhine, would not be new. Partially due to the adoption of the Directive, the IZOM-project was terminated however. The question arises whether the decision to revert to EU legislation was truly a step forward or a step back. Rather than maintaining fluency in patient mobility, the termination of the project and reliance solely on the Directive's procedures may have subjected the residents of border regions to obstacles that the IZOM-scheme had been designed to avoid. This suggests that, **in the light of the current EU legal framework, establishing agreements between the Member States' respective authorities may be the best solution to organise well-functioning healthcare in cross-border regions.**

However, national governments may traditionally be hesitant to engage in cross-border healthcare cooperation – the political sensitivity of healthcare traces back to its financing. The reimbursement system established by the Directive, as well as the prior authorization system established by the

were 1281 forms, mostly from the Netherlands, issued for healthcare in Belgium (mainly in Genk and Tongeren), for Dutch and German patients. Dutch patients coming for treatment in Belgium do so because of waiting times in the Netherlands.

⁸⁵ European Commission, 'European Cross-border Cooperation on Health: Theory and Practice' 2017 https://ec.europa.eu/regional_policy/sources/cooperate/crossborder/cbc_health/cbc_health_en.pdf, p. 63.

⁸⁶ European Commission, 'Enhancing healthcare cooperation in cross-border regions' https://ec.europa.eu/futurium/en/system/files/ged/booklet_enhancing_healthcare_cooperation.pdf. Find about more at <https://euprevent.eu/nl/>.

Regulation, reflect the Member States' willingness to limit the access to and the funding of healthcare abroad. Nonetheless, as stated at the beginning of the dossier, cross-border healthcare in border regions does not necessarily equate with medical tourism, and collaboration on healthcare provision in border regions may be mutually beneficial for both sides of the border: the ZOASTs, for example, resulted in a reduction in the costs of healthcare.

The financial impact of cross-border healthcare also depends on the costs of healthcare in each country. When looking at healthcare spending in Belgium, the Netherlands, and Germany (Table 2), the values do not differ significantly. Healthcare expenditure in these countries has actually been subject to a similar, increasing trend, which would speak for assessing the potential of cross-border cooperation in terms of realising (greater) efficiency in healthcare provision.⁸⁷ Furthermore, according to patient mobility statistics, planned care sought abroad is of minor financial impact⁸⁸, and the Directive has not had a major budgetary impact on the sustainability of health systems.⁸⁹ Moreover, to support the organisation of cross-border healthcare cooperation, the authorities could make use of EU subsidies. For instance, the Interreg-programme used in the context of euPrevent may provide funding options in order to initiate such cooperation.

Finally, yet importantly, the public consultation on the evaluation of the Directive has highlighted that the barriers identified regarding the cooperation of hospitals, health authorities and health insurers in border regions relate mainly to the differences in health systems and resources.⁹⁰ This implies that effective cross-border cooperation requires careful study of the differences between the health systems. The above analysis effectively confirms this point. Furthermore, as demonstrated by the seven different ZOASTs along the Belgian-French border, there is no "one-size-fits-all" solution to organizing cross-border healthcare for each border region.⁹¹ Healthcare needs are not always directly applicable from one border region to the next: each border region is distinct in its own way. As a result, border-regions may benefit from tailor-made agreements for their citizens' access to services. However, some common elements, such as using the existing Regulation system to settle bills between relevant institutions, could provide a beneficial basis for many (cross-border) agreements (see Table 4). Nevertheless, although such tailor-made agreements could be advisable, it is also important to ensure flexibility. As demonstrated by the termination of the IZOM-project, in the absence of national willingness, such agreements could be more sustainable if organized in a more flexible manner, and between smaller (organizational) actors. As a result, practical solutions may be beneficial alongside structural solutions. Given the unique characteristics of each border region, establishing such

⁸⁷ M. Bouwmans, D. Baeten, A. Cansel, C. Frasier, S. Mattson, M. Midiere, P. Steskens, 'Obstacles and opportunities in the cross-border provision of pediatric surgical care through the Euregional Center for Pediatric Surgery' PREMIUM-project (unpublished), pp. 19-20.

⁸⁸ Planned healthcare under the framework of the Regulation amounted to 0.02-0.03% of total healthcare spending in 2019, European Commission 'Member State data on cross-border patient healthcare following Directive 2011/24/EU' 2019, pp. 44-45.

⁸⁹ European Commission, 'Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare' COM(2018) 651 final.

⁹⁰ European Commission, 'Evaluation of patient rights in cross-border healthcare: Public Consultation Factual Report' Ref. Ares(2021)6103901 - 07/10/2021, p. 5.

⁹¹ This may raise the question whether a stronger legislative role of the EU on the organisation of (cross-border) healthcare is desirable, as the border regions may benefit from bottom-up approaches, rather than top-down.

agreements necessitates cooperation and political commitment, not only from the national level, but also from local and regional authorities, as well as health insurers and healthcare providers.⁹²

Table 4: Factors of success for establishing well-functioning healthcare in border regions

Cooperation	<ul style="list-style-type: none"> •EU, Member States, local and regional authorities, health insurers, healthcare providers, patients •Continuity of network, knowing and trusting each other
Attention to the differences between border regions	<ul style="list-style-type: none"> •Health systems and their incongruences •Identification of the region's characteristics: territorial dynamics, demographics, healthcare availability and needs, particular barriers
Agreements	<ul style="list-style-type: none"> •Overcoming obstacles & financial and administrative burden for border region inhabitants •Inspiration from other successful cross-border cooperation projects •Flexibility
Funding and payment	<ul style="list-style-type: none"> •Possibilities of EU-level funding •Using existing payment mechanisms, e.g. Regulation 883/2004

5. Conclusions

5.1 Substantive Conclusions

The dossier conducted an ex-post assessment of the Patients’ Rights Directive 2011/24, focusing on the inhabitants of (cross-)border regions’ access to cross-border planned medical care.

At first, the dossier discussed the importance of cross-border healthcare provision in border regions. In this regard, it was determined that border regions, as well as their populations, have distinctive characteristics and needs compared to national centres. Border regions may lack adequate healthcare services due to their peripheral location and unique demographics, necessitating the availability of these services across the border. Border region inhabitants as healthcare users also distinguish themselves from domestic users, ‘medical tourists’ or even frontier workers, in that they may have a

⁹² “Addressing bottlenecks requires a robust organization involving both regional and national authorities. Border obstacles are experienced locally or regionally and addressing them will primarily benefit that border region. This is where the dynamic in tackling them must be located primarily located”, Rijksoverheid, *‘Niet aanpassen, maar afwijken - Verslag van de bestuurlijke werkgroep grensbelemmeringen’* 20 October 2020, p. 34.

structural need for healthcare services across the border. Thus, cross-border healthcare provision may foster economic, social, territorial cohesion, and **Sustainable Development** in border regions.

Despite the importance of cross-border healthcare for border regions, the incongruences between the health systems of Belgium, the Netherlands and Germany create barriers for their citizens seeking treatment across the borders. The study has found that key obstacles usually emerge from cross-border inhabitants being required to obtain and then being refused prior authorization from their health insurers. In several situations, healthcare obtained abroad was only partially reimbursed. The diversity of the health systems particularly shows itself in the complications due to misaligned invoicing systems and insurance coverage, resulting in additional administrative and financial burdens for the patient.

These obstacles were then examined in light of the theme of **European Integration**. The dossier concludes that, although the EU legal framework does promote patient mobility in general, the Directive does not necessarily address the special characteristics and needs of cross-border regions. The EU's legal framework on cross-border healthcare generally seems more suitable for individuals who seek healthcare services in another Member State on an occasional basis than for inhabitants of cross-border regions who may have a structural need for cross-border healthcare services. The legal framework may thus disfavour residents of cross-border regions, in comparison to those who live in central areas. Nevertheless, the Directive also shows the potential to mitigate certain obstacles examined here – notably, those relating to prior authorisation and reimbursement – given its express reference to the healthcare needs of border regions and their populations. From a legal perspective, proper realisation of this “cross-border regional dimension” of the European framework, however, seems difficult to achieve as long as healthcare services remain a national prerogative. An even further strengthening of this dimension appears improbable at this point, due to the EU's restricted competences in terms of healthcare organisation.

That is why the role of the national authorities in Belgium, the Netherlands and Germany is important. Under the theme of **Euregional Cohesion**, it was explored how cooperation can help to eliminate disadvantages arising from the limited EU legal framework and from the peripheral location of the cross-border regions. Since cooperation between these countries is not new, several agreements were presented as examples of best practices that could further inspire and improve healthcare provision in these regions. In this respect, the dossier has identified several “factors of success” in establishing well-functioning healthcare provision in border regions. Here, the focus lies on cooperation best being realised through dialogue with actors at multiple levels: from health insurers to local, regional and national authorities (‘bottom-up approach’), and through flexible arrangements. The dossier also shows that any effort to establish successful cross-border healthcare frameworks would benefit from a careful study of the differences between health systems and the unique features of each border region resulting from these differences.

5.2 Outlook and further research

This cross-border impact assessment can be further developed by performing more detailed research on several aspects. This includes the collection of border obstacles, setting up consultations between the relevant actors in Belgium, the Netherlands and Germany, and performing an in-depth comparison of domestic legislations and each health system's incongruences. As this dossier has focused on the Patients' Rights Directive, more research could be performed on other instruments of cross-border healthcare, i.e. established under bi- or multilateral agreements (whether established between Member States or for instance, health insurers), national legislation or insurance schemes. Additionally, more data on cross-border healthcare could be collected: the study points to a particular lack of data on patient mobility in border regions.⁹³ Only after thorough investigation of all of these aspects can conclusions be drawn on cross-border healthcare in border regions. The European Commission's upcoming evaluation of the Directive in 2022 will certainly be much anticipated in this regard.

⁹³ The Association of European Border Regions (AEBR) is currently conducting research on cross-border patient mobility in selected EU regions. AEBR will collect information on the number of patients crossing borders using the Patients' Rights Directive. As a result, AEBR and DG SANTÉ will produce reports on four case studies of cross border regions. See more at <https://www.aebr.eu/focusing-on-patients-in-border-regions/>.

Annex: Further examples of obstacles to access to care facilities for inhabitants of (cross-) border regions

Long-term care

Obstacles arise from the different systems in Germany and the Netherlands regarding an indication to live in a care institution and/or to receive nursing services at home. The procedures and requirements according to the German Long-term Care Insurance Act (*Pflege-Versicherungsgesetz, PflegeVG*) relying on nursing level (*Pflegestufe*) classifications differ markedly from the indications (*verpleegindicatie*) determined based on the Dutch Long-Term Care Act (*Wet Langdurige Zorg (Wlz)*). Furthermore, as reported by the GIPs, systemic discrepancies make it hard for elderly (former) cross-border workers and their families to acquire access to appropriate care facilities. In some instances, people who live in Germany but are insured against healthcare costs in the Netherlands are unable to claim “*Pflegegeld*” (a benefit qualified as cash benefit) and are also excluded from the Dutch “*persoongebonden budget*” (a benefit qualified as benefit in kind that will not be exported). Complaints have also been received regarding reimbursement when families residing in Germany want to take care of a family member who is not insured in Germany.

Medical indications for access to special education

The mismatches and differences in the health systems may also have other negative effects on free movement. One example of these situations relates to the discrepancy between the Dutch and the Belgian system in setting ADHD diagnosis for children and young people to have access to adequate education facilities when living in a cross-border setting. Particular difficulties arise as a result of the disparities in medical personnel competencies: in the Netherlands, this diagnosis can be made by a nurse, whereas in Belgium, it can only be made by a doctor.

Health insurance costs

Persons who are living in Belgium and working in the Netherlands are insured by a Dutch insurance. As they are formally frontier workers, they have the possibility to receive healthcare also in their Member State of residence, in Belgium. For this purpose, the Dutch insurance company issues a S1-form (‘portability document’). With this document, the worker is able to register at a health insurer in Belgium and receive healthcare at the cost of the Dutch healthcare insurance. However, it is reported that often the frontier workers must pay membership fees of the Belgian health insurance (‘mutualiteit’) although they also pay health insurance premiums in Netherlands.

Emergency care in cross-border regions

Cross-border cooperation on ambulance services is necessary because response times set to adequately answer to medical emergencies are not always met in the border region, thereby resulting in life-threatening situations. Despite the obvious need for cross-border ambulance and emergency care, cooperation in this area is anything but obvious. Differences between national systems in the Netherlands, Belgium, and Germany concerning, for example qualifications, medical practice, organisational structure, reimbursement of care and technical requirements complicate the provision of cross-border ambulance services.⁹⁴

⁹⁴ See Kortese, L., Sivonen, S., ‘Cross-border Cooperation on Ambulance and Intensive Care Transport: Examining Opportunities to Strengthen Cooperation’ PANDEMERIC. See also European Commission, ‘Inventory of legal and administrative obstacles in EU border regions Entry no: 157 Border obstacle System differences for emergency health care’ https://ec.europa.eu/regional_policy/sources/policy/cooperation/european-territorial/cross-border/factsheets/157.pdf.