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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

{COM(2022) 210 final}

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Glossary

Term or acronym	*Meaning or definition*
Competent Member State	Member State under whose social security system the patient concerned is insured at the time of the cross-border treatment.
Cross-border healthcare	Cross-border healthcare refers to medical treatment outside the patient's country of residence, whether or not insured under the social security legislation of another Member State. The treatment is considered to be cross-border when received in any EU/EEA Member State or (but only in case of the application of the Regulations) in Switzerland and the UK.
CBHC Directive	Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.
European Economic Area (EEA)	The European Economic Area includes the Member States of the European Union and three countries of the European Free Trade Association: Iceland, Liechtenstein and Norway.
European Health Insurance Card (EHIC)	Free card, issued by the national health insurance institution that allows the patient to receive medically necessary, state-provided healthcare during a temporary stay in another EU/EEA country, Switzerland or the UK, under the same conditions and at the same cost (free of charge in some countries) as the persons insured in that country.
European Reference Networks (ERNs)	European Reference Networks are virtual networks involving healthcare providers across Europe, aiming to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources (https://ec.europa.eu/health/european-reference-networks/overview_en)
Follow-up care	Healthcare that may be required in the home country as a result of cross-border treatment or medical intervention with the purpose of providing aftercare or surveillance to ensure a good recovery.
Home country	The country where the patients reside and are entitled to sickness benefits, regardless of whether or not they are insured under the social security system of that country.
Insured person	Person or family member of a person who is subject or has been subject to the social security legislation of an EU/EEA Member

	State or (but only in case of the application of the Regulations) of Switzerland or the UK.
Member State of affiliation	Member State which under the Regulations is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence and issue the S2 form. This will normally be the country under whose social security system the patient is insured.
Member State of treatment	Member State on whose territory the cross-border treatment is actually provided or in the case of telemedicine the Member State where the healthcare provider is established.
National Contact Points (NCPs)	Under Directive 2011/24/EU, all EU/EEA Member States are obliged to designate one or more National Contact Points which provide patients with information on all aspects of cross-border healthcare.
Planned healthcare	Healthcare provided during a temporary stay abroad of which the explicit purpose was to receive it there.
Prior authorisation	Authorisation that patients need to receive from their national health insurance institution/health insurer in advance of their travel abroad in order to be guaranteed reimbursement for cross-border healthcare.
Regulations on the coordination of social security systems	Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems.
Reimbursement	Repayment to the patient by the national health insurance institution/health insurer, on certain conditions, of the costs incurred for cross-border healthcare services.
Necessary (unplanned) healthcare	Healthcare received by a patient in an EU/EEA country, Switzerland or the UK, which becomes necessary on medical grounds during a temporary stay in that State for work, study or leisure (i.e. without the initial purpose of the patient's travel being to receive treatment there) and that, taking into account the length of the stay, cannot wait until the patient returns home. This includes treatments provided in conjunction with chronic or existing illnesses. See explanatory note from the European Commission: https://ec.europa.eu/social/BlobServlet?docId=6481&langId=en

Acronyms and abbreviations

AEBR	Association of European Border Regions
ANEC	European consumer voice in standardisation
CBA	Cost-Benefit Analysis
CBHC	Cross-Border Healthcare
CPMS	Clinical Patient Management System
DG	Directorate-General
DG SANTE	Directorate-General for Health & Food Safety
ECA	European Court of Auditors
EDF	European Disability Forum
EEA	European Economic Area
EFTA	European Free Trade Association
EHDS	European Health Data Space
EHIC	European Health Insurance Card
ePAGs	European Patient Advocacy Groups
EPF	European Patients' Forum
EPHA	European Public Health Alliance
EQ	Evaluation Question
EQM	Evaluation Questions Matrix
ERICA	European Rare disease research Coordination and support Action
ERN	European Reference Network
EU	European Union
EUR	Euro
EXPH	Expert Panel on Effective Ways of Investing in Health
IT	Information Technology
JC	Judgement Criteria / Criterion
LGBTIQ	Lesbian, gay, bisexual, transgender, intersex, and queer/questioning
MS	Member State(s)
NCP	National Contact Point
OECD	Organisation for Economic Co-operation and Development
PGEU	Pharmaceutical Group of the European Union
SWD	Staff Working Document
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
ZOAST	Zones Organisées d'Accès aux Soins Transfrontaliers

1. INTRODUCTION

Access to high quality health services is a priority for EU citizens. *Directive 2011/24/EU on the application on patients' rights on cross-border healthcare*[1] (the CBHC Directive or the Directive) aims to ensure patients with safe and high quality healthcare services in a Member State other than the Member State of affiliation. It also provides a legal framework for reinforcing voluntary cooperation between EU countries in healthcare. While the Regulations on the coordination of social security systems have enshrined the right to receive healthcare in another Member State for various categories of insured persons since the beginning of the European integration[2], the Directive is the first piece of EU legislation in the area of health services. At the same time, the organization and financing of health systems remain the responsibility of the Member States.

Thanks to the application of the Directive, around 300,000 patients a year take advantage of the systems put in place under this Directive to receive (partial) reimbursement for the healthcare costs incurred in another EU country. The first 24 European Reference Networks (ERNs) bring together highly specialised medical experts from 900 healthcare units located in 313 hospitals offering their expert advice on the diagnosis and treatment of thousands of patients with rare or low prevalence complex diseases. The Commission encourages cross-border cooperation in healthcare, particularly in border regions, where EU funding has supported an estimated 400 cross-border initiatives to cooperate in healthcare[3]. European cooperation in health technology assessment and digital health has evolved significantly to meet new needs in healthcare across the EU.

The purpose of this evaluation is to assess how well the CBHC Directive has performed, a decade after its adoption in 2011 and eight years since its transposition deadline in

[1] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

[2] One of the first measures ever taken by the European Community were Regulations No. 3 and 4 on social security for migrant workers (OJ 30, 16.12.1958), which entered into force on 1 January 1959. On 1 October 1972, these Regulations were completely revised and replaced by Regulation (EEC) No 1408/71 (Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ L 149, 5.7.1971, p. 2)) and its Implementing Regulation (EEC) No 574/72 (Regulation (EEC) No 574/72 of the Council of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community (OJ L 74, 27.3.1972, p. 1)). Since 1971, these Regulations were the subject of several amendments in order to accommodate trends in national legislation and progress resulting from the rulings of the Court of Justice. On 1 May 2010, a new set of Regulations, Regulation (EC) No 883/2004 (Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166, 30.4.2004, p. 1)) and its Implementing Regulation (EC) No 987/2009 (Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems (OJ L 284, 30.10.2009, p. 1)) became applicable. On 13 December 2016, the Commission proposed a revision of the EU social security coordination rules. The proposal is currently under negotiations.

[3] EU funded projects from 2007-2017 (Bobek, J. et al. (2018). Study on Cross-Border Cooperation "Capitalising on existing initiatives for cooperation in cross-border regions", http://dx.doi.org/10.2875/825256).

2013. Its objective is to check whether the Directive is still relevant and "fit for purpose" to meet current and future patient needs. It also identifies where the Directive was not applied effectively and draws conclusions based on the evidence gathered for future policy decisions on the Directive.

This report assesses two key parts of the CBHC Directive using the evaluation criteria of effectiveness, efficiency, relevance, coherence and its EU added value. First, the CBHC Directive's provisions (Articles 1-9) covering the responsibilities of Member States with regard to cross-border healthcare, including the National Contact Points (NCPs). Secondly, this evaluation covers the provisions governing the recognition of prescriptions issued in another EU country (Article 11 and Implementing Directive 2012/52/EU[4]), the mutual assistance and European cooperation between regions (Article 10) and, in the area of rare and low prevalence complex diseases, the setting up of the ERNs (Article 12 including the Commission Delegated and Implementing Decisions[5]).

The evaluation covers the CBHC Directive's application in the EU-27[6] and EEA EFTA States Norway, Iceland, Liechtenstein from the period 2015, the time by which most EU countries had transposed the Directive into national law[7], until the end of 2020.

The CBHC Directive's provisions on eHealth (Article 14) have been evaluated separately as part of the work on the Commission's proposal for a Regulation on the European Health Data Space (EHDS). Following the adoption and entry into force of the Regulation on cooperation in health technology assessment in 2021, the CBHC Directive's relevant provision (Article 15) was repealed and therefore not part of this evaluation.

This evaluation largely draws on the evaluation study conducted by an external contractor, the replies received to the Commission's public consultation, which ran from May to July 2021, as well as several events organised by the Commission to gather feedback on the CBHC Directive. An important limitation was that little research has been conducted on the Directive and that there is insufficient comparative research across

[4] Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (OJ L 356, 22.12.2012, p. 68).

[5] Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (OJ L 147, 17.5.2014, p. 71), Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79) and Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).

[6] Although the UK ceased to be an EU Member State on 1 February 2020, the Directive still applied in that State transitionally until 31 December 2020. Thus, this report includes the UK patient mobility data (see below Section 3).

[7] Infringement proceedings were launched against 26 Member States on the grounds of non-notification or incomplete notification of transposition measures. After the Member States notified such measures, the infringement proceedings were closed: three proceedings closed in 2014, 19 – in the first half of 2015, one – end of 2015, two – in 2016 and the last one – in 2017.

countries on the impact of the Directive. The engagement of some stakeholders was also low: the researchers found it difficult to contact and engage the stakeholders during the course of the Covid-19 pandemic. In addition, there was evidence of stakeholder fatigue, as there were many concurrent activities in the area of healthcare. As not all sources of evidence are equally robust, consideration was given as to when and how the evidence was collected and whether there was any bias or uncertainty in it. The contractors used triangulation of data from the different data collection as a method to arrive at robust and evidence-based results that could be confirmed by more than one source. More information on the methodology and process to carry out this evaluation is available in Annex II and can be found on the Commission's dedicated webpage for the evaluation of the Directive[8].

This evaluation is part of the Commission's regulatory fitness and performance programme (REFIT[9]). It refers to the opinion of the Fit for Future platform adopted on 10 December 2021[10].

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

Description of the intervention and its objectives

EU legislation to facilitate cross-border healthcare in the European labour market has been in place since 1958[11]. Currently, Regulation No 883/2004 on the coordination of social security systems ensures the reimbursement for healthcare that becomes necessary on medical grounds during an insured person's temporary stay in another EU country using the European health insurance card (EHIC). It also covers planned healthcare subject to prior approval by the EU country where the citizen is insured.

In 1998, the Court of Justice of the EU (the Court of Justice) clarified principles for cross-border healthcare reimbursement through its rulings in two cases[12]. Over the next decade, there were further Court rulings on the principles on the freedom to provide health services based on Article 56 of the TFEU. The case law has made clear that the TFEU provisions on free movement apply to the reimbursement of health services regardless of how they are organised and financed at national level. To provide legal certainty of the 10-year case law on the freedom to provide health services in the EU and to give effective application of the citizens' rights in the EU internal market, the Commission proposed a Directive on the application on patients' rights in cross-border healthcare in 2008[13]. The CBHC Directive was adopted on 9 March 2011 and entered

[8] https://ec.europa.eu/health/cross-border-healthcare/evaluation-cross-border-healthcare-directive_en
[9] https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-less-costly-and-future-proof_en
[10] Fit for Future Platform Opinion, ref. 2021/SBGR3/14, available here: https://ec.europa.eu/info/sites/default/files/final_opinion_2021_sbgr3_14_patient_rights.pdf
[11] See footnote 2.
[12] Judgments of 28 April 1998, *Decker*, C-120/95, EU:C:1998:167; and *Kohll*, C-158/96, EU:C:1998:171.
[13] Proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, 2.7.2008, COM(2008) 414 final.

into force on 24 April 2011. It was due to be transposed by the Member States by 25 October 2013[14]. It is important to bear in mind that the CBHC Directive came into being at a time of economic recession with huge impacts on healthcare budgets in the EU.

The CBHC Directive's main aim was therefore to **provide sufficient legal certainty for citizens wishing to use cross-border healthcare**. It does this by setting out patients' rights, including the rules on reimbursement for cross-border healthcare costs in accordance with the Court of Justice's rulings, to ensure that EU citizens could use those rights in practice[15]. The legal provisions put in place complemented the existing legal framework for cross-border healthcare provided by Regulation (EC) No 883/2004 by removing certain obstacles to cross-border healthcare and by aiming to give citizens in certain instances the right of choice to healthcare services in the internal market. While both these EU instruments are about cross-border healthcare, their approaches differ: the Directive centres around *patients' rights* and encouraging cross-border cooperation in healthcare whereas the focus of the Regulation is *coordinating social security systems*. The Directive was *not* intended to replace the rights to cross-border healthcare under the Regulations nor to deprive patients of the more beneficial rights guaranteed therein when the conditions are met.

The second objective of the CBHC Directive was to **make sure that the necessary requirements for high quality and safe cross-border healthcare were respected throughout the EU**. The Commission's impact assessment accompanying the legal proposal[16] recognised that while citizens prefer healthcare to be available close to where they live and work, there are certain situations where the citizen may wish to be treated abroad. This is the case for highly specialised care requiring resources or expertise that is not available in every EU country such as for rare diseases, as well as where the nearest appropriate healthcare provider may be across the border or where the local services are unable to provide the appropriate healthcare yet there is capacity in another EU country. Some citizens may wish to be treated abroad to be close to their family, who may live in another EU country, or to seek a better quality or a cheaper procedure in another Member State. At the same time, patient flows between Member States were expected to remain limited.

The CBHC Directive also intended to **promote EU cooperation between health systems** in several areas where economies of scale of coordinated action between Member States could bring significant benefits to national health systems. EU countries were encouraged to provide mutual assistance and to cooperate in **border regions** to improve access to healthcare for patients and using resources more efficiently. In the **area of rare and low prevalence complex diseases**, the aim of the ERNs was to provide healthcare to patients who have conditions requiring a particular concentration of resources and to act as focal

[14] The Directive was due to be transposed by the EEA EFTA States by 1 August 2015.
[15] See proposal for a directive referred to in footnote 13.
[16] Commission Staff Working Document. Accompanying document to the Proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare – Impact Assessment, 2.7.2008, SEC(2008) 2163.

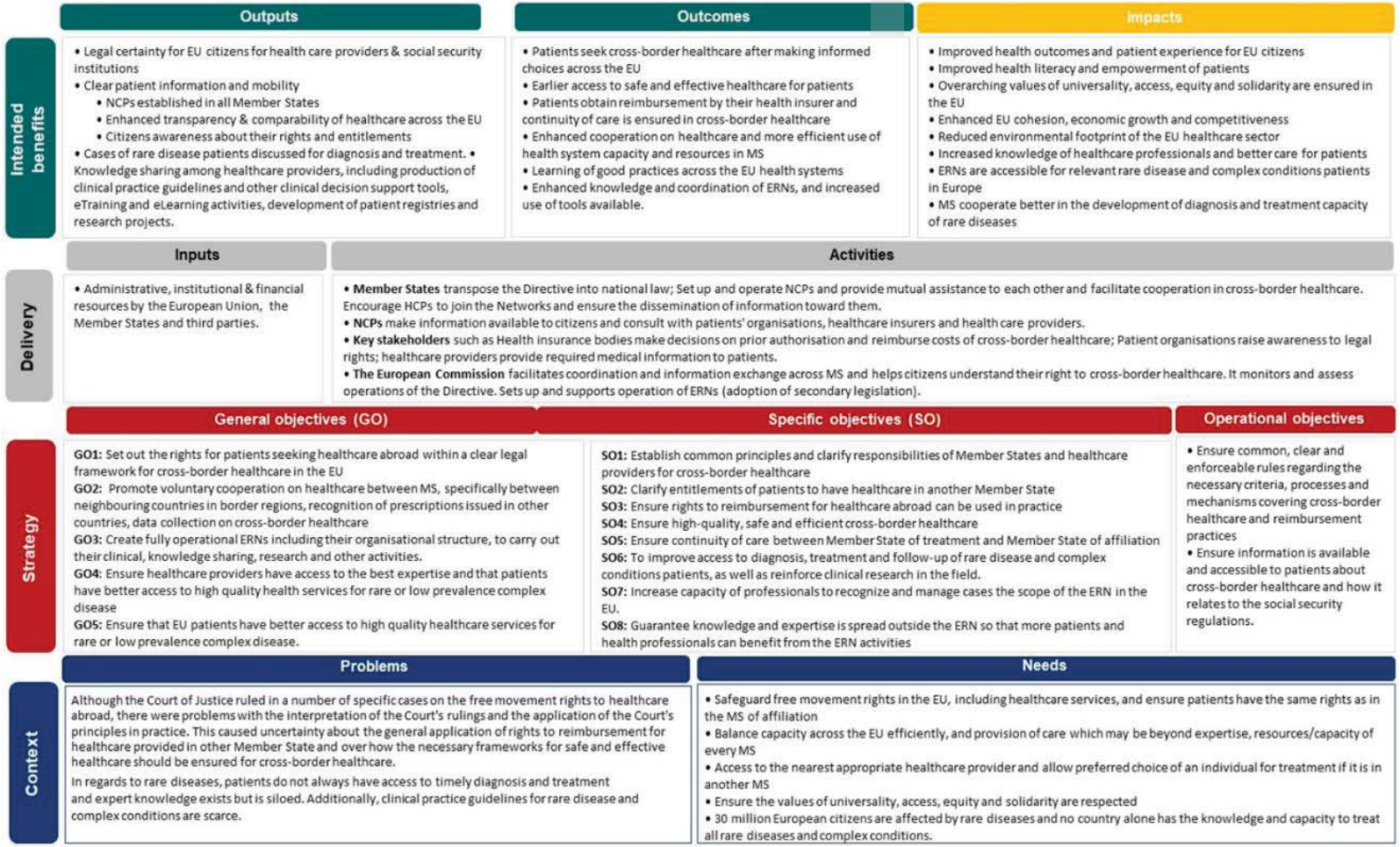
points for medical training and research, information dissemination and evaluation. A European network exchanging information to assess **health technology** could provide important evidence-based strategic advice to policy-makers and, lastly, in the area of eHealth, where different and incompatible formats and standards hampered the provision of **eHealth services**, a network of national authorities could work together to improve the interoperability of systems.

The Directive's Intervention Logic

The Commission's impact assessment accompanying the legal proposal did not develop an **intervention logic model** to describe how the CBHC Directive was expected to work at the outset. The Commission, with the support of an external contractor[17], therefore developed an intervention model retrospectively by analysing available document sources. This analytical work shows the different steps involved in the implementation of the Directive and highlights the expected cause and effect relationship regarding patient rights and rare diseases. The intervention logic in **Figure 1** excludes health technology and eHealth for the purposes of this evaluation.

[17] Study on enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU, https://ec.europa.eu/health/publications/study-enhancing-implementation-cross-border-healthcare-directive-201124eu-ensure-patient-rights-eu_en.

Figure 1: Intervention Logic of Articles 1-13 of the Directive



Source: Study on enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU

Legal Framework

The CBHC Directive's framework for ensuring patients' rights in cross-border healthcare applies to all health services provided by health professionals to patients, excluding organ transplants, public vaccination programmes and long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks. It ensures that all citizens who are insured in a Member State are eligible to receive treatment in another Member State and be reimbursed for it from the social security system of their own Member State. It sets out the responsibilities of the Member State of treatment and the Member State of affiliation. It requires Member States to have complaint procedures in place and sets out the rights of patients, such as the right to information and the right to follow-up care back home. It establishes the NCPs for cross-border healthcare to provide information to patients and it covers the administrative procedures for patients seeking healthcare in another EU country. Moreover, the Directive encourages voluntary cooperation on healthcare between Member States. Its provisions ensure the recognition of prescriptions for medicinal products and medical devices issued in other countries under the conditions established therein. It puts in place the legal framework for the creation of the ERNs in the area of rare and low prevalence complex diseases and promotes cooperation in the areas of health technology assessment and eHealth. It also requires Member States to provide mutual assistance as is necessary for the implementation of the Directive and encourages cooperation in the provision of cross-border healthcare at regional and local level, particularly in neighbouring countries and in border regions.

The CBHC Directive co-exists with the Regulations on the coordination of social security systems.

Points of comparison

This evaluation uses the Commission's first evaluative study on the Directive of 2015 as the point of reference[18] as most EU countries had transposed the Directive's provisions by then. Also since 2015, Member States provided the Commission with data to monitor the Directive's application in the EU.

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

Implementation in the Member States

The CBHC Directive came into force on 24 April 2011 and was due to be transposed into national law in the Member States by 25 October 2013. However, transposition was not completed until 2015 following infringements proceedings against 26 Member States (and 21 Member States in the case of Implementing Directive 2012/52/EU). More than five hundred national measures transposing the Directive were notified to the Commission. The large number of national laws involved was partly due to the fact the

[18] European Commission (2015). Evaluative Study on cross-border Healthcare Directive 2011/24/EU, available here: https://ec.europa.eu/health/system/files/2016-11/2015_evaluative_study_exsum_en_0.pdf

Directive regulated a number of issues which fell under regional competences and were subject matter of separate pieces of national legislation. The Commission's conformity checks focused on the application of the Directive in four key areas with the greatest potential to act as barriers to patients seeking cross-border healthcare: the systems of reimbursement, the use of prior authorisation, the administrative requirements and charging incoming patients. Infringement proceedings started against three Member States – Finland, Austria and the Netherlands – for a breach of the Directive in relation to the reimbursement of cross-border healthcare costs.

The Directive's provisions have been subject to four preliminary rulings of the Court of Justice that further clarified its rules on reimbursement of cross-border healthcare costs, also in light of the TFEU and the Charter of Fundamental Rights of the EU, as well as on recognition of prescriptions issued in other Member States[19].

Operation of the Directive 2015-2020

The Commission triennial reports describe how the operation of the CBHC Directive has progressed since 2015[20]. The Commission reported in 2015 and 2018 on cross-border patient flows, the financial dimension of patient mobility, the limitations on the application of the rules for reimbursement and the application of prior authorisation and the functioning of the ERNs and the NCPs[21]. The Commission's third report, due by October 2021, was postponed until April 2022 so as to include the key findings of the Commission's evaluation of the Directive as described in this staff working document[22].

In summary, the Commission reports conclude that the Directive has improved the legal certainty for cross-border patients as well for domestic patients over their rights, however there remain important shortcomings in the application of the Directive in the EU as described in the evaluation findings in Section 4 below. In terms of **patient flows**, in the countries that provided data for all reference years 2016-2020[23], the number of prior authorisation requests received and granted peaked in 2018 followed by a modest decline in 2019 and a larger decrease in 2020 (in view of Covid-19). Similarly, in countries for

[19] Judgments of 18 September 2019, *VIPA*, C-222/18, EU:C:2019:751; of 23 September 2020, *WO*, C-777/18, EU:C:2020:745; of 29 October 2020, *A*, C-243/19, EU:C:2020:872; and of 28 October 2021, *Y*, C-636/19, EU:C:2021:885.

[20] Article 20(1) of the Directive requires the Commission to draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council by 25 October 2015, and every three years thereafter.

[21] Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2015) 421 final, 4.9.2015 and Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2018) 651 final, 21.9.2018.

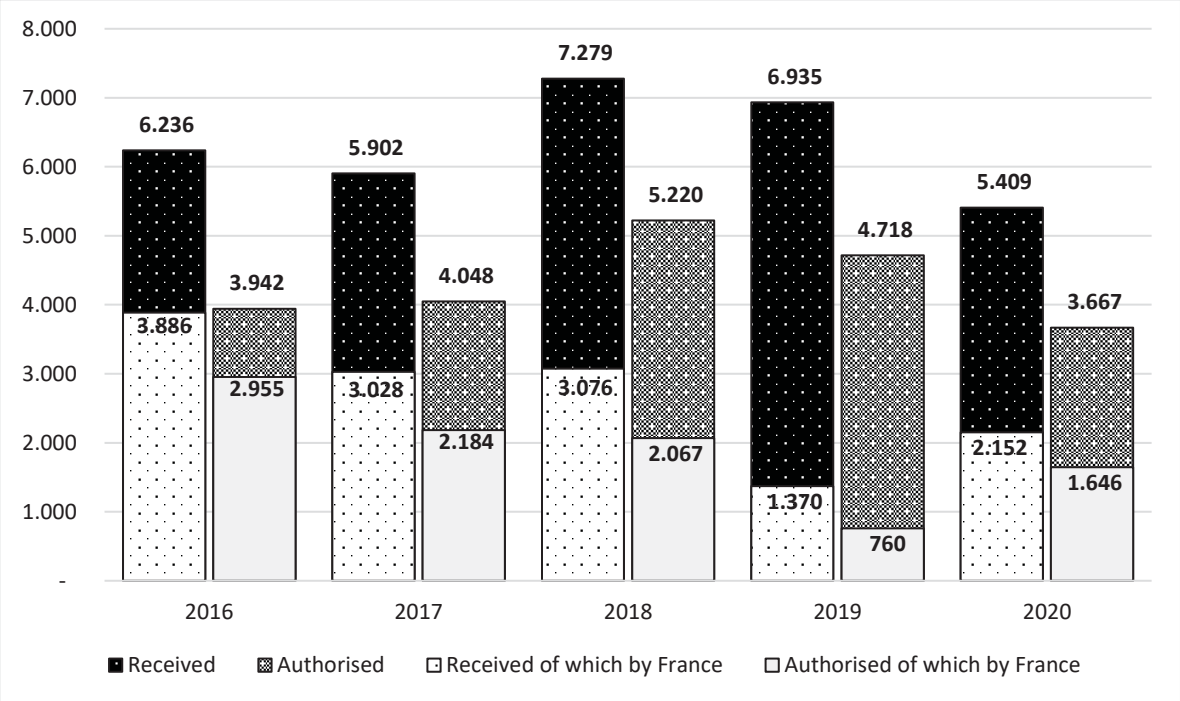
[22] Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2022) 210 final.

[23] This concerns 15 Member States (BE, BG, DK, ES, FR, EL, HR, IE, IT, LU, MT, PL, RO, SI, SK) and the UK.

which there is complete data[24], the number of requests for reimbursement received and granted saw a steady increase until 2018 and a slight decline in 2019 and 2020.

The total numbers of prior authorisation and reimbursement requests received by all the countries are illustrated in **Figures 2** and **3**[25].

Figure 2: Number of prior authorisation requests received and granted for all countries that provided data, 2016-2020



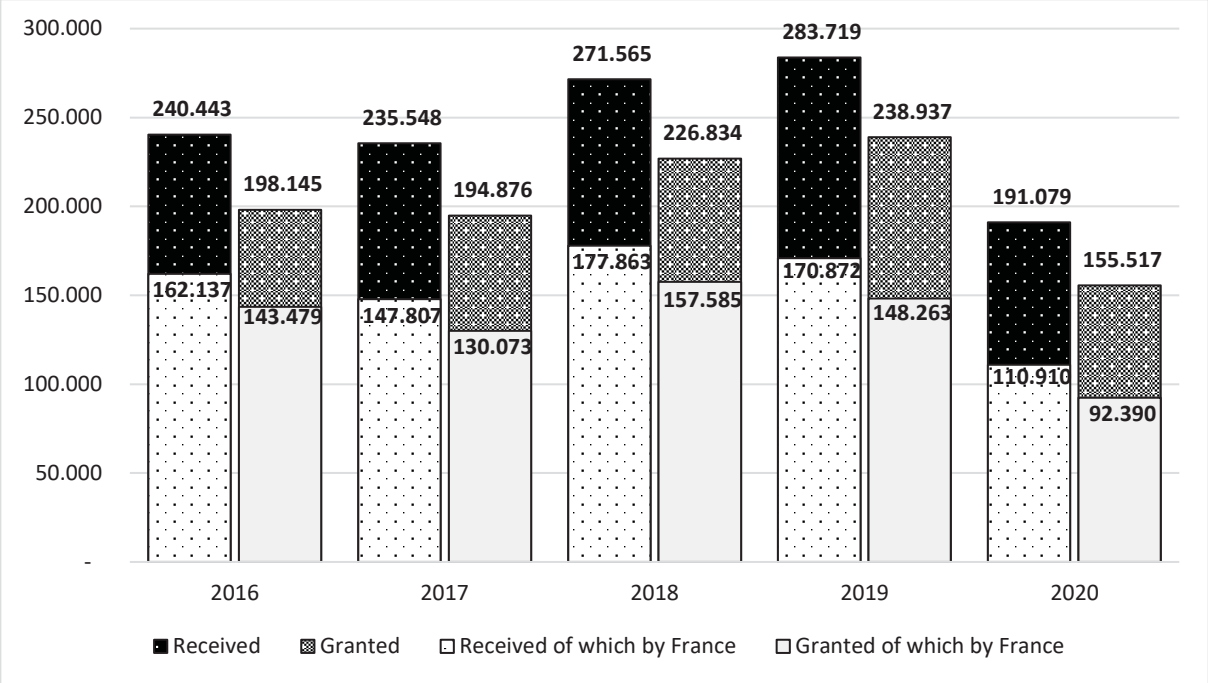
The totals excluding the UK are as follows: in reference year **2016**: 6,009 prior authorisation (PA) requests received and 3,822 granted; in **2017**: 5,471 PA requests received and 3,727 granted; in **2018**: 6,301 received, 4,447 granted; in **2019**: 5,352 received, 3,291 granted; and in **2020**: 5,218 received, 3,542 granted.

Source: Questionnaires on Directive 2011/24/EU reporting on patient mobility

[24] This concerns 17 Member States (BG, CZ, DK, EE, ES, FR, EL, HR, IE, IT, LT, LV, MT, PL, RO, SI and SK), the UK and NO.

[25] FR was not able to separate between the data for cross-border healthcare under the Directive and the Regulations on coordination of social security systems or under parallel schemes. In light of this, the numbers for FR are highlighted separately in **Figures 2** and **3**.

Figure 3: Number of requests for reimbursement without prior authorisation received and granted for all countries that provided data, 2016-2020



The totals excluding the UK are as follows: in reference year 2016: 238,680 reimbursement requests received and 197,152 granted; in 2017: 233,508 reimbursement requests received and 193,803 granted; in 2018: 269,006 received, 225,186 granted; in 2019: 280,594 received, 236,891 granted; and in 2020: 188,013 received and 153,960 granted.

Source: Questionnaires on Directive 2011/24/EU reporting on patient mobility

The most prominent patient flows have remained stable over the years and the majority take place between neighbouring countries and North European citizens using healthcare during short-term stays in the South. In 2019, the largest flows were from Ireland to the United Kingdom, France to Germany, France to Spain and from Norway and Sweden to Spain[26].

In addition, the Commission reports that the period 2018-2020 saw **significant progress to enhance cross-border cooperation in healthcare** with the adoption of EU implementing and delegated acts, paving the way for the creation of the ERNs in 2017 followed in 2021 by the adoption of a new EU Regulation on health technology assessment with the subsequent repeal of Article 15 from the Directive.

[26] Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020.

In 2017, the **ERNs** were established on the basis of Article 12 of the Directive, Commission Implementing Decision 2014/287/EU and Commission Delegated Decision 2014/286/EU. Currently there are 24 ERNs on rare or low prevalence complex diseases (see Annex VI).

By 2021, the ERNs were bringing together more than 900 highly-specialised healthcare units from over 300 hospitals in 26 EU countries and Norway. As of January 2022, the existing ERNs have been joined by 620 new members, bringing the total number of members to almost 1,500 and covering all the EU Member States and Norway. The members of the existing ERNs currently treat more than 1.7 million patients with rare or low prevalence complex diseases. The Commission launched a continuous monitoring system of the ERNs based on the set of 18 agreed key performance indicators in 2020. The analysis of the collected data is on-going.

Other EU institutions and bodies have drawn up reports on the implementation of the CBHC Directive. In 2018/2019, the **European Court of Auditors** (ECA) carried out an audit on the Commission's work overseeing the Directive's implementation and EU actions in cross-border healthcare. Its special report concluded that, while EU actions had enhanced cooperation between Member States, the impact on patients was rather limited. The ECA recommends improving information provided by the NCPs to patients and calls for more EU actions on eHealth and rare diseases[27]. Both the **Council**[28] and the **European Parliament** supported the ECA's recommendations. The European Parliament called for simpler administrative procedures and improving access to healthcare to patients[29]. In 2020, the **European Committee of the Regions** recommended more support for the authorities to comply with the Directive's obligations and recognised the value of prior notification of reimbursement costs and the use of prior authorisation to protect national health systems[30]. The **Fit for Future Platform Opinion**[31] recognizes the same obstacles to the Directive and makes eight concrete suggestions how to make it easier for European patients to understand their care options and access the best possible treatment and care.

The CBHC Directive has had an unexpected positive **impact on domestic healthcare systems** according to evidence from the literature review. It has acted as a *driver for the development and greater transparency of patients' rights* as well as leading to the introduction or adaptation of mandatory professional liability insurance and the implementation of quality indicators and standards[32]. Examples include the adoption of

[27] ECA Special Report 7/2019 *EU actions for cross-border healthcare: significant ambitions but improved management required*, 4.6.2019.
[28] Council conclusions in response to the ECA Special Report 7/2019, 12913/19 FIN, 23.10.2019.
[29] European Parliament Resolution on the implementation of the Cross-Border Healthcare Directive, 2018/2108(INI), 12.2.2019.
[30] ECR Opinion *Implementation and future perspectives for cross-border healthcare*, CDR 4597/2019, 14.10.2020.
[31] Referred to in footnote 10.
[32] Azzopardi-Muscat, N., Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E. (2018). The role of the 2011 patients' rights in cross-border health care directive in

explicit benefit packages in Malta and Finland; reimbursement of telemedicine services in Belgium; the introduction of mandatory professional liability insurance in Malta and Poland (and expected in Estonia); and the adaptation of this liability insurance in Germany. Some efforts to lower waiting times for healthcare in Poland and Malta may also be attributed to the influence of the Directive. In addition, other studies show that the Directive encouraged Member States (such as Austria, Belgium, Finland, Hungary, Latvia, Luxembourg, Malta, Norway, Poland, Spain) to be more transparent about patients' rights in general and that existing national rules on, for example, informed consent, privacy and access to medical records apply to cross-border patients in the same way as for domestic patients[33]. Another change that can be attributed to the Directive is related to private clinics in Belgium, which will be made subject to quality standards that previously only applied to hospitals as from 2022. There are also examples of countries (as mentioned above) which have introduced explicit statements of what is included in a patient's benefit basket, and those which have introduced or adapted mandatory liability insurance for professionals[34].

Secondly, there is evidence that **medical tourism agencies**, for example in Ireland and Poland, have emerged since the CBHC Directive was adopted[35]. However, there is a lack of data on the actual extent of usage and reimbursement of these services, both within and outside the framework of the Directive.

With regard to external factors, due to the temporary restrictions on the free movement of people in response to the Covid-19 pandemic[36], patient mobility under the Directive dropped significantly from 283,719 applications for reimbursement without prior authorisation received in 2019 to 191,080 in 2020.

The Commission has published all the above reports and external studies on the implementation of the CBHC Directive on its website[37].

4. EVALUATION FINDINGS

4.1. To what extent was the intervention successful and why?

Overall the evaluation found that the Directive has been successful in delivering its objectives to a certain extent. It has brought additional legal clarity on the rights of patients to use healthcare services anywhere in the EU and it has enshrined important

shaping seven national health systems: Looking beyond patient mobility. *Health Policy*, *122*(3), pp.279-283.

[33] European Commission (2016). Patients' Rights in the European Union Mapping eXercise, available here: https://limo.libis.be/primo-explore/fulldisplay?docid=LIRIAS1950327&context=L&vid=Lirias&search_scope=Lirias&tab=default_tab&fromSitemap=1

[34] European Observatory on Health Systems and Policies (2019). Everything you always wanted to know about European Union health policies but were afraid to ask, 2nd ed., available here: https://apps.who.int/iris/bitstream/handle/10665/328267/9789289051767-eng.pdf

[35] *Ibid*.

[36] Frontier workers were exempted from these border restrictions.

patient rights, such as equal treatment of EU and domestic patients. It has achieved a more consistent approach at EU level to reimbursement of cross-border healthcare costs for EU citizens. It has acted as a driver for patient rights in general, increasing transparency on treatment prices and bringing about changes in various national health systems to the benefit of patients. EU citizens are making use of their rights and the reimbursement mechanisms provided by the Directive, although their numbers remain small. The general public has largely benefited from the Directive's provisions regulating the recognition of prescriptions.

The Directive has made a significant contribution in the area of rare diseases with the creation of the ERNs to support the diagnosis and treatment of rare disease patients. It has also played a crucial role to deepen European cooperation between health systems in the area of health technology assessment, leading to the adoption of a separate Regulation in 2021, and also in eHealth, leading to the proposal for a Regulation on the EHDS.

Effectiveness

4.1.1. How effective was the Directive in the area of patients' rights?

The CBHC Directive has facilitated access to safe and high quality cross-border healthcare *to some extent* by clarifying the responsibilities of the Member States with regard to cross-border healthcare and the rules on reimbursement of costs of such healthcare.

To enable citizens to make an informed choice regarding healthcare abroad, the Directive obliges Member States to ensure that citizens receive the relevant information and sets out other important responsibilities with regard to cross-border healthcare. Among the responsibilities of the Member States' of treatment are the obligations to ensure that patients from other Member States are treated equally with domestic patients regarding access to treatment, that standards and guidelines on quality and safety laid down by that Member State and EU legislation are ensured, as well as that the healthcare providers apply the same scale of fees for services for patients from other Member States as for domestic patients or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients. The Member State of affiliation is required, among other things, to ensure the same medical follow-up as would have been available if the healthcare at issue had been provided on its territory.

Unequal access to health services in the Member State of treatment has not been reported as encountered by patients. The same is true regarding the different quality of healthcare in the Member State of treatment for domestic and cross-border patients. Nor has the Commission identified that healthcare providers are setting, or are allowed to set, discriminatory prices for patients from other Member States. This evidences *certain success* of the CBHC Directive in ensuring patients' rights.

[37] https://ec.europa.eu/health/cross-border-healthcare/overview_en

However, the CBHC Directive is *perceived* as less effective in creating legal certainty and clarity over the patients' rights to cross-border healthcare based on the replies of the majority of public consultation respondents, particularly patients and patient organisations. Conversely, 34% of healthcare authorities, providers and insurers consider the Directive has achieved clarity and certainty *to a limited extent*. Insufficient and unclear information on cross-border healthcare, multiple interpretations of the relevant rules and uncertainty over the level of reimbursement were among the reasons cited. The gaps in information for patients about their rights alongside with financial burdens are considered as the most important problems resulting from cross-border healthcare.

By codifying the case law, the CBHC Directive has ensured a *more consistent approach* at EU level to reimbursement of cross-border healthcare costs for EU citizens compared to the situation where Member States were to comply directly with the TFEU provisions, as interpreted by the Court of Justice. At the same time, recognising the organisation and delivery of healthcare as a national competence, the Directive's provisions are formulated in a way that leaves sufficient room for manoeuvre for Member States to limit certain patients' rights on overriding reasons of general interest, if the principle of proportionality is respected. However, the conformity checks undertaken by the Commission show that this resulted in quite a divergent implementation of the Directive across EU countries and each restrictive national measure has to be assessed on a case-by-case basis[38]. This also essentially means that patients' rights to cross-border healthcare cost reimbursement might differ in each Member State and full clarity about the content of these rights could only be ensured on a national level.

EU citizens are using the CBHC Directive to seek healthcare across borders as a result of the Directive removing some obstacles to cross-border healthcare. Patient mobility data from 2015-2020[39] shows that reimbursement cases for treatment in another EU country under the Directive steadily increased until 2018 and then declined in 2019 and 2020. Patient mobility under the Directive remains low with around 300,000 requests for the reimbursement of cross-border healthcare. However, taking into account the data robustness and that several countries fail to report patient flow data[40], the Directive has to some extent met the expectations of the Commission's impact assessment accompanying the legal proposal[41], which anticipated an estimated 390,000-780,000 patients annually to benefit from the preferred option. Moreover, while the Directive's impact on patient flows is rather limited, the promotion of cross-border healthcare is not the objective of the Directive.[42] At the time of the adoption of the Directive, it was expected that patient flows would remain limited[43]. Stakeholders indicated that most patients prefer to receive healthcare close to home and that going abroad is very difficult and costly. Even if they

[38] See COM(2022) 210 final.
[39] See the report referred to in footnote 26.
[40] DE, NL and LI have not been able to provide data on patient flows due to structural reasons.
[41] Commission Impact Assessment, referred to in footnote 16, Table 1 "Comparing the Options" (preferred option 3A 780,000 patients and sub-option 3b 390,000 patients).
[42] Recital 4 of the CBHC Directive.
[43] Recital 39 of the CBHC Directive.

do go abroad, in most instances they prefer to do so under the Regulations on the coordination of social security systems or any existing parallel schemes as there might be no or less out-of-pocket expenses for the patient to bear.

Information to patients on cross-border healthcare

Limited access to information for patients about their rights was highlighted by public consultation respondents as a key reason why the CBHC Directive do not meet patients' needs adequately[44]. According to a 2021 Eurobarometer survey[45], EU citizens still do not feel well informed about their healthcare rights, indicating that many are not able to make an informed choice about cross-border healthcare: 25% of EU citizens surveyed felt "well-informed" about what healthcare they have the right to receive and to be reimbursed for in another EU country compared to 17% in 2015; however 72% felt "not well informed" compared to 78% in 2015. Survey findings by country shows a higher awareness of rights in Northern/Western Europe over respondents in Southern/Eastern Europe.

The NCPs for cross-border healthcare play a key role in enhancing patients' opportunities to seek healthcare abroad. By 2016, all Member States had established a NCP for cross-border healthcare to provide clear and accessible information to citizens about cross-border healthcare in accordance with Article 6 of the Directive. Through the creation of the NCPs, the Directive has effectively contributed to the gradual improvement of patients' awareness of their rights. However, awareness remains rather low with just over half of the public consultation respondents aware that NCPs existed. Those that found information on the NCPs websites ranked it higher for clarity and quality rather than completeness. Overall, information on cross-border healthcare has improved between 2015 and 2021 according to an analysis of NCPs websites in 2018[46] and in 2021[47]. A Commission study in 2018[48] considered the information adequate. Nonetheless, many stakeholders, particularly patient organisations, highlighted information gaps, which hinder the effectiveness of the Directive to facilitate access to healthcare in another country. The European Patients' Forum states in its position paper that clear information about patients' entitlements, even within the domestic healthcare system, was a gap. When it comes to receiving treatment abroad, financial implications of the choices available are quite important to know in advance[49]. The Fit For Future

[44] 21% of public consultation respondents. 3rd most popular issue raised in the consultation response.
[45] Standard Eurobarometer 95 - Spring 2021, available here: https://europa.eu/eurobarometer/surveys/detail/2532
[46] European Commission (2018). Study on Cross-border health services: enhancing information provision to patients, available here: https://ec.europa.eu/health/publications/final-report-study-cross-border-health-services-enhancing-information-provision-patients_en
[47] Study on enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU, available here: https://ec.europa.eu/health/publications/study-enhancing-implementation-cross-border-healthcare-directive-201124eu-ensure-patient-rights-eu_en
[48] See the study referred to in footnote 46.
[49] The European Patients' Forum (EPF) Response Statement "Public consultation on Cross-border Healthcare – evaluation of patients' rights", 11.2.2021, available here: https://www.eu-

Platform also highlights how the NCPs are generally not known as information point for healthcare abroad and there is a lack of awareness at regional level[50].

Information on healthcare providers has increased considerably when comparing the results of 2021 with those of 2015 and 2018, although there are significant differences between countries. Gaps were identified particularly in relation to the provision of contact details and the provision of search tools to help patients find specific healthcare providers.

Particularly important for patients is information on whether to seek healthcare under the CBHC Directive or the Regulations on the coordination of social security systems, and to know whether prior authorisation is a pre-requisite for reimbursement of medical costs. A 2021 Commission study found that out of the 22 Member States and EEA EFTA countries having prior authorisation system in place, only 17 NCPs websites provide a specific list of treatments subject to prior authorisation in their country[51]. Other countries, both in their implementing legislation and on the NCPs websites, only refer to general criteria of healthcare that could be made subject to prior authorisation in accordance with Article 8(2) of the Directive thereby undermining legal certainty for patients about the exact content of their rights to healthcare abroad. Moreover, less than half the NCPs were found to provide information on the distinction between the Directive and the Regulations, according to an analysis of NCP websites[52]. The ECA noted that this issue affected patients' choice for reimbursement of healthcare.

While for 20 out of 30 NCPs information on reimbursement costs improved, information on pricing of treatments is generally lacking. This is due to a lack of information at national level.

Only 10 out of 31 websites provided options for people with decreased sensory functions. The European Disability Forum (EDF) report[53] stated that patients with disabilities seeking cross-border healthcare face difficulties finding information on their rights under the CBHC Directive, due to the lack of options for people with decreased sensory functions and due to the amount of information being limited.

To improve the information provision to patients, the Commission developed and published a multi-lingual toolbox for NCPs with the support of the EPF. This includes guiding principles for the practice of NCPs under the CBHC Directive (see **Box 1**) and a Manual for Patients[54]. While sixteen NCPs have published the toolbox on their websites,

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patient.eu/globalassets/events/old/2014/2014_cbhc_gr/presentations/day2/epf_cbhc_consultation-feedback_final.pdf

[50] See the opinion referred to in footnote 10.

[51] Study supporting the evaluation of the Directive, Annex 1.5.8.

[52] *Ibid*, Annex 1.5.5.

[53] European Disability Forum (2021). Report on access to cross-border healthcare by patients with disabilities in the European Union, available here: https://www.edf-feph.org/content/uploads/2019/08/EDF-report_on_health_revised-accessible.pdf

[54] https://ec.europa.eu/health/cross-border-healthcare/toolbox-cross-border-healthcare_en

respondents to a survey of patients' organisations, healthcare insurers and healthcare providers showed that they are not very familiar with the toolbox[55].

Box 1: Guiding Principles for the Practice of NCPs

General Principles:

- Principle of visibility
- Principle of accessibility
- Principle of transparency
- Principle of inclusion

Information provision in accordance with Directive 2011/24/EU:

- Principle of duality
- Principle of information to outgoing patients in accordance with the Directive
- Principle of information to incoming patients in accordance with the Directive

Cooperation:

- Principle of information to healthcare providers
- Principle of cooperation

The CBHC Directive has contributed *to some extent* to enhance transparency and comparability of healthcare (regarding safety, quality, costs and waiting times) across the EU, according to interviewees. In many cases, it has acted as a driver for Member States to make information on patients' rights and quality of care more transparent and to adapt professional liability standards for health professionals. However, this has not been systematic across all Member States. Moreover, according to an analysis of NCPs websites[56], there are persisting gaps in the provision of information regarding safety and quality standards, costs, waiting times etc. Only 9 NCPs websites provide information on national laws regarding patient safety.

The Directive requires that NCPs consult with key stakeholders. However, a 2021 Commission funded study[57] showed that, in total, only 16, 19 and 21 of the NCPs had such consultations arrangements (informal or formal) with patient organisations, insurers and healthcare providers respectively. Moreover, where they are in place, the NCPs are in contact with these stakeholders on an irregular or rare basis.

Obstacles to access healthcare abroad

Citizens continue to face important obstacles hindering the effectiveness of the CBHC Directive to meet its main objectives. The public consultation responses identified the five biggest barriers (out of 20 listed) as paying for healthcare costs upfront, extensive

[55] See the study referred to in footnote 17.
[56] Study supporting the evaluation of the Directive, referred to in footnote 51.
[57] *Ibid*.

use of prior authorisation, complex administrative procedures and uncertainty over reimbursement and information to patients.

Paying for healthcare costs upfront represented the biggest barrier to healthcare abroad according to the public consultation respondents (117 out of 169 respondents) and interviewees. While the Directive provides a mechanism for citizens to seek (partial) reimbursement from their health insurer, patients must pay upfront for their treatment abroad and face additional costs for travel and accommodation as usually these are often not reimbursed in Member States (nor is this required under the Directive). Because patients are reimbursed at the same level of costs as if treated where they are insured, patient organisations in particular take the view that the Directive increases inequalities in healthcare, as there is a discrepancy in tariffs for healthcare services between EU countries. Patients from countries with lower tariffs for healthcare have to pay a large difference out of their own pocket if treated in a country with higher tariffs/prices and seek reimbursement under the Directive, thereby undermining the Directive's aim to facilitate access to healthcare EU-wide. Paying costs upfront also impacts those unable to afford to pay in advance for healthcare abroad. The issue of access becomes particularly acute for patients with rare and low complex diseases whose only option may be to receive care and life-saving treatment via a specialized centre in a different country.

In this context, it is important to recall the objectives of the Directive to facilitate cross-border healthcare: first, it complements the Regulations on the coordination of social security systems. In cases such as for rare disease patients where highly specialised and cost-intensive care is necessary, the Regulations offer a more favourable route to treatment in another country as the social security bodies are responsible for the reimbursement of the treatment costs and in most instances, the patient will not need to pay costs upfront[58]. Secondly, under the Directive, patients pay costs upfront as it is the only viable way to *empower* the citizen to choose a healthcare provider, whether public or private, in another EU country without prior approval *outside the circumstances coordinated under the Regulations for the coordination of social security systems* while also giving the patient the right to reimbursement of (some) costs by their health insurer.

The **extensive use of prior authorisation** to access cross-border healthcare and associated application processes prevents the realisation of the Directive's full potential and hampers its effectiveness. In line with case law of the Court of Justice, making reimbursement of costs for cross-border healthcare subject to prior authorisation is a restriction to the free movement of services[59]. Therefore, *as a general rule*, the Member States *should not require* prior authorisation[60]. Indeed, the highest added value of the Directive's route for cross-border healthcare reimbursement compared with the

[58] Cross-border healthcare under the Regulations on the coordination of social security systems in general and the prior authorisation requirement for planned treatment abroad under the Regulations in particular is out of the scope of this evaluation.

[59] See, e.g., judgment of 23 September, *WO*, C-777/18, cited in footnote 19, paragraph 58 and the case law cited therein.

[60] Recital 38 to the Directive.

Regulations is the reduction of administrative burden for patients in that they can choose, for example to have outpatient treatment or a day surgery in another country without the need for prior authorisation and be reimbursed for the costs according to the domestic tariff where they are insured. The Directive only allows Member States to use a system of prior authorisation for the categories of healthcare and under specific conditions set out therein, including with due respect to the principle of proportionality. However, currently, only seven EU Member States and one EEA EFTA State[61] have no prior authorisation system in place, giving patients freedom to choose a healthcare provider abroad and reducing administrative burden. Other countries have introduced a prior authorisation system mainly for cross-border healthcare that involves overnight hospital accommodation and/or for major non-hospital healthcare. The Member States' lists of healthcare subject to prior authorisation also differ significantly in the extent to which the healthcare is further specified and in the number of the separate items on the lists[62]. At the same time, a steady very low number of prior authorisation requests, as well as a relatively low number of reimbursement requests for healthcare that is not subject to prior authorisation, having marginal impacts on national healthcare budgets, do not generally point to a need of extensive prior authorisation systems under the Directive.

Complex administrative procedures for prior authorisation for cross-border healthcare and **reimbursement** are hampering the effectiveness of the Directive to facilitate the access to cross-border healthcare to the benefits of patients. The Directive requires that administrative procedures relating to prior authorisation requests and reimbursement must be based on objective, non-discriminatory criteria that are necessary and proportionate. Yet 66 out of 169 respondents to the public consultation, from most stakeholder groups, particularly patients and citizens, selected administrative procedures to cross-border healthcare as a key barrier. In 2018, the Commission in its triennial report identified administrative procedures as a key area with potential to act as barriers to healthcare[63] and the European Parliament report refers to "unduly burdensome and/or restrictive" systems implemented at national level[64]. Recent research into national administrative procedures for cross-border healthcare confirm that some national requirements may pose disproportionate barriers to patients seeking healthcare in other EU countries.

Box 2: Examples of potentially disproportionate administrative requirements for cross-border healthcare[65]

Requirements for prior authorisation:

[61] CY, CZ, EE, FI, LV, LT, SE and NO have not chosen to introduce a prior authorisation system or have decided to remove it. In addition, NL has not introduced a prior authorisation system in its national legislation, but where persons insured under the NL social security system have access to cross-border healthcare, prior authorisation seems to be required by the health insurers.

[62] Mapping and Analysis of Prior authorisation lists: analytical report, see the study referred to in footnote 17.

[63] COM(2018) 651 final, referred to in footnote 21.

[64] European Parliament resolution of 12 February 2019, referred to in footnote 29.

[65] See further Mapping and Analysis of Administrative Procedures: analytical report, the study referred to in footnote 17.

- In three countries, patients have to submit, together with the application, documentation issued directly by the foreign healthcare provider, either confirming information on the healthcare to be received abroad, or on the healthcare provider and/or its availability to provide the requested service.
- In one country, patients have to submit the calculation of expected costs for the planned healthcare abroad prepared by the foreign healthcare provider which will provide healthcare.
- In nine countries, the patient seems to be required to provide in the application information concerning the availability of the healthcare and/or the waiting time for the service in the country of affiliation. For example, in one country, it is required to provide a certificate from at least two hospitals confirming that the proposed healthcare cannot be provided in that country within a medically acceptable period.
- In one country, it is required to provide a document issued by the NCP in the country of treatment showing that the healthcare provider does not give rise to serious and specific concerns relating to the observance of the standards and guidelines regarding the quality of medical assistance and safety of patients, including provisions regarding supervision.
- In seven countries, the practitioner whose referral is necessary for prior authorisation must be a national/contracted doctor, whilst in other twelve countries, the sources consulted do not seem to provide any indication on the country affiliation of the practitioner, thus the legal certainty is not ensured for patients.
- In two countries, official/certified translations of supporting documents have to be provided together with the application.

Requirements for reimbursement:

- In one country, a certificate from the treating doctor regarding the legal status of the institution of treatment must also accompany the request. In addition, all documentation shall be legally issued and certified by the consulate and officially translated.
- In one country, the reimbursement request should include an evaluation of the national treating physician on the effectiveness of the treatment abroad.
- In two countries, patients are required to inform whether they have applied for reimbursement at a private insurance company or whether they have travel insurance with medical coverage.
- In one country, flight tickets must be submitted as a proof of travel abroad to substantiate reimbursement applications.
- In seven countries, patients might be required to provide official translation of documents.

Uncertainty about the amount that the health insurer will reimburse for healthcare abroad was among the biggest barriers to cross-border healthcare identified by respondents to the public consultation. While the **system of voluntary prior notification** is believed to be a useful way of reducing the financial risk for patients, providing them

with an estimation of the amount to be reimbursed after being treated abroad, only eight countries[66] apply this system.

The uncertainty about the reimbursable amount is due to several factors, such as the disparities in Member States' healthcare baskets and their transparency, complicated systems on assumption of costs for healthcare in certain Member States, lack of transparency of the public tariff applied for the purposes of reimbursement, varied medical coding systems etc.

The uncertainty about the prices charged by healthcare providers in other EU countries was another barrier mentioned, but this was ranked in the eleventh place. The Fit For Future Platform recalls that, in general, information on the applicable fees is not readily available and urges healthcare providers and hospitals to supply patients with cost estimates.

Problems with the continuity of care after treatment abroad was pointed out by 84 out of the 181 respondents (46%) in public consultation, mostly concerning patients, citizens and HCPs, with 54 respondents describing problems, which mainly concerned unrecognised medical prescriptions/referrals, lack of effective transfer of medical records between treating doctors and difficulties in accessing follow-up treatment[67]. Patients continue to face challenges in continuity of care, according to 46% of public consultation respondents, often arising from differences in health systems between their country of treatment and of affiliation. Administrative and language issues also play a role as does a lack of effective data-sharing. While 46% of respondents said that healthcare providers transferred medical records or a patient summary to the healthcare provider back home to a great or to some extent, 41% said this was done to a limited extent or not at all. An organisation representing health professionals noted that continuity of care raised issues of professional liability as health professionals from different countries are responsible for the treatment and the aftercare and healthcare is to be provided in accordance with the legislation, standards and guidelines of different countries[68].

Recognition of prescriptions

The CBHC Directive provides for the mutual recognition of prescriptions in the EU to make it easier for patients to receive a prescribed medicinal product or medical device in a Member State different from where the prescription originated. Implementing Directive

[66] DK, EE, EL, IE, IT, PL, SE and NO.

[67] See Study supporting the evaluation of the Directive, referred to in footnote 51. See also Footman, K, Knai, C, Baeten, R, Glonti, K, McKee, M. (2014). Cross-border health care in Europe, *Policy Summary 14*, available here: https://www.euro.who.int/__data/assets/pdf_file/0009/263538/Cross-border-health-care-in-Europe-Eng.pdf

[68] In this context, it could be mentioied that under Article 4(2)(c) of the CBHC Directive, if patients suffer harm arising from cross-border healthcare, they must seek remedies in accordance with the legislation of the Member State of treatment. This might represent an additional deterrent for patients from other Member States to seek cross-border treatment. However, neither the public consultation respondents, nor complaints received from citizens highlight this as one of the most important obstacle to cross-border healthcare in practice.

2012/52/EU gives effect to the principle of mutual recognition of medical prescriptions and lays down measures for uniform implementation in the EU by setting out a non-exhaustive list of contents to be included in cross-border medical prescriptions that should enable health professionals to verify the authenticity of prescriptions issued in other Member States. National authorities interviewed noted that the mutual recognition of prescriptions is an example of where the Directive has worked to decrease barriers for citizens. The Pharmaceutical Group of the European Union (PGEU)[69] highlighted persisting issues with regards to the mutual recognition of medical prescriptions despite the issuing of rules and/or guidance for the recognition of foreign prescriptions at European level and at national level in several countries.

Patients continue to experience issues in relation to the verification of prescriptions in another EU country. Four in ten public consultation respondents (38%) said that they were aware of problems with pharmacists in another EU country not recognising prescriptions and three in ten said they were not aware of problems (another 31% did not provide an opinion on this). Issues commonly identified by respondents included pharmacists refusing prescriptions provided by a doctor in another EU country; a pharmacist not being able to verify whether the prescription was issued by a doctor legally entitled to do this in another EU country; or a pharmacist who could not understand the language of the prescription. To a lesser extent, respondents reported the inability of the pharmacists to understand the doctor's handwriting or the failure to provide for a substitute medicine to that prescribed in the home country, and "other" situations such as the lack of a standardised format of prescriptions across countries, the variation of packages and dosages across Member States, the presence of different medical product names and the different legislative obligations regarding who can issue prescriptions.

Patients may also face challenges in having prescriptions prescribed as part of cross-border treatment recognised by their home country. In an open question related to problems that patients may face when seeking follow-up care at home, the unrecognised medical prescriptions from abroad was one of the most frequent issues mentioned by the public consultation respondents. They are sometimes presented with prescriptions written in a language they do not understand and are often unable to contact the prescriber.

The PGEU contribution[70] notes that many patients might not be aware of their rights under the CBHC Directive and the need to inform prescribers about their intention to present any prescriptions for medicines or medical devices to a pharmacist in another country, allowing the prescribing healthcare provider to issue the prescription in line with the guidelines for cross-border use. The public consultation results revealed that six in ten respondents were aware of the possibility of having their prescriptions recognised by

[69] PGEU feedback on the Commission's evaluation roadmap, available here: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights/details/F1670930_en.

a pharmacist in another EU country, whereas a third (31%) were unaware of that possibility[71]. However, citizens were significantly less aware of this, with only 38% being aware, compared to those representing organisations working at the EU/international (79%) or national (66%) level.

The issues identified by the PGEU are the same as those highlighted in the Commission's impact assessment accompanying the legal proposal[72], the academic papers reviewed and the targeted survey of pharmacists conducted in 2021. This indicates that, despite a reduction in the rate of non-dispensation of prescriptions, **the CBHC Directive and Implementing Directive 2012/52/EU did not completely resolve the issues (language, verification and authenticity problems) that continue to hamper the recognition of prescriptions in Member States**. According to the PGEU and several national authorities, the ongoing initiatives to develop the interoperability of systems facilitating the cross-border provision of electronic healthcare services, including the **exchange of ePrescriptions**, has the potential to strongly improve the recognition of prescriptions across the EU and overcome the barriers.

4.1.2. How effective was the Directive to encourage cross-border cooperation in the EU?

The CBHC Directive provides the legal framework for voluntary cooperation in healthcare between Member States and regions as well in the areas of ERNs, rare diseases, health technology assessment and eHealth (the latter two are outside the scope of this evaluation).

Cross-border cooperation between regions and neighbouring countries

The CBHC Directive requires the Member States to provide mutual assistance and to facilitate cooperation in cross-border healthcare between neighbouring countries and border regions. The Commission is to encourage such cooperation.

Well-functioning healthcare in cross-border regions contributes to the well-being of populations and is essential from the perspective of economic, social and territorial development and the sustainability of these regions[73]. A specific objective of the Directive is to facilitate healthcare for citizens living in border regions where adequate healthcare services may be lacking and the nearest healthcare provider is across the border. Multiple layers of cooperation and mechanisms exist to address the structural

[70] *Ibid*.
[71] 9% did not know or had no opinion.
[72] Referred to in footnote 16. The Impact Assessment found that the recognition of prescriptions issued in another Member State was hampered by the fact that effective recognition was limited to prescriptions issued only in certain countries depending on the country of the dispensing pharmacist, and that it was not always possible to verify the validity of the prescriber prior to dispensing, as required by local law.
[73] Sivonen, S., & Büttgen, N. (2021). Is the EU Patient's Rights Directive fit for providing well-functioning healthcare in cross-border regions? An ex-post assessment, available here: https://cris.maastrichtuniversity.nl/ws/portalfiles/portal/76750571/EN_FD21_dossier_4_healthcare_final_met_kaft_1_.pdf

need for healthcare in border regions and between neighbouring countries, which pre-date the Directive. An assessment of the Directive in the EU region Meuse–Rhine found that the Directive does not necessarily address the unique demographics, characteristics and needs of patients seeking healthcare across the borders of Belgium, the Netherlands and Germany. The use of the Directive's mechanism for cross-border healthcare is hampered by prior authorisation and reimbursement procedures as well as differences in health systems and healthcare baskets. On the other hand, the Directive explicitly encourages Member States, particularly between neighbouring countries, to conclude agreements between themselves with more favourable and flexible conditions adapted to the healthcare needs in border regions. The ZOAST framework agreement[74] along the French-Belgian border represents a benchmark for good practice of healthcare cooperation in the EU by providing conditions more favourable than those in the Directive. In this way, ZOAST overcomes the obstacles of prior authorisation and upfront payment as well as reducing costs in healthcare. The Committee of the Regions "Regional Hubs" found that few "regional hubs" were monitoring patient flows[75] as did the Association of European Border Regions' (AEBR) study on patient mobility in four case studies carried out in border regions[76]. It also found that few regions monitor patient flows and therefore the extent of cross-border healthcare in border regions is unknown. However, the AEBR study concludes that the Directive provides an additional framework to share information and cooperate in healthcare at regional level. This view is borne out by the public consultation respondents where six in ten believe that the exchanges of information and good practices promoted by the Directive have at least somewhat supported cross-border healthcare cooperation in between neighbouring countries.

The ECA report[77] highlighted positively how the Commission has encouraged and financially supported cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships as provided by the Directive. A 2018 Commission study provided a picture of 423 EU-funded projects supporting regional cooperation in healthcare and implemented over the period 2007-2017[78], the large majority of which took place between countries with similar welfare state traditions to share knowledge in treatment and diagnosis of patients. However, there is no evidence to support to what extent the Directive can be credited

[74] Zones Organized for the Access to Cross-border Healthcare (ZOAST): https://futurium.ec.europa.eu/en/border-focal-point-network/good-practices/developing-cross-border-complementarities-health-french-belgium-observatory

[75] European Committee of the Regions (2020). Network of Regional Hubs for EU Policy - Implementation Review - Implementation Report - Third Consultation, on Cross-border Healthcare, available here: https://cor.europa.eu/en/engage/Documents/RegHub/report-consultation-03-cross-border-healthcare.pdf

[76] AEBR (2021). Cross-border patient mobility in selected EU regions, available here: https://ec.europa.eu/health/publications/cross-border-patient-mobility-selected-eu-regions_en

[77] Referred to in footnote 27.

[78] European Commission (2018). Study on Cross-Border Cooperation - Capitalising on existing initiatives for cooperation in cross-border regions: Cross-border. Care, available here: https://op.europa.eu/en/publication-detail/-/publication/52088b97-3234-11e8-b5fe-01aa75ed71a1/language-en

with the promotion of regional cooperation in healthcare by the Member States and the Commission.

European Reference Networks

This evaluation provides a preliminary assessment of how the ERNs are meeting their objectives with the support of the Commission and the Member States as required by the CBHC Directive. An in-depth performance assessment and evaluation of all ERNs and their members in line with the requirements of Article 14 of Commission Implementing Decision 2014/287/EU will start in 2022.

The Directive aims to ensure the right of EU citizens, including people living with a rare disease, to have access to treatment in another EU country. Article 12 sets out that the Commission shall support Member States in the development of the ERNs to pool knowledge and expertise in the area of rare diseases. The ERNs are required to work towards a number of aims to improve prevention, diagnosis, treatment, care and research in this area. Besides the Commission's financial support for the ERNs as described in more detail below, the Commission supported the ERNs system by preparing their establishment and then ensuring secretariat support and policy input for the work of the ERN Board of the Member States and the ERN Coordinators Group. The Commission (DG SANTE) also supported the work of the ERN working groups on specific topics. They include the working group on ERN knowledge generation and dissemination, a working group on the ERN monitoring, a working group on legal, ethical and stakeholder issues, the ERN IT advisory group, working group on the ERN integration in national healthcare systems and working group on ERN research (including a task force on patient registries). Research activities of the ERNs are also supported via several projects under the EU research and innovation funding programmes.

The evaluation findings show that the CBHC Directive has been effective in meeting its objectives in the area of cooperation in rare and low prevalence complex diseases, bearing in mind that it has been less than five years since the 24 ERNs were set up in 2017. The rare disease patient community claims that the ERNs "*are the greatest achievements that the rare disease community as a whole has ever accomplished*"[79] (while also highlighting shortcomings in the Directive's objective to ensure access to treatment for rare diseases patients with regard to information, prior-authorisation and reimbursement). The public consultation showed that respondents who were aware of the ERNs were quite positive about the extent to which the ERNs helped healthcare providers provide diagnosis and treatment options for patients with rare and low prevalence complex diseases, and contributed to the delivery of and access to high-quality healthcare by patients.

[79] EURORDIS. An empty promise: accessing cross-border healthcare for people living with a rare disease, July 2021, available here: https://download2.eurordis.org/documents/pdf/CBHC_evaluation_standalone_response.pdf

There has been a continuous growth of the ERNs patient population, with 1.7 million patients being treated by the ERNs members. There is increasing involvement from patient organisations and patient representatives participating in the ERN activities[80] and being represented in the governance structure of all ERNs. Many ERNs have also developed action plans to foster an operational collaboration with different patient associations European Patient Advocacy Groups (ePAGs) have been developed by EURORDIS for each ERN disease group so patient organisations are able to participate in the ERN decision making.

The ERNs have been effective in providing healthcare providers with access to a large pool of expertise and knowledge to help rare disease patients with diagnosis and treatment options. 85% of respondents to a targeted survey of the ERN representatives carried out for this evaluation agreed that ERNs effectively contributed to the exchange of knowledge and best practices in rare diseases (43% strongly agree and 42% agree). 87% of survey respondents agreed that the Directive has been effective in supporting the diagnosis and treatment of patients, including through the virtual consultation panels. Similarly, the majority of respondents to the public consultation who were aware of the ERNs (mostly NGOs but also public authorities, businesses, EU citizens) believe that the ERNs help health professionals provide diagnosis and treatment options for patients with rare and low prevalence complex diseases to at least some extent (6% completely, 21% to a great extent and 48% to some extent)[81]. Interviewees also pointed out that the effectiveness of the ERNs varied between the ERNs and that, in the initial years of their existence, the networks had mainly focused on setting up the ERNs and therefore had less time available to treat and diagnose patients.

For the time being, the impact of the ERNs' collaboration is likely to be more important in improving diagnosis and treatment of rare diseases patients by knowledge generation, the development and sharing of best practices and guidelines with practitioners within and beyond the ERNs, and in advancing research on rare diseases than in providing diagnosis and treatment to individual patients through the Clinical Patient Management System (CPMS). This is partly due to the fact that only the most complex cases should be submitted to the CPMS and the lack of clear national pathways for patient referral to the ERNs (to be developed under national law). Nor is the ERN process often fully understood by the patients and health professionals. Both the ERNs and NCPs stakeholders consulted noted the lack of readily available information for patients and doctors on the ERNs. To address this shortcoming some stakeholders suggested that NCPs could in the future play a more proactive role in assisting patients and health professionals beyond just making the standard information about the ERNs available on their websites.

[80] Minutes of the ERN Board meetings and outcome from ERN monitoring exercise, available here: https://ec.europa.eu/health/european-reference-networks/board-member-states_en

[81] Less than a fifth of participants thought ERNs helped to a limited extent (15%) or not at all (3%). Finally, 7% did not provide an answer.

The CPMS, supported and financed by the Commission[82], is increasingly used by health professionals in the ERNs for the diagnosis and treatment of patients with rare and low prevalence complex diseases through virtual expert panels and it is seen as a positive development by stakeholders. However, only 2,100 patients' cases have been dealt with through the CPMS so far. This relatively low number is due to the combination of factors, including the fact that the CPMS currently handles only the most complex and very rare patient cases, which require the consultation of experts from different specialisations in different EU countries. Another issue affecting the effectiveness of the clinical collaboration through the ERNs is the fact that healthcare providers are often not reimbursed for the time that their health professionals dedicate to providing their medical advice on foreign patient cases through their participation on the virtual panels. Clinicians highlighted the lack of clarity regarding resourcing responsibilities for ERNs[83]. They noted that whereas payment schemes for physical cross-border patient referrals were well established, no reimbursement system exists for virtual consultations via the CPMS. Although the Directive's rules on reimbursement do apply to cross-border telemedicine, its mechanism for cross-border healthcare cost reimbursement entails that patients pay for healthcare directly to the foreign healthcare provider and then are being reimbursed up to the public tariff in their Member State of affiliation, bearing the price difference. Thus, this mechanism does not represent a viable solution for reimbursing for the CPMS consultations with a panel of medical specialists from different countries.

Lastly, some issues with the CPMS related to the system itself were identified as limiting its use and effectiveness. 20% of the respondents who were aware of the ERNs saw the non-interoperable IT facilities as an issue. The CPMS is quite burdensome with regard to the amount of information that needs to be entered onto its database for each patient and the time required to set up and use the CPMS virtual panels. A modification of the CPMS is already underway to improve its user-friendliness and to provide a mobile version of the tool in addition to the existing desktop version.

Financing and sustainability of ERNs

Article 12 of the CBHC Directive requires the Commission to support Member States in the development of ERNs between healthcare providers and centres of expertise. The Commission has supported the ERNs' operations with funding from different spending programmes (primarily the Third Health Programme and the Connecting Europe Facility (CEF) and the EU Research and Innovation (R&I) programme Horizon 2020 for research activities[84]. Over the period of 2016-2019 the overall funding contribution provided by the Commission to the ERNs amounts to just under EUR 31 million under the Third

[82] The CPMS is dedicated IT platform and telemedicine tool developed by the Commission to enable healthcare providers from the ERNs to work together virtually to diagnose and treat rare diseases patients, https://cpms.ern-net.eu/login/

[83] European Commission (2018). EXPH Report on Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area, available here: https://ec.europa.eu/health/system/files/2019-11/021_erns_en_0.pdf

[84] ECA Special Report, referred to in footnote 27.

Health Programme and around EUR 12 million under the CEF. The Commission's support includes grants for ERN coordination and management activities, grants for establishment of ERN patient registries, grants for ERN IT related activities (such as CPMS Helpdesk services, data collection for ERN monitoring exercise or maintenance of ERN registries), funding for an independent assessment body to conduct the assessment of ERNs at the time of their establishment and of new members wishing to join existing ERNs, support for the ERN clinical guidelines programme, support for the ERN professional mobility programme or support for development of ERN integrated quality improvement system (AMEQUIS). The ERNs are also important beneficiaries of the research projects such as the European Joint Programme Rare Diseases, SOLVE-RD or ERICA funded under Horizon 2020[85].

The consultation highlighted the importance of continuous financing to ensure sustainability of the ERNs and therefore its future effectiveness. A Commission survey of the ERN coordinators showed that sustainability of financing is one of the main challenges facing the ERNs[86]. Currently the grant application, management and reporting under the EU Health Programme entail a high administrative workload for the ERNs[87]. The ECA recommended that the Commission should "*work towards a simpler structure for any future EU funding to the European Reference Networks and reduce their administrative burden*"[88]. The Commission intends to address this recommendation by streamlining the existing funding sources for ERNs under the Health Programme with the launch of new direct grants for ERNs under the new EU4Health Programme.

In the context of ERN funding with regard to other activities such as drug development, knowledge building, collaboration with the private sector (pharmaceutical and medical devices industry) has been considered, for example, in the area of the ERNs' research and clinical trials on rare and low prevalence complex diseases (while taking appropriate transparency and conflict of interest management measures)[89]. Recognising the importance of the role of industry to improve the knowledge of rare conditions and to develop diagnostics tools and therapies, the Board of Member States for ERNs adopted "Statement on ERNs and industries"[90] in 2019 that provides general principles for this future collaboration.

Integration into national healthcare systems

[85] The EU has supported the field extensively through its research and innovation framework programmes, with more than €1.8 billion made available - just from the two past programmes - under the Seventh Framework Programme (FP7) and Horizon 2020, to more than 320 projects on interdisciplinary research in the area of rare diseases, see https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en

[86] Minutes of meeting of the Board of Member States for ERNs of 6 March 2018, available here: https://ec.europa.eu/health/european-reference-networks/board-member-states_en

[87] Tumiene, B. et al. (2021). European Reference Networks: challenges and opportunities, *Journal of Community Genetics*.

[88] ECA Special Report, referred to in footnote 27.

[89] Tumiene, B. et al. (2021), referred to in footnote 87.

[90] ERNs. Statement of the ERN Board of Member States on ERNs and industry, 25.6.2019, available at: https://ec.europa.eu/health/system/files/2020-03/statement_industry_conflictofinterest_en_0.pdf

The CBHC Directive requires Member States to facilitate the development of the ERNs. All interviewees representing the ERNs stressed the importance of integrating the ERNs into the national healthcare systems to increase their visibility and, more importantly, to ensure appropriate referral and reimbursement mechanisms for rare and low prevalence complex disease patients. The Board of Member States for ERNs addressed this key issue in 2019 with a statement encouraging Member States to facilitate the integration of the ERNs into national healthcare systems[91]. However, feedback from the consultation (17% of public consultation respondents) clearly shows that the general principles set out by the Board of Member States for ERNs have not yet been fully implemented in the Member States. An additional reported barrier is the lack of awareness or knowledge on how to access the ERNs among healthcare providers which are outside the networks. The Commission intends to further support Member States in their efforts to better integrate the ERNs into their national healthcare systems by launching in 2022 a Joint Action on ERN integration under the EU4Health Programme.

ERNs' role in knowledge generation and information sharing on rare and low prevalence complex diseases

Beyond the general support for the ERNs' coordination and management activities (including training programs or conferences organised within the respective ERNs), the Commission supported the ERNs in the area of knowledge generation and sharing through various specific projects including the ERN clinical guidelines programme, the ERN professional mobility programme or EU high-level ERN conferences. The ERNs have organised workshops and webinars to increase capacity building, and surveys to identify educational gaps in medical knowledge on patients with rare and low prevalence complex diseases. The ERNs have also invested in enhancing highly specialised knowledge about rare diseases through various dissemination activities (websites, newsletters, scientific journals, conferences etc.).

The majority of stakeholders and respondents to the public consultation agree that the ERNs have been effective in developing knowledge sharing activities to support health professionals, in enhancing professional training and mobility of expertise in this area and in facilitating exchange of knowledge and best practices. According to interviewees, effective knowledge sharing is one of the areas where the objectives of the networks are being best achieved.

The level of awareness provides an important indicator to assess the extent to which the use of the ERNs and the knowledge sharing has been effective. In relation to this, the public consultation results showed that a majority of respondents were aware of the ERNs and the possibilities to seek diagnosis and treatment of rare diseases in another EU country with prior approval from their healthcare insurer (11% completely, 16% to a great extent and 25% to some extent). However, both the ERNs and NCPs stakeholders

[91] ERNs. Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States, 25.6.2019, available at: https://ec.europa.eu/health/system/files/2019-07/integration_healthcaresystems_en_0.pdf

consulted also noted the lack of coordination between the NCPs and the ERNs resulting in a lack of clear information for patients on how to access the ERNs services and on how to get from the national system to the ERNs. They noted that doctors are often not aware of the existence of the ERNs and are not always willing to bring patients into these networks.

The ERNs' role in research on rare and low prevalence complex diseases

With regard to the **impact of the ERN collaboration on the research**, knowledge sharing and networking activities within the ERNs have resulted in increased collaboration between experts and directly contribute to the research on rare and low prevalence complex diseases. The interviewees considered that collaboration in various cross-ERN expert groups has been quite fruitful and pointed out that many important research initiatives have emerged from the ERNs, such as the EU-funded ERICA project[92], which is a "Coordination and Support Action" for coordinating clinical research efforts of the 24 ERNs. ERNs are also important beneficiaries of the research projects such as the large European Joint Programme on Rare Diseases[93] (EJP RD, co-fund with Member States research funding agencies) and the Solve-RD project[94] closely cooperating with several ERNs. It is important to keep in mind that many other EU-funded research projects are relevant and involve ERN clinicians and researchers from specific ERNs (for example ImmunAID[95] for ERN RITA), thus also enhancing the research potential of the ERN community as a whole. Other EU-funded projects involving ERN clinicians and researchers are: Conect4Children (C4C)[96], Screen4Care[97] (both funded under the IMI joint undertaking thus with public (H2020) and private funding) or Rare2030[98], led by the patients organisation EURORDIS.

In addition, with the financial support from the Commission, all 24 ERNs have established or they are in the process of setting up or consolidating ERN patient registries

[92] European Rare Disease Research Coordination and Support Action (ERICA, 2021-2025). Total budget: EUR 2,3 million (EU funding: EUR 2,3 million), all 24 ERNs are represented in the project. See https://cordis.europa.eu/project/id/964908 and https://erica-rd.eu/

[93] European Joint Programme co-fund on Rare Diseases (EJP RD, 2019-2023). Total budget: EUR 100 million (EU funding: EUR 55 million), more than 140 partners, all 24 ERNs are represented. See https://cordis.europa.eu/project/id/825575 and https://www.ejprarediseases.org

[94] Solve-RD - Solving the unsolved Rare Diseases (2018-2022). Total budget (= EU funding): EUR 15,4 million. See https://cordis.europa.eu/project/id/779257 and https://solve-rd.eu/

[95] ImmunAID - Immunome project consortium for AutoInflammatory Disorders (2018-2023). Total budget (= EU funding): EUR 15,8 million. See https://cordis.europa.eu/project/id/779295

[96] Conect4children (C4C, Collaborative Network for European Clinical Trials For Children), 2018-2024. Total budget EUR 182 million, EU funding of EUR 67 million. See https://www.imi.europa.eu/projects-results/project-factsheets/c4c and https://cordis.europa.eu/project/id/777389

[97] Screen4Care (Accelerating Rare Disease diagnosis by using newborn genetic screening and digital technologies), 2021-2026. Total budget EUR 25 million, EU funding of EUR 11,9 million. See https://www.imi.europa.eu/projects-results/project-factsheets/screen4care

[98] Rare 2030 (2019-2021) is a foresight study that gathered the input of a large group of patients, practitioners and key opinion leaders to propose policy recommendations leading to improved policy and a better future for people living with a rare disease in Europe. The project ended in a presentation at the European Parliament with recommendations on the most critical areas needing sound policy. See https://www.rare2030.eu/

in order to create a critical mass of patients' data. These are essential building blocks for advanced research in the area of rare and low prevalence diseases. Furthermore, the ERNs have facilitated large clinical studies to improve understanding of diseases and develop new drugs by gathering a large pool of patient data[99]. Patients participated in 732 clinical trials within the ERNs. 162 new clinical practice guidelines were drafted by ERNs as well as the development of 143 clinical decision making tools. Moreover, 405 observational studies were conducted within the ERNs.

When asked to assess the contribution of the ERNs in several areas, six in ten respondents to the public consultation believed that the ERNs had helped to exploit innovation in medical science and health technologies completely (9%), to a great extent (15%) or to some extent (36%). The same proportion agreed that the ERNs had helped to collect, analyse and make available health data completely (6%), to a great extent (16%) or to some extent (38%). Overall, a majority (79%) of respondents who were aware of the ERNs believed to at least some extent that the ERNs helped to generate knowledge and contribute to research on rare and low prevalence complex diseases in the EU (9% completely, 23% to a great extent and 47% to some extent)[100].

Cooperation in Rare Diseases

Article 13 of the CBHC Directive has strengthened existing European cooperation in rare diseases supported by the Commission. Between 2010 and 2015, a series of activities were carried out to support the development of Orphanet as a European portal for information of rare diseases and orphan drugs, to enhance the visibility and recognition of rare diseases, the development and dissemination of knowledge and support improvements in access to quality services and care. As of 2015 this was followed by further support to Member States to promote implementation of recommendations on policy, information and data, and to implement the European rare diseases codification system, as well as to Orphanet. Between 2010 and 2021, financial support for these efforts totalled nearly EUR 12.5 million via funds provided through subsequent European health programmes.

The registration of rare diseases across Europe is supported by the European Platform on Rare Disease Registration (EU RD Platform), set up in 2019 by the European Commission's Joint Research Centre[101].

The EU RD Platform facilitates information exchange on rare disease patients and supports registries at national, regional and local level as well as the ERNs to collect and share information.

[99] European Commission (2015). Report of the EXPH on Cross-border Cooperation, available at: https://ec.europa.eu/health/system/files/2019-11/009_crossborder_cooperation_en_0.pdf

[100] An additional 11% believed this was to a limited extent and 2% not at all. Lastly, 9% did not provide an answer.

[101] https://eu-rd-platform.jrc.ec.europa.eu

The EU RD Platform makes rare diseases patient data searchable and findable - something that so far was not possible- and is available for patients as well as for the community of researchers, healthcare professionals and policymakers. While the Platform's infrastructure is openly accessible and training is being provided for people working in existing registries or willing to create new registries, it also sets EU-wide standards for data collection and exchange.

The pillars of the EU RD Platform are 1) the European Directory of Registries, 2) the Central Metadata Repository and 3) the Pseudonymisation Tool, which makes sure patient data is held under a pseudonym, thus not traceable back to the individual but permitting the cross-border or cross-registries data exchange.

The EU RD Platform collaborates closely with the ERNs supporting the creation of ERN registries and aims at linking patients' clinical data with other health-related data like genomic data and biobanks.

Interviewees representing the ERNs, the ERN Board of Member States and researchers in the field of rare diseases, noted that ERNs are an appropriate tool that fit well with initiatives such as the Orphanet database, the European Joint Programme on Rare Diseases. With support from the Commission and Member States, this is creating a rare diseases research eco-system in Europe, bringing together researchers and practitioners. The programme has generated important ties with health professionals who are and who are not involved in the ERNs. With regard to Orphanet particularly, stakeholders working in the field highlighted the synergies with the ERNs which helped develop, for example, the ORPHAcodes. Another area of good synergies with the ERNs mentioned in the interviews is the EHDS, for which the networks will be a building block.

ERNs and Orphanet thus constitute a unique European framework dedicated to rare diseases with key complementary roles. ERNs have the clinical and scientific expertise on rare diseases and Orphanet has the expertise on databasing and standardisation. Through the objectives outlined in Article 12 (on ERNs) the CBHC Directive takes into account this complementary role and supports the existing framework on rare diseases not only by promoting these tools under Article 13, but also by reinforcing their role through shared objectives.

Efficiency

The evaluation on the efficiency of the CBHC Directive focuses on the actual costs and benefits associated with the implementation of the Directive as well the administrative burden linked to it[102].

[102] See Annex IV for further information on the cost/benefit analysis and Annex II on the availability and robustness of the data.

Cost/benefits on Member States

The additional **costs arising from cross-border treatment under the CBHC Directive** have had a very minor impact on national healthcare budgets. Based on data received from Member States as well as data from Eurostat, the Commission's 2022 report[103] estimates that the share of the amount reimbursed under the Directive on the total government expenditure on healthcare corresponded to 0.01%. This estimate is in line with the ECA estimate[104] and also corresponds to feedback received from stakeholders. They also noted the Directive's very modest impact on public health funding. National health insurers and health ministry representatives interviewed for the evaluation confirmed that the costs of treatment are low as the Directive provides that patients are reimbursed up to the same level of costs that would have been assumed by the Member State of affiliation if they had been treated domestically and therefore the financial burden is negligible. Member States' reimbursements to cross-border patients grew between 2016 and 2019, from EUR 67 million to EUR 92.1 million, while remaining low in absolute terms[105]. It is important to note that, as pointed out in the Commission's patient mobility data trend report 2018-2020, the countries which provided data on reimbursements differ between the reference years. In the countries for which there is complete data for all reference years 2016-2020[106], the total amount of reimbursement peaked in 2019 (EUR 41.0 million), with a substantial drop in 2020 (EUR 29.2 million).

The exact magnitude of the costs arising from the implementation of the Directive, for example, processing prior authorisation and reimbursement requests is not known as Member States countries do not collect this cost data. Moreover, while resources apportioned for cross-border authorisation and reimbursement cannot be easily calculated as health insurance staff are usually also processing domestic reimbursements, no stakeholder reported that the Directive has created excessive or disproportionate costs for public authorities or health insurers.

In terms of **benefits for health systems**, the CBHC Directive has not yet delivered efficiency gains for national health systems as the volume of cross-border healthcare cases facilitated remains negligible in most Member States with an estimated 6 out of 10,000 people across the EU receiving reimbursement for cross-border healthcare treatments under the Directive[107]. Even when allowing for variances in the use of the Directive across Member States, the benefits remain very minor. However, qualitatively,

[103] COM(2022) 210 final.
[104] ECA Report, referred to in footnote 27.
[105] EUR 82.3 million, excluding the UK. For 2020, the total amounts to EUR 77.5 million (EUR 74.9 million excluding the UK). Given the Covid-19 related restrictions in 2020, the figures of 2019 are considered for the analysis (see the report referred to in footnote 26, as well as COM(2022) 210 final).
[106] It concerns 17 Member States (BE, BG, CZ, DK, EE, ES, FI, EL, HR, IT, LT, LV, MT, PL, RO, SI, SK), the UK and NO.
[107] Calculations by contractor Tetra Tech based on Commission (2019). Member State data on cross-border patient healthcare following Directive 2011/24/EU, available at: https://ec.europa.eu/health/system/files/2021-03/2019_msdata_en_0.pdf

the Directive has enabled comparisons between health systems and increased transparency.

Nor is there evidence that the CBHC Directive provided direct benefits for health systems during the Covid-19 crisis. For example, while several regions in Germany provided life-saving assistance for Covid-19 patients to alleviate the burdens of overstretched hospitals across borders, these acts of European solidarity are attributable to existing regional cooperation[108]. However, responding whether the Directive could tackle the backlog of postponed treatments arising from the pandemic, out of 184 public consultation respondents, 28% considered the Directive could help to a large extent and 20% to some extent.

Costs/benefits to the patient

The total quantitative benefits for patients using the Directive's reimbursement mechanism is marginal due to the low cross-border patient mobility flow of around 300,000 reimbursements per year. Less than 1% of citizens on a waiting list benefit from faster treatments, however there is no data available on the reduction of waiting times overall. The Regulations on the coordination of social security systems are generally more favourable route to healthcare abroad as the patients do not normally bear the costs of treatment and are being reimbursed based on the level of the tariff in the Member State of treatment. For example, in the reference year 2020, Member States and EFTA States issued 23,400 Portable Documents (PD) S2[109] for planned cross-border healthcare and received around 1.9 million claims to be settled/reimbursed for necessary cross-border healthcare based on the EHIC[110].

However, **in terms of qualitative benefits, patients with rare and low prevalence complex diseases have benefitted from the Directive**, particularly through the intermediate outcomes of better diagnosis and understanding of treatment options available by health professionals participating in the ERNs. For physical treatment in a healthcare facility abroad, the Regulations' route represents a better option in most instances, as explained above, because where the Member State of treatment provides benefits-in-kind to its insured persons, cross-border patients also have access to such benefits under the same conditions.

There is no quantitative data available on the use of the Directive by different patient groups. However, qualitative evidence shows that several patient groups benefit from the Directive's rules on cross-border healthcare cost reimbursement. These include patients

[108] Communication from the Commission. Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis, C(2020) 2153 final, 3.4.2020.

[109] PD S2 certifies the entitlement of the insured person to planned health treatment in a Member State other than the competent Member State.

[110] Cross-border healthcare in the EU under social security coordination – Reference year 2019 and Reference year 2020, Table 1 and Table 4. Available here: https://ec.europa.eu/social/main.jsp?pager.offset=5&advSearchKey=ssc_statsreport2021&mode=advancedSubmit&catId=22&doc_submit=&policyArea=0&policyAreaSub=0&country=0&year=0

who need an outpatient treatment that is quicker to access or cheaper abroad; patients who travel frequently to other EU countries for work or family purposes; patients from smaller countries or for whom the closest facility is in another Member State; tourists who need necessary treatments which they cannot access under the Regulations on the coordination of social security systems[111]; pensioners who live part of the year abroad, but do not qualify as residents of that country; patients who are expats who wish to be treated in their country of origin.

For certain groups of patients the costs of using the Directive can be substantial. This financial barrier is hindering the effectiveness of the Directive as described above. The patient pays the costs of treatment directly to the healthcare provider and then requests reimbursement back home. If the public tariff (or a price calculated under Article 4(4) first paragraph of the Directive) is higher in the country of treatment than where the patients are insured, they cover the difference out-of-pocket. Moreover, the Directive is without prejudice to national legislation, which allows healthcare providers to set their own – private – prices, if they do not discriminate against patients from other EU countries. Cross-border patients under the Directive are also charged private prices in some Member States where public/contracted healthcare providers providing benefits-in-kind in the public system can also act in private capacity. Thus, the difference that the patient has to cover out-of-pocket can in certain instances be even higher than the difference between the public tariffs in the Member States of treatment and affiliation.

In addition, in the vast majority of Member States, patients bear costs for travelling and accommodation abroad, or extra costs, which persons with disabilities might incur, as the Directive does not oblige the Member States to reimburse such costs, even where prior authorisation is issued for healthcare abroad. Furthermore, as highlighted above in Section 4.1.1, burdensome administrative procedures in many countries add to the costs for patients. Processing times are slow and varied ranging from three weeks up to six months for prior authorisation applications and from one month up to six months for reimbursement requests. In several countries, processing times are not laid down in the national legislation[112]. Patients might also bear indirect costs related to the administrative procedures, such as postage costs, where applications cannot be submitted by electronic means (as illustrated in **Box 2**, in certain instances certified translation is required)[113]. In addition, patients might also be required to provide translation of the medical records, for the purposes of accessing treatment abroad or receiving follow-up treatment back home.

Nor are the costs of the Directive borne proportionately by different patient groups. The costs can be particularly significant for those from lower income countries, for patients with lower socio-economic status or patients requiring access to more expensive highly specialised treatment as is particularly the case for patients with rare and low prevalence complex diseases.

[111] For example, in certain countries, the healthcare provider at issue has exceeded the limit of consultations per month free of charge.
[112] Mapping and Analysis of Administrative Procedures: analytical report, the study referred to in footnote 17.

Data gathered for the cost/benefit analysis are insufficient to estimate the costs across different stakeholder groups and thus prevent an assessment on whether the costs of the Directive are proportionate to the associated benefits for these patient groups.

On the other hand, as mentioned above, the Directive's rules on reimbursement of cross-border healthcare costs supplement the relevant rules under the Regulations on the coordination of social security systems. Thus, in particular in those instances where the Regulations do not apply or where cross-border patients failed to ascertain and pursue their rights under the Regulations (for example, where the healthcare provider did not consider the treatment as "necessary care" under Article 19 of Regulation (EC) No 883/2004) the Directive's rules allow them to receive reimbursement of at least part of cross-border healthcare costs (compared to zero reimbursement under the Regulations).

With regard to the ERNs, a quantitative assessment of the cost effectiveness of the ERNs is challenging as only data on the EU level funding is available while there are no estimates for the total funding from the ERN coordinating centres and hospital hosting the ERNs. Similarly, data on the funding from private donors, patient organised campaigns and Member States is not available and not all costs incurred by the ERNs are taken into account. As a result, it was not possible to quantitatively assess the extent to which the costs of the ERNs and their tools were justified and proportionate given the objectives achieved and benefits obtained.

To support the ERNs' operations, the Commission has provided funding through different funding mechanisms. These amount to just under EUR 31 million under the Third Public Health Programme and EUR 12.4 million under the Connecting Europe. The co-funding provided by the ERN coordinating centers is estimated at EUR 12.4 million (40% co-funding of the grants provided). This brings the estimated total cost of the ERNs to EUR 48.2 million. However this estimate does not take into account all costs incurred by the ERNs. Nor does it take into account research activities of the ERN members.

With regard to the objectives achieved, the ERNs have improved the care of patients with rare and low prevalence complex diseases across the EU through diagnosis and treatment (diagnosing patients and ensuring access to and delivering high-quality healthcare). The members of the ERNs treat 1.7 million patients with rare and low prevalence complex diseases, including almost 600,000 new patients referred to the ERN healthcare providers with a diagnosis of diseases/conditions that fall within the scope of expertise of the ERNs. The ERNs have also contributed to research and innovation by generating knowledge, exploiting innovation in medical science and health technologies, and collecting, analysing and making available health data. The ERNs have also provided support to healthcare systems by developing quality and safety benchmarks and helping EU countries with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality.

[113] *Ibid*.

52% of respondents to the public consultation believe that the ERNs have helped to make cost-effective use of resources within EU-wide networks to reduce the burden and fill gaps at national level to at least some extent; while 19% reported that the ERNs have contributed on this matter to a limited extent or not at all. The relatively high cost at the development and initial implementation stage of the ERNs, especially in the IT organisational infrastructure, were to be expected at this early stage of the ERN project. This is supported by the findings from the public consultation whereby 81% of respondents believed the costs of the ERNs and their IT tools to be justified and proportionate to at least some extent, given the objectives achieved and benefits obtained. However, the absence of a mechanism for reimbursement of healthcare providers' costs incurred as part of the ERNs services was also highlighted as an issue potentially affecting the cost-effectiveness of the ERNs.

In addition, the ERNs provide the framework allowing rare and low prevalence complex disease patients to receive diagnosis and treatment without necessarily physically transporting the patient to another Member State. Therefore, and as highlighted during the EU Health Programme Conference in 2019, the ERNs are more cost effective as they save the patient or, as the case might be, the health insurer the expense of travelling abroad for a diagnosis (including related costs of accommodation, cost of family members moving with the patient etc.). This assessment of the cost-effectiveness of the ERN model was supported to at least some extent, by 75% of the ERN members consulted as part of the ERN targeted survey. By shortening the time of diagnosis and improvements in treatment through virtual consultations, knowledge sharing or development of clinical guidelines, the ERNs produce cost-savings in the long run. This is particularly significant as patients with rare diseases tend to remain undiagnosed (for many years) or to be misdiagnosed[114] resulting in a higher number of hospital visits and accompanying costs per rare diseases patient compared to the general patient population[115]. Interviewees noted however that given the relatively low uptake of the virtual consultations in the first years since the establishment of the ERNs, specific data on cost-savings were limited so far. In addition, research takes time and given the 'young age' of ERNs, their research potential is not yet fully deployed.

Coherence

The evaluation of coherence involves assessing whether or not different actions related to the CBHC Directive work well together. It helps highlighting areas where there are complementarities or synergies, which improve overall performance; or sheds light on issues that are contradictory or cause inefficiencies. In the evaluation, the complementarities or overlaps between different provisions of the Directive (internal

[114] Genetic Alliance (2016). The Hidden Costs of rare Diseases: A Feasibility study, available at: https://www.geneticalliance.org.uk/media/2502/hidden-costs-full-report_21916-v2-1.pdf

[115] Imperial College Health Partners (2018). A preliminary assessment of the potential impact of rare diseases on the NHS, available at: https://imperialcollegehealthpartners.com/wp-content/uploads/2019/05/ICHP-RD-Report-Nov-2018-APPROVED-002.pdf

coherence), as well as the alignment with other inter-related EU policies and initiatives (external) has been assessed.

Internal coherence

The evaluation has not revealed any specific issues relating to the internal coherence of the CBHC Directive. The feedback from different stakeholder groups suggested that the Directive is well structured and that its objective to facilitate the access to safe and high quality cross-border healthcare has *largely* translated into legal provisions. However, there are some issues with regard to the application of the provisions of the Directive across the EU, most importantly, around the level of reimbursement of cross-border healthcare costs, the prior authorisation systems, administrative procedures for cross-border healthcare and reimbursement of telemedicine. In addition, as mentioned above, in recognition of national competences, the Directive's provisions allow the Member States to introduce certain limitations based on overriding reasons of general interest, if the principle of proportionality is respected. As a result, each restrictive national measure has to be assessed on a case-by-case basis.

Level of reimbursement of cross-border healthcare costs: Member States use different methods to define "the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided on its territory". For example, it has been established that three Member States[116], with varying conditions and extent, use the levels of reimbursement for cross-border healthcare that apply to healthcare received from private/non-contracted healthcare providers within their own territory. Those levels are lower compared to the level of reimbursement within the public healthcare system. The Commission considered this not being in line with the Directive and as a result, initiated proceedings for failure fulfil the obligations under the Directive against those Member States. In this context, it is also questioned whether, and to which extent, Member States are allowed to apply deductions for administrative costs to the reimbursement requests for cross-border healthcare.

Prior authorisation systems: Only seven EU Member States and one EEA EFTA State have no prior authorisation system in place. The main reason for introducing prior authorisation systems for the Member States was the protection of their healthcare systems. At the time the Directive was transposed in the national legislation, its effect on the healthcare systems was uncertain and the introduction of prior authorisation for some countries was a means to monitor this effect[117]. The Member States' lists of healthcare subject to prior authorisation also differ significantly in the extent to which the healthcare is further specified and the number of the separate items on the lists. The main concern here is whether the option to make cross-border healthcare subject to prior authorisation is overused, as this would be regarded as an unjustified restriction of the free movement of services[118] and would not allow the Directive to reach its full potential. Another

[116] FI, AT, NL.
[117] Mapping and Analysis of Administrative Procedures: analytical report, the study referred to in footnote 17.
[118] Recital 38 of the CBHC Directive.

identified concern is the insufficient level of legal certainty and transparency for patients about which treatments in Member States are made subject to prior authorisation. The CBHC Directive allows the Member States sufficient room for maneuver, if the general principles of EU law related to the restriction on fundamental freedoms are respected. This however results in quite divergent prior authorisation systems under the Directive across EU countries and each limiting national measure should be assessed on a case-by-case basis, also in light of changing circumstances in that Member State.

In addition, there had been some doubts whether Member States could apply prior authorisation requirement with regard to urgent treatments undergone by insured persons in other EU countries, as the Directive does not contain concrete provisions to this effect. However, this has now been clarified by the Court of Justice, which established that national legislation that excludes the reimbursement without prior authorisation of the costs connected to urgent treatment undergone by an insured person in another Member State is not consistent with the free movement of services principle and the Directive[119].

Administrative procedures for cross-border healthcare: Some Member States had introduced administrative procedures for cross-border healthcare, which are questionable regarding their justified purpose, necessity and proportionality, such as requirements for certified translations of medical documentation to obtain prior authorisation or reimbursement[120]. In addition, under Article 7(7) of the CBHC Directive, the proportionality test also applies with regard to the requirements that are set for healthcare provided on the territory of the Member State and that, at the same time, apply for cross-border healthcare. Here also the Directive allows Member States to impose such non-discriminatory requirements based on the reasons listed in that provision, thus the relevant national requirements might differ from one EU country to another and their compliance with the Directive should be assessed on a case-on-case basis.

Telemedicine: The Directive has clarified some issues concerning the provision of cross-border telemedicine. In particular, it has specified that in the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established. This means that cross-border telemedicine is to be provided in accordance with the legislation and standards and guidelines on quality and safety of the Member State of establishment of the healthcare provider (Articles 3(d) and 4(1)). The Directive makes it clear that cross-border healthcare costs incurred using eHealth services are also to be reimbursed[121]. Article 7(7) of the Directive specifically mentions telemedicine when it allows the Member States to impose on an insured person *the same* conditions, criteria of eligibility and regulatory and administrative formalities, as it would impose if this healthcare were provided in its territory, if these comply with the principle of proportionality.

[119] Judgment of 23 September 2020, *WO*, C-777/18, cited in footnote 19, paragraph 85.
[120] See Section 4.1.1 above. See also Mapping and Analysis of Administrative Procedures: analytical report, the study referred to in footnote 17.
[121] Recital 26 of the CBHC Directive.

However, the Directive does not aim to solve all legal issues related to the provision of cross-border health services in the EU[122], such as Member States' limitations on the exercise of telemedicine activities (including their inclusion in the scope of national health insurance systems), data protection or jurisdiction and applicable law in case of damage. In 2008 and 2012, the Commission assessed the applicability to telemedicine services of the EU legal framework existing at the time. This assessment showed that legal questions related to the provision of telemedicine go far beyond the CBHC Directive[123].

With the Covid-19 pandemic, Member States have started opening up financing and reimbursement of telemedicine services on the national level. In light of the Directive, benefits to which insured persons are entitled domestically have to be reimbursed if received cross-borders, including telemedicine services. There is currently no case law clarifying conditions under which Member States can limit the reimbursement of cross-border telemedicine costs in line with the Directive, thus the newly developing rules in the Member States might result in varied approaches.

Coherence with other EU legislation

a. Regulations on the coordination of social security systems

There are two routes for reimbursement of healthcare costs in another Member State: under the Regulations on the coordination of social security systems and under the CBHC Directive. The Regulations and the Directive overlap in terms of personal and material scope, but are not identical. Therefore, one of the Directive's objectives is to clarify its relationship with the Regulations. The aim is that these two systems are coherent and clear in the sense that either the Regulations apply or the Directive applies[124].

In many cases, the Regulations' route to cross-border healthcare is more beneficial to patients. For example, under the Regulations, where the Member State of treatment provides benefits-in-kind to its insured persons, cross-border patients should also have access to such benefits under the same conditions (see Annex VII). Thus, patients (insured persons) should not be deprived of the more beneficial rights guaranteed by the Regulations when the conditions are met[125]. In light of this, under Article 8(3) of the Directive, the Member State of affiliation shall grant prior authorisation under Regulation (EC) No 883/2004 where the conditions laid down therein have been met unless the person specifically requests otherwise. However, no provisions of the CBHC Directive

[122] Commission staff working document on the applicability of the existing EU legal framework to telemedicine services, Accompanying the document Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century, SWD(2012) 414 final, 6.12.2012.

[123] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689 final, 4.11.2008 and SWD(2012) 414 final.

[124] Recital 30 of the CBHC Directive.

[125] Recital 31 of the CBHC Directive.

ensure that patients benefit from the more beneficial rights under the Regulations in other circumstances.

This is in particular the case with regard to care, which becomes necessary on medical grounds during the insured person's stay in another Member State (Article 19 of Regulation (EC) No 883/2004). Whether such cross-border healthcare will be reimbursed under the Regulations or the Directive might depend in practice on several conditions: how the individual healthcare provider assesses the (initial) intention of the person to travel abroad[126], as well as on the choices made by the person, or on the advice they may have received, in particular when they are directed to private providers or charged private prices within public/contracted healthcare providers for necessary treatment. Whereas pursuant to the Directive, the patients have the right to reimbursement of costs of necessary treatment provided by a private healthcare provider, they have to bear the price difference, as the Member State of affiliation is only obliged to reimburse such costs up to the level of public healthcare tariff in that Member State (Article 7(4) of the Directive). Although the exact extent to which patients are reimbursed for necessary care under the Directive's provisions is not known, the lack of information about their rights under the Regulations at the national level and the resulting failure by cross-border patients to ascertain and pursue these rights in practice can lead to the application of less beneficial rules under the Directive.

Complex issues related to the Directive's relationship with the Regulations concern prior authorisation and reimbursement of costs of cross-border healthcare to insured persons and their family members residing outside the competent Member State. The issue of whether such persons benefit from the Directive's rules of reimbursement if they are not insured under the compulsory sickness insurance scheme of the competent Member State has even been subject to a preliminary ruling of the Court of Justice[127]. In some cases, the Member State in which the persons at issue have to ask for prior authorisation under the Directive and under the Regulations is not the same. Thus, it cannot be ensured that the prior authorisation is issued to them under the more beneficial set of EU rules.

Moreover, where, under the Directive, healthcare is not subject to prior authorisation, the Member State of affiliation (where the patient is insured) is not obliged to check whether the terms laid down in the Regulations are met for planned healthcare abroad. Thus, it will depend on the patients to get acquainted with their rights and to choose between going abroad using the Directive's route for cost reimbursement or applying for prior authorisation under the Regulation.

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[126] FreSsco. Analytical Report 2016 Access to healthcare in cross-border situations, p. 35-37 and 40-43 (available at: file:///C:/Users/janecru/Downloads/FreSsco_AR2016_Cross-borderHC_20170210FINAL%20(3).pdf) where it is pointed out that it is not always easy, and in many cases, impossible to determine the purpose of a journey or a patient's actual intentions in order to establish tablwhether they should be reimbursed for necessary care under the Regulations.

[127] Judgment of 28 October 2021, *Y*, C-636/19, cited in footnote 19. Moreover, judgments of 23 September 2020, *WO*, C-777/18 and of 29 October 2020, *A*, C-243/19, both cited in footnote 19, also provide additional clarity on the relationship between those two instruments.

In 2012, the Commission services provided to the Member States (Administrative Commission[128]) Guidance note aimed to ensure the coherent application of the Directive and the Regulations by the Member States with regard to social security aspects, which are covered by both instruments[129]. The Commission has also produced guiding principles for the practice of NCPs, a toolbox for cross-border healthcare, including a Manual for Patients to clarify the two cross-border healthcare routes[130]. It has also organised several workshops aimed at increasing capacity of the Member States in applying the patients' rights in cross-border healthcare and clarifying the relationship between the Directive and the Regulations[131].

However, public and stakeholder consultations suggest that the complex legal relationship between the Directive and the Regulations is very difficult for citizens to understand, as well as for health insurance institutions to communicate to patients. The complexity of the systems for reimbursement of cross-border healthcare costs and the challenges in providing clear information to patients led several Member States to introducing voluntary prior notification systems for cross-border healthcare (Article 9(5) of the Directive)[132] or advising patients to seek counsel at the respective institution *before* engaging in a cross-border treatment. An analysis of NCPs' websites in 2021 found that fewer than half websites provided information on the distinction of the patients' rights under the CBHC Directive and the Regulations. Although the provision of such information is required under Article 5(b) of the Directive, some NCPs claimed not providing it for reasons of simplicity for patients. Stakeholder consultation raised questions whether providing full information about the relationship between the Directive and the Regulations would be necessary, if the patients were ensured access to the route that is the most beneficial to them. The European Parliament has noted the complexity of the current legal situation deriving from the interaction between the Directive and the Regulations and has invited the Commission to further clarify it, including by means of comprehensive public information campaigns, as well as to establish guidelines for implementation, especially on the areas where those two instruments interact[133].

For the respondents to the public consultation, the main obstacles to cross-border healthcare were the financial problems and the fear of an incomplete reimbursement, as well as the lack of clarity for patients about their rights. The expert reports and complaints received from citizens suggest that patients find the EU schemes challenging to navigate. As illustrated above, in many instances, the burden in choosing the route that

[128] The Administrative Commission for the coordination of social security systems established pursuant to Article 71 of Regulation (EC) No 883/2004.
[129] European Commission (2012) AC 246/12, Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare; and Appendix to the Guidance note of 2013 (ref. Ares(2013)1443508).
[130] https://ec.europa.eu/health/cross-border-healthcare/toolbox-cross-border-healthcare_en
[131] Workshops in 2016 and in 2018 for national experts and NCPs; training in 2021 to SOLVIT centers.
[132] Mapping and Analysis of Administrative Procedures: analytical report, the study referred to in footnote 17.
[133] European Parliament resolution of 12 February 2019, referred to in footnote 29.

is more beneficial is left on patients[134] with some resorting to private contractors specialised in assisting in cross-border healthcare. In this context, it is important to note that in many cases, the patient's "choice" will have financial consequences that could not be fully corrected by applying the more beneficial set of rules at the reimbursement stage. This is due to the fact that, although the Directive gives patients the right to choose a private healthcare provider abroad, it also means that these patients might be charged by healthcare providers – even in certain instances public/contracted providers – private prices whereas both under the Directive and the Regulations, the Member States are only obliged to cover expenses up to the level of the public tariff.

All the above raises doubts as to whether the coherence of the Directive with the Regulations on the coordination of social security systems has been achieved for the benefit of patients.

b. Directive 2005/36/EC on the recognition of professional qualifications

Recital 50 of CBHC Directive explains that it is without prejudice to Directive 2005/36/EC. The evaluation has not established incoherence between the CBHC Directive and Directive 2005/36/EC.

Title II of Directive 2005/36/EC regulates services provided on a temporary or occasional basis in another Member State than the Member State of establishment of the service provider, including health professionals.

The CBHC Directive only concerns healthcare provided or prescribed in a Member State other than the Member State of affiliation (Article 3(e) of the CBHC Directive). Telemedicine is to be considered to be provided in the Member State where the healthcare provider is established (Article 3(d) of the CBHC Directive). Under Recital 50 of the CBHC Directive, cooperation between Member States may concern, e.g. practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis.

On the other hand, provision of healthcare services provided by health professionals on the territory of another Member State on a temporary and occasional basis is not addressed in the CBHC Directive. It thus does not specify which quality and safety standards should apply to such healthcare services, whether the systems of professional liability insurance should extend to such services and how the costs of such cross-border services should be reimbursed to patients (or the health professionals). These issues should therefore be assessed under the TFEU, Directive 2005/36/EC and/or national laws of the Member States, as appropriate.

[134] Judgment of 23 September 2020, *WO*, C-777/18, cited in footnote 19, paragraph 37, where the Court of Justice noted that, in order for the Regulations on the coordination of social security systems to apply, it is necessary for the healthcare in question in the main proceedings to have been dispensed to the patient by the private provider in the Member State of treatment *in accordance with the social security legislation of that Member State*.

3. Interaction with other European structures: the Civil Protection Mechanism

The Civil Protection Mechanism is an example for the CBHC Directive's relationship and good interplay with existing European structures related to the Covid-19 crisis. As described in **the Commission guidelines on EU emergency assistance in cross-border cooperation in healthcare**[135], the Directive provided clarity on patients' rights across borders, while the Civil Protection Mechanism was used to provide emergency assistance to regions to alleviate overburdened hospitals and the coverage of healthcare costs was governed by the Regulations on the coordination of social security systems.

4.2. How did the EU intervention make a difference?

The CBHC Directive has made a difference in a number of ways based on the evidence gathered for this evaluation:

The Directive provides that patients have equal access to treatment in another Member State and the right not be discriminated with regard to the price.

Patients have been able to benefit from the Directive's rights to choose a public or private healthcare provider to meet their medical needs better and to be (at least partially) reimbursed the medical costs. This applies particularly for citizens accessing healthcare in neighbouring countries and in border regions where the nearest medical facility is across the border or waiting lists are long in the country of residence as evidenced by EU annual patient mobility data and the case study findings of the AEBR[136].

The highest added value of the Directive for cross-border healthcare reimbursement compared with the Regulations is **the reduction of administrative burden for patients**, although some of burdens still persist. As a general rule, the Member States should not make reimbursement of costs for cross-border healthcare subject to prior authorisation. Whereas under the Regulations, prior authorisation is always necessary for planned healthcare abroad.

In addition, the Directive requires that administrative procedures for cross-border healthcare are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved. In accordance with the general principles of EU law, the same rules also follow with regard to the administrative procedures for cross-border healthcare under the Regulations. However, contrary to the Directive, the former do not contain concrete provisions to this effect. At the same time, further efforts are necessary to ensure that prior authorisation system is not overused, that administrative procedures are not too restrictive and that legal certainty is thus ensured for patients.

The Directive has **enshrined other patients' rights in cross-border healthcare**. The most important of those are equal access to health services, equal quality and safety

[135] Guidelines referred to in footnote 108.
[136] See the study referred to in footnote 76.

standards, non-discriminatory prices in the Member State of treatment, the right to follow-up care back home and the right to information provision on cross-border healthcare.

A number of stakeholders recognise that the Directive has provided a very good framework to reinforce patient rights. It has acted as a catalyst for patients' rights, bringing about changes in a number of national health systems to the benefit of patients, for example increasing transparency of pricing and professional liability of health professionals.

The creation of the ERNs in the area of rare and low prevalence complex diseases are considered by stakeholders to provide the highest added value of the Directive through the better diagnosis and treatment of patients by facilitating the exchange of knowledge and best practices among medical specialists cooperating in the 24 ERNs. These outputs would not have been as effective without the pooling of expertise and patient data at the EU level. The ERNs could help Member States lacking the technology or expertise to meet the needs of patients with a particular medical condition, to provide highly specialised services of high quality.

Information on patients' rights to cross-border healthcare: the creation of the NCPs has increased the provision of relevant information to patients about cross-border healthcare, including healthcare under the Regulations on the coordination of social security systems.

Cross-border recognition of prescriptions: steps taken under the Directive have increased the recognition of cross-border prescriptions, although several areas for improvement remain.

4.3. Is the intervention still relevant?

The CBHC Directive is still relevant as its key objective to facilitate access to healthcare in another EU country remains important and its legal framework is largely adequate for ensuring EU citizens' rights in line with the TFEU, as interpreted in the case law of the Court of Justice.

The Directive is highly relevant in ensuring EU patients' rights to equal treatment with domestic patients in the Member State of treatment, as well as the same medical follow-up back home. In addition, based on the Directive, patients are ensured access to information about cross-border healthcare, including under the Regulations on the coordination of social security systems.

Evidence shows that EU citizens are still willing to travel abroad for healthcare for a variety of reasons[137]. Moreover, EU citizens continue to use the Directive's mechanism

[137] According to ANEC survey, 47% respondents considered they would travel abroad for their healthcare. ANEC (2018). Cross-border healthcare Accessing medical treatment in other EU countries: Consumer

for cross-border healthcare reimbursement, although there has been a slight decline in the number of reimbursement cases since 2019 as a result of the Covid-19 pandemic. The public consultation views were divided on the extent to which the Directive has met patient needs with around half of healthcare authorities, healthcare providers and insurers believing the Directive met needs completely or to a great extent compared patient organisations, citizens and NGOs who felt needs were met to some or limited extent. Implementation issues were cited as an important reason why the Directive was not meeting patient needs. This view is supported by the stakeholder interviews as well as the reports on the implementation of the Directive[138].

The Directive's reimbursement mechanism is not seen as relevant for many stakeholders, in particular patient organisations, including cancer patients, and the rare disease community. This is because certain treatments, including gene therapy, are highly costly and therefore not possible to pay in advance and therefore out of reach for patient in need of specialist treatment is only available in a few specialised health clinics in the EU. However, as explained above, the Directive was not intended to replace the rights to cross-border healthcare under the Regulations on the coordination of social security systems nor to deprive patients of the more beneficial rights guaranteed therein when the conditions are met. Thus, in the above-cases, the patients' needs could be better met under the Regulations under which patients do not have to pay for healthcare upfront where the social security system of the country of treatment provides such benefits to their own insured persons[139].

On the other hand, the Directive continues to be highly relevant for the pooling of knowledge and expertise as well as for structuring much needed research activities to support the treatment and diagnosis of rare and low prevalence complex diseases through the ERNs as described above.

70% of public consultation respondents viewed the Directive as relevant at least to some extent in ensuring that patients have better access to high quality healthcare services for rare and low prevalence complex diseases; 77% of respondents viewed the Directive as relevant at least to some extent in giving healthcare providers across the EU access to the best expertise and timely exchange of life-saving knowledge.

Most of the respondents to the original 2013 public consultation on the implementation of the ERNs pointed out that the ERNs should focus on complex, highly specialised and rare diseases for which expertise is scarce[140]. In addition to rare diseases, some ERNs have also been established for other conditions which require complex procedures (e.g.

attitudes and experiences, available here: http://www.anec.eu/images/Publications/technical-studies/ANEC-TS-2017-SERV-008.pdf

[138] See COM(2015) 421 final and COM(2018) 651 final.

[139] The prior authorisation requirement for planned treatment abroad under the Regulations is out of the scope of this evaluation.

[140] European Commission (2013). Summary Report of the replies on the public consultation on the implementation of European Reference Networks (ERNs), available here: https://www.uems.eu/__data/assets/pdf_file/0005/1499/cons_ern_report_en.pdf

ERN TransplantChild, which focuses on paediatric transplantation or ERN eRUOgen on rare uro-recto genital diseases and complex conditions). A 2018 expert panel assessment found this appropriate and saw no need to extend the ERNs model to other areas such as healthcare in remote areas, border regions, the development of new medicines or interventions, or other specific areas such as the care of homeless people, for which they felt there were better mechanisms[141].

The ERNs may further serve patient needs by improving research collaboration in relation to rare conditions. While rare and low prevalence complex diseases collectively present a significant burden on the healthcare systems, the small number of cases in each country may mean that certain conditions do not receive a significant amount of research funding or attention in the healthcare settings. The increasing visibility of different conditions as a result of the ERNs could help justify further allocation of funding to research and help build research economies of scale[142] and inform the EU research agenda for which rare diseases have been a priority area as shown by the establishment in 2011 of the International Rare Disease Research Consortium (IRDiRC) by the Commission and the US National Institute of Health[143]. A survey carried out as part of the mid-term evaluation of the third Health Programme found that the majority (75%) of the 39 ERNs experts that took part in the survey expect that the initiatives supported in the post-2020 period may reasonably contribute to increasing the amount of research being produced through cooperation within the ERNs[144]. In particular, the ERNs have started to facilitate large clinical studies to improve understanding of diseases and develop new drugs by gathering a large pool of patient data through registries.

The **Covid-19 pandemic** and the scale of its impact has clearly shown the importance of **cross-border cooperation in healthcare**. Six in ten public consultation respondents agreed that the Directive could help health systems tackle a possible backlog of postponed treatments arising from the pandemic either completely (12%), to a great extent (28%) or to some extent (20%). In practice, this would wholly depend on domestic waiting lists and hospital capacity to receive cross-border patients. Populations in border regions have different demographics and needs as described above (Section 4.1.2) and their weaknesses and vulnerabilities were re-affirmed by the Covid-19 pandemic. According to the AEBR, the Directive remains relevant as an additional instrument to enable access to healthcare across borders and to encourage cross-border cooperation in healthcare[145].

In terms of the **Directive's relevance to meet future healthcare needs**, trends in unmet need for healthcare within Member States provide an indicator for such future needs. The

[141] EXPH Report referred to in footnote 83.
[142] European Commission (2017). Mid-term Evaluation of the Third Health Programme (2014 – 2020), Annex B, available at: https://ec.europa.eu/health/other-pages/basic-page/mid-term-evaluation-3rd-health-programme-2014-2020_en
[143] EXPH Report referred to in footnote 83.
[144] Mid-term Evaluation of the Third Health Programme (2014 – 2020), Annex B, referred to in footnote 142.
[145] See the study referred to in footnote 76.

European Statistics on Income and Living Conditions (EU-SILC) 2020 survey shows that most healthcare needs are met in most countries, but some significant unmet needs remain. Access to healthcare can be limited for a number of reasons, including cost, distance to the closest health facility and waiting times, which means the Directive's objective to provide access to healthcare EU-wide remains relevant.

Europe's digital transformation is a long-standing Commission priority and the digitalisation of healthcare was already included in the scope of the Directive ten years' ago. Its provisions created a voluntary eHealth network to develop common standards to facilitate the electronic transfer of data in healthcare. Europe's Digital Decade sets a target of 100% of citizens' having access to electronic health records by 2030[146]. The Commission's proposal for a Regulation on the EHDS is expected to help deepen this cooperation.

The Covid-19 pandemic has accelerated the trend towards tele-consultation in the light of social distancing, although in-person consultations remain the norm. Before 2020, only few countries had policies or legislation that defined the reimbursement of digital health services. With the pandemic, new national policies have emerged to facilitate the use of digital health tools, including the opening up of financing and reimbursement for these services together with the digitalisation of invoices and prescriptions. These developments are reducing burdens and costs for patients, health professionals, health insurers and administrations alike. However, the literature suggests there is still relatively little formal adaption of the regulatory framework for digital health tools across Europe[147].

In light of this trend on the national level, as well as with the proposed EHDS, the Directive will become more prominent with regard to telemedicine services provided cross-border. The Directive is relevant to address the increasing use of cross-border telemedicine in the sense that it sets out some important rules relating to the applicable legislation, standards and guidelines on quality and safety and makes it clear that cross-border healthcare costs incurred using eHealth services are also to be reimbursed. However, it does not aim to solve all legal issues related to the provision of (cross-border) telemedicine in the EU, as the EU legal framework applicable to telemedicine services goes far beyond the CBHC Directive[148].

The Directive thus remains relevant to meet patient needs. As explained in Section 2.2, if the Directive did not exist or if it were to be repealed, there would no EU legal framework for ensuring a consistent approach to reimbursement of cross-border healthcare costs as set out in the rulings of the Court of Justice.

[146] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. 2030 Digital Compass: the European way for the Digital Decade, COM(2021) 118 final, 9.3.2021.
[147] Study supporting the evaluation of the Directive, referred to in footnote 51.
[148] See Section 4.1 above.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

The performance of the CBHC Directive must be viewed within the wider context as there are several options open to the EU citizen to access healthcare in another EU country whether under the Regulations, the Directive or bi-lateral and multilateral agreements at national or regional level.

Moreover, this evaluation highlighted the large data gaps to assess the wide range of impacts of the Directive. Data on patient mobility remains incomplete and inconsistent, with data lacking from important Member States. It was not possible to document the type of services more frequently used under the Directive as Member States are not required to provide this data under the Directive and most do not collect this data.

Within this context, this evaluation draws the following conclusions regarding the Directive's effectiveness, efficiency, coherence, relevance and added value which offer a number of lessons for the future improvement of the Directive's implementation in the EU:

Effectiveness

The Directive has been moderately effective in delivering its objectives to facilitate access to safe and high-quality healthcare in another EU country. It has contributed to removing obstacles to cross-border healthcare and to the free movement of healthcare services by bringing additional legal certainty in relation to patients' rights in cross-border healthcare and establishing a legal framework that enables citizens to exercise those rights. It enshrined patients' rights in cross-border healthcare, such as equal access to health services, equal quality and safety standards, non-discriminatory prices in the Member State of treatment, the right to follow-up care back home and the recognition of prescriptions. The Directive has been somewhat effective in regulating these matters, although some issues persist. The Directive has also acted as a driver for patients' rights in general, increasing the transparency on treatment prices, bringing about changes in a number of national health systems to the benefit of patients.

In addition, the Directive has ensured a more consistent approach at EU level to reimbursement of cross-border healthcare costs for EU citizens compared to the situation where Member States were to comply directly with the TFEU provisions, as interpreted by the Court of Justice. At the same time, the Directive recognises the Member States' competences and leaves sufficient room for manoeuvre to limit patients' rights to cross-border healthcare cost reimbursement which has resulted in quite divergent implementation of the Directive across EU countries. For example, the evaluation showed that not enough Member States help **reduce the financial risk for patients** by making use of the voluntary prior notification system, currently used by only eight countries, to confirm the amount to be reimbursed as provided by the Directive. In addition, it was acknowledged by stakeholders and the Fit for Future Platform that making information available about the prices charged for treatment abroad and tariffs

for reimbursement back home is of utmost importance to reduce uncertainty for patients wishing to be treated abroad.

While the Directive is used, cross-border healthcare reimbursements remains low with around 300,000 requests for reimbursement annually. The Directive's potential for improving access to cross-border healthcare are undermined by important barriers: the low level of awareness over patients' rights to cross-border healthcare, disproportionate administrative burdens and uncertainty over reimbursement. Patient organisations, in particular, criticise the requirement for patients to pay upfront for treatment abroad as creating inequalities in access to healthcare with only those who can afford it using the Directive for healthcare in another EU country.

Raising awareness on patients' rights to cross-border healthcare and **improving information for patients are critical factors** for easing access to healthcare abroad. The creation of the NCPs has made information to patients on cross-border healthcare available where none had previously existed. Despite improvements and continuous efforts by many NCPs, information gaps persist in relation to the availability, completeness, clarity of information, and also on the accessibility of information for people with disabilities. Moreover, the role of the NCPs remains limited, partly as there is no obligation under the Directive to promote cross-border healthcare and therefore there is a lack of awareness that they exist. This finding shows the importance of the NCPs' consultation arrangements with patient organisations, health professionals and health insurers to raise awareness and share information, however these remain under-developed in most Member States. In addition, the information the NCPs provide is drawn from national legislation implementing the Directive, which sometimes does not ensure legal certainty for patients. For example, while the NCPs are obliged to make transparent the categories of healthcare for which prior authorisation is required, the availability and clarity of that information depends on national rules.

The Commission has effectively encouraged cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships between these countries and regions as provided by the Directive. While there is some evidence that the Directive provides an additional instrument to facilitate healthcare in border regions, there is no robust data to assess to what extent the Directive has promoted cooperation over and above pre-existing regional cooperation arrangements in healthcare. Despite the importance of cross-border healthcare in border regions, the diversity of health systems in invoicing and reimbursement systems may result in administrative and financial burdens for the patient. This is why several regional cooperation projects along border regions joined forces to find solutions to overcome these differences. The Covid-19 pandemic has shown that citizens in border regions could benefit greatly from structured regional cooperation in healthcare and show that good practice examples exist to show how to overcome differences in national health systems to meet patients' needs in those regions. Within the context of Covid-19, special

exemptions from restrictions to free movement were agreed for persons living in border regions and travelling across the border on a daily basis[149]. The Directive could help to a large or to some extent to address the backlog of postponed treatments arising from the pandemic.

The Directive has been very effective with regard to cooperation in rare and low prevalence complex diseases. The ERNs have contributed to considerable progress in knowledge sharing and in research on rare diseases find solutions for patients encountering diagnosis difficulties or diagnoses for one of estimated 6000-8000 rare disease with no treatment option[150]. Bearing in mind that the ERNs have only existed since 2017, there are still important issues to address including the complex and sometimes non-interoperable IT facilities, the complexity of the ERN funding, the absence of reimbursement mechanism for cross-border virtual expert panels, the insufficient integration of the ERNs in the national health systems and the absence of clear patient pathways on how to access the ERNs at the national level.

Efficiency

The Directive has had important benefits in providing legal certainty for cross-border healthcare, enhancing cross-border cooperation in healthcare between neighbouring countries and border regions and in the field of rare and low prevalence complex diseases, as well as indirectly acting as a driver for the development of patients' rights in some Member States and greater domestic transparency on treatment prices, rules, procedures and standards. For Member States, the overall costs including reimbursement and treatment costs under the Directive are minor. The Directive's financial impact on national healthcare budgets has been marginal. On the other hand, for patients opting for the Directive's route, costs are potentially significant. The costs of the Directive are therefore not borne in a proportionate manner by EU citizens within and between countries.

Patients with rare or low prevalence complex diseases have particularly benefitted from the existence of the ERNs under the Directive.

Coherence

The Directive's legal framework is well structured and the evaluation has not revealed any specific issues regarding its internal coherence. The ERNs are coherent with wider EU policy objectives in rare diseases and the Directive has reinforced existing tools such as Orphanet. However, there are important issues with regard to the consistent application of the provisions of the Directive in the Member States, most importantly, around the level of reimbursement of cross-border healthcare costs, the prior

[149] Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the Covid-19 pandemic (OJ L 337 14.10.2020, p. 3). The consolidated text available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02020H1475-20210202

[150] https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en

authorisation systems, administrative procedures for cross-border healthcare and reimbursement of telemedicine.

In terms of the Directive's external coherence, the complex legal relationship between the Directive and the Regulations of the coordination of social security systems is difficult for citizens to understand and for the NCPs and health insurers to communicate to patients. Patients cannot easily navigate the cross-border healthcare pathways under the Directive and the Regulations on the coordination of social security systems. These mechanisms are not perceived as "user-friendly" for patients seeking sometimes very urgent treatment for their medical condition. At the same time, in many instances, the responsibility in choosing the route that is more beneficial is left to patients with ensuing financial implications that could bring scepticism about cross-border healthcare in general. This raises doubts as to whether the clarity of the relationship between the Directive and the Regulations has been achieved for the benefit of patients.

However, the evaluation has not established incoherence between the CBHC Directive and Directive 2005/36/EC on the recognition of professional qualifications.

EU added value

The Directive has provided EU added value in that it brought about a more consistent EU level approach to patients' rights in cross-border healthcare, including the right to reimbursement of cross-border healthcare costs and to the mutual recognition of prescriptions in the EU. It reduced administrative burden for patients accessing planned care in other Member States compared with the Regulations on the coordination of social security systems. Through the creation of the NCPs the patients have access to relevant information about cross-border healthcare, including healthcare under the Regulations. Rare disease patients have benefitted from the establishment of the ERNs. Repealing the Directive would remove the legal certainty the Directive's objectives sought to provide. There is some evidence that the Directive provides an additional instrument for people living in border regions who have particular need to access "structural" healthcare if the closest medical facility is across a border.

However, the problems raised in this evaluation mean that the full EU added value of the Directive is not currently being realised.

Relevance

Despite persisting problems with regard to implementation, the Directive remains relevant to the needs of EU citizens to facilitate access to cross-border healthcare as citizens continue to use its mechanism for the (partial) reimbursement of their medical costs for treatment abroad. The Directive also remains relevant to address the increasing use of telemedicine, a major development in recent years, however some elements need further examination. The ERNs remain relevant to meet the needs of rare and low prevalence complex diseases patients.

ANNEX I. PROCEDURAL INFORMATION

Lead DG

The European Commission's Directorate-General (DG) for Health and Food Safety is the lead DG for this evaluation (PLAN/2021/10183 and Commission Work Programme 2021 COM 2020/690)

Organisation and timing

The Commission published a roadmap on the evaluation of patients' rights on 15 January 2021 that was open for feedback until 11 February 2021. A public consultation ran for 12 weeks from 4 May until 27 July 2021 with 193 responses received in total.

An interservice steering group (ISSG) was established on 20 January 2021 involving representatives from DG Employment, DG Communications Networks, Content and Technology, DG Internal Market, Industry, Entrepreneurship and SMEs, DG for Regional Policy, DG for Research and Innovation, Joint Research Centre, DG Justice, DG for European Civil Protection and Humanitarian Aid Operations, the Legal Service and the Secretariat-General. The ISSG contributed to the evaluation and ensured that it met the necessary standards for quality, impartiality and usefulness. Five meetings were held.

Exceptions to the Better Regulation Guidelines

None. This evaluation was not selected for scrutiny by the Regulatory Scrutiny Board.

Evidence, sources and quality

This evaluation report drew on the following sources of evidence:

- Study supporting the evaluation of Directive 2011/24/EU on patients' rights in cross-border healthcare
- Study on the Better Implementation of the Directive 2011/24/EU to ensure patients' rights in the EU
- Study on patient mobility in selected EU border regions
- Commission report on patient mobility data 2020
- Submissions to the online public consultation from May-July 2021 and the factual summary report of these as well as the synopsis report of all consultation activities in Annex V
- Input from a stakeholder event on 9 November 2021 and a summary report of this event
- Meetings with stakeholders and the minutes of these meetings
- Meeting with the cross-border healthcare expert group and the National Contact Points and the minutes of those meetings
- Opinion of the Fit for Future Platform

Annex II of this report describes the data collection tools used to gather the relevant information including a document review, stakeholder interviews, Commission public consultation, targeted surveys, case studies, workshops and contracted studies.

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

Study design

A consortium led by Tetra Tech, carried out a support study to provide input for this evaluation. The study was delivered over a period of eight months and the public consultation was available between 4 May and 27 July 2021.

There were no major changes made to the original plan set out in the roadmap. However, mitigating measures were taken, to adjust to unforeseen conditions. Firstly, as there were only 193 respondents to the public consultation, the study team conducted additional targeted consultation activities, reaching to a total of 287 stakeholders. Secondly, the study team took several mitigating measures to ensure the reliability of the data, as presented below.

Limitations and reliability of data

The public consultation was launched on 4 May 2021 and remained open for 12 weeks until 27 July 2021. There were a total of 193 respondents. The respondents were re-categorised to better reflect the stakeholder categories in the Commission's consultation strategy for the Directive[151]. Substantial efforts were made to engage stakeholders from all the categories identified in the stakeholder engagement strategy and across the study countries. While overall this objective was achieved, some sectors were less engaged in the study than what was desirable Response rates from healthcare providers to the targeted questionnaire, from pharmacists to the dispensers' survey in some study countries and from national health insurers invited to the interviews were particularly low. Two main reasons have been identified for this result. Firstly, many targeted stakeholders have been occupied in the response to the Covid-19 pandemic and were not always available to answer the evaluation team's requests. Secondly, there have been several concurrent research activities on this topic area (or in related topics), which may have led to some stakeholder fatigue. It is also important to note that key stakeholders were distributed among several categories, which means that for some answers, the qualitative data comes from a small number of individuals. To overcome this 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. As the number of responses were relatively low and spread across many different categories of respondents, the evaluation team grouped the (re)categorised respondents into two categories, contribution type and organisation type, to enable different cross-tabulations.

Methodology, sources of information and data analysis

The methodology for this support study was based on:

- **Desk-based research**, including a **literature review** which reviewed and extraction of evidence from the following types of documents: EU legislation, Staff Working Documents; reports and documents produced by the Commission and available on the DG SANTE's dedicated website; 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. In order to carry out the desk research, the study team made use of different legislative acts, studies and data. The sources of information used included:
    - Impact Assessment of the Directive 2008 on patients' rights in cross-border healthcare,
    - Commission Reports 2015 and 2018 on the operation of the Directive on patients' rights in cross-border healthcare,
    - Special Eurobarometer 425 Patients' rights to cross-border health services in the EU,
    - Studies carried out by the European Commission available on the Europa website,
    - Commission reports on Member States' data on cross-border patient mobility,
    - Preliminary rulings of the Court of Justice and citizen complaints,
    - Special Report by the ECA, the Resolution of the European Parliament on the implementation of the Directive & the Outlook Opinion of the Committee of the Regions.
- In addition, the study made use of the Commission's annual collection of data on the budgetary impact of cross-border planned healthcare used to quantify the regulatory costs. It examined the costs and benefits of cross-border treatment, using available healthcare data to identify any unintended/unexpected effects of the Directive. **Field research,** including surveys and requests of information, interview programme, one case study on the recognition of medical prescriptions and a public consultation.
    - Targeted consultations: 285 stakeholders engaged through targeted consultation activities in the form of interviews, surveys and questionnaires. They were categorised into: the European Commission, national authorities, EU-level organisations, ERNs, national level stakeholders and others.
- **Analysis of quantitative and qualitative data**, from which conclusions and recommendations were formulated.

The evaluation was based on the evaluation criteria – effectiveness, efficiency, relevance, coherence and EU-added value.

[151] The new categories used were: individual citizens, patient organisations, NGOs representing specific groups, public authorities (national, regional and local, including NCPs), healthcare providers, health insurers, industry, research organisations, organisations or projects promoting regional cooperation and ERNs.

The study did not mention specific models used, however the statistical analysis of the public consultation responses were conducted through different analytical approaches. The public consultation dataset is composed of qualitative consultations as well as quantitative data. For the quantitative data coming from 38 questions, the evaluation team used a descriptive statistical analysis. It entailed a cross-tabulation of variables to check whether there were differences across different groups of respondents; frequencies of satisfaction, revealing trends in the degree to which the Directive has achieved its intended goals; and averages in terms of responses across respondents.

Robustness of results

The evaluation was designed to ensure the robustness of the data and analytical results of the supporting studies. However, there are some limitations to the robustness of certain data identified in the supporting study. Overall, evidence was structured according to the judgment criteria (JC) and indicators presented in the evaluation matrix (Annex III). As not all sources of evidence are equally robust, consideration was given as to when and how the evidence was collected and whether there was any bias or uncertainty in it.

The study team used triangulation of data from the different data collection activities as a method to arrive at robust and evidence-based results that could be confirmed by more than one source. The evaluation triangulated at three different levels:

- Triangulation of data: primary data from stakeholder consultation activities and secondary data derived from the desk research.
- 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 were several cases where the public and targeted consultation and literature review did not produce enough robust evidence to provide a complete answer to evaluation questions, including

- limited evidence to assess the functioning of the system of prior notification in the reduction of administrative burden and improved patient experience (EQ 7);
- limited quantitative data on cross-border cooperation in healthcare (e.g. meetings, events, exchange of information/best practices, etc.);
- important data gaps on patient mobility and the use of the Directive compared to the Regulations and other parallel mechanisms in border regions (EQ 8);
- no quantitative data on the use of the Directive by different patient groups (EQ10);
- not enough evidence on the effectiveness of the Commission in supporting MS in cooperating in the development of diagnosis and treatment of rare diseases by making health professionals aware of the possibilities offered by the Regulation on the coordination of social security systems 883/2004 for the referral of patients to other Member States;

- no evidence regarding the reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients' insurance affiliation (EQ 26);
- insufficient information to assess the extent to which the Directive is coherent with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector (EQ36);
- insufficient information to assess whether there have been any problems with regard to the application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision) (EQ37).

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.

Quality of analysis

To prepare the dataset for analysis of the public consultation responses, the evaluation team assessed the quality of the data obtained. This data clean up included a missing values clean-up, a test for consistency and plausibility a clean-up of cases with high partial non-response. None of the answers were moderated and therefore all contributions were taken into account in the analysis. The cleaned-up dataset became the basis for the analysis.

The study team merged and compared data sets. The study team quality-reviewed the public consultation dataset to check whether different respondents' assessments could be analysed in combination to provide a more detailed analysis of views and perceptions of patient's rights in terms of cross-border healthcare. The following aspects were integrated into their approach: comparing and contrasting different respondent groups, meaning that there is a risk that groups that bear no resemblance or relevance to each other. This could be compared as if they were in fact similar and as such, that their responses were comparable, without taking into account their fundamental differences. Therefore, a minimum set of meta-data must be present in order to judge aspects such as, respondent sector (e.g. whether the respondents were receivers of the healthcare services or healthcare providers/organisers/payers). In sum, merging data to provide a basis for analysis must take place under strict conditions of quality assurance, since the data quality may vary (e.g. number of respondents from a particular group or to a particular question, etc.).

Critical assessment of work carried out by external contractor

The work carried out by the contractors is of good quality in the light of the evaluation's time constraints and the limitations described. There is a logical progression from the evidence gathered to the analysis and conclusions. The Commission services agree

broadly with the conclusions presented as these address the key issues arising from the evaluation.

ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

The table below presents the final Evaluation Questions Matrix (EQM), outlining the evaluation questions assessed as part of the study, judgment criteria, quantitative and qualitative indicators, the quality of the evidence and the data sources. For the assessment of the quality of the evidence, the study team has applied the following grading system:

- **High:** The evidence collected allows to confidently answer the evaluation question.
- **Moderate:** The evidence collected only allows to have moderate confidence in the answer to the evaluation question.
- **Low:** The evidence presented only allows to have limited confidence in the answer to the evaluation question.
- **Very low:** The evidence presented only allows to have little confidence in the answer to the evaluation question.

Evaluation Questions Matrix

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
Effectiveness				
2. To what extent has the Directive contributed to removing obstacles to access to healthcare in another Member State and to free movement of health services more generally in practice? a. Since the Directive entered into force, what factors help or hinder such access and movement?	JC 2.1: The Directive has contributed to removing obstacles to access to healthcare in another MS JC 2.2: The Directive has contributed to free movement of health services JC 2.3: There are factors that have helped or hindered such access and	• Incoming and outgoing patients per MS per year • Evidence on existing/overcome obstacles to access CBHC; ways in which the Directive has contributed to free movement of health services; other factors that have helped/hindered access to CBHC and movement of health services • Stakeholders' perceptions on clarity of responsibilities regarding CBHC; clarity of reimbursement	**Rating of the evidence: Moderate** There are gaps and limitations in the data presented in the annual patient mobility reports. The data from 2015 to 2018 is incomplete, with reference year 2019 being the first time that all countries responded to the request for information. Nonetheless, even in 2019 many countries were only able to provide limited information and not all countries differentiated between cases under the Directive, the Coordination Regulations or under bilateral cross-border agreements. This data limitation was caveated through the use of quantitative data presented in the	Literature review Survey of healthcare providers Interviews of the European Commission's officials, national authorities (CBHC expert group), ERNs, patients, healthcare providers/ professionals, healthcare insurers Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	movement	rules on CBHC costs	Commission's report on "*Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020"*. In addition, qualitative data collected through targeted questionnaires, interviews and the workshop discussion provided further evidence and validation of the findings.	
3. How effective has the Directive been in ensuring that clear information is available and accessible to patients about cross-border healthcare from healthcare providers and the National Contact Points? a. To what extent are citizens aware of their rights and entitlements to be able to make an informed choice? b. What factors hinder the provision of clear and transparent information to patients?	JC 3.1: The Directive has contributed to ensuring that clear information on cross-border healthcare is available and accessible to patients from healthcare providers and NCPs JC 3.2: Citizens are aware of their rights and entitlements on cross-border healthcare to be able to make an informed choice JC 3.2: There are factors hindering the provision of clear and transparent information to patients by MS (healthcare providers and NCPs)	• Extent and clarity of information provision by NCPs and healthcare providers (rights and entitlement) • Accessibility and quality of information provided to citizens/patients by MS (healthcare providers and NCPs) on cross-border healthcare, incl. on their rights and entitlements • Improvements to the information provided to patients by NCPs, including their websites • Citizens/patients' level of awareness of their rights on cross-border healthcare • Factors hindering the provision of clear and transparent information to citizens/patients by MS (healthcare providers and NCPs)	**Rating of the evidence: High** The NCP websites of all EU MS, Norway, Iceland and Liechtenstein, were analysed. There were no limitations in the data collected and the methodological approach adopted was the same approach used in the 2015 Evaluative study on the cross border healthcare Directive (2011/24/EU) and the 2018 Study on enhancing cross-border health services. This ensured comparability of the data. In addition, triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity results obtained.	Literature review Web analysis of NCPs websites Interviews with patients, national authorities (CBHC expert group), healthcare providers/ professionals Information request to national patient ombudsmen Virtual workshop Public consultation
4. To what extent has the information provided to	JC 4.1: Transparency and comparability of	• Extent and clarity of information	**Rating of the evidence: High** As per EQ3.	Literature review Web analysis of NCPs

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
patients under the Directive contributed to enhanced transparency and comparability of healthcare (regarding safety, quality, costs, waiting times, etc.) across the EU?[152] a. To what extent have Member States made the standards for quality and safety of care, applicable standards for health professionals transparent for EU citizens?[153]	healthcare as regards safety standards, quality, costs, waiting times have been enhanced across the EU since the adoption of the Directive JC 4.2: MS (healthcare providers and NCPs) provide clear information to citizens on their standards for quality and safety of care, as well as applicable standards for health professionals	provision by NCPs and healthcare providers on standards for quality and safety of care, as well as applicable standards for health professionals • Evidence on improvements to information provided on transparency and comparability of healthcare safety standards, quality, costs, waiting times across the EU since the adoption of the Directive.		websites Public consultation Interviews of the European Commission's officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients Information request to national patient ombudsmen
5. To what extent have the National Contact Points implemented consultation arrangements with patient organisations, healthcare providers and healthcare insurers and how effective have these been?	JC 5.1: NCPs have implemented consultation arrangements with patient organisations, healthcare providers and healthcare insurers JC 5.2: Information collected through consultation of patient organisations, healthcare providers and healthcare insurers has helped to	• Evidence on consultation arrangements with patient organisations, healthcare providers and healthcare insurers implemented by NCPs (incl. ways in which the information/opinions collected were used)	**Rating of the evidence: High** The assessment was based on evidence provided by a mapping exercise on consultation arrangements between NCPs and patient organisations, healthcare insurers, and healthcare providers conducted by Ecorys. The evidence of that study was collected through 1) written inquiries with NCPs and 2) online questionnaires with patient organisations, healthcare insurers, and healthcare providers.	Subject of another commissioned study: Mapping NCP consultation arrangements with key stakeholders: draft analytical report (Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU)

[152] The wording of this question was slightly amended. The original question in the ToR read: "To what extent has the enhanced transparency and comparability of healthcare (with regard to safety, quality, costs, waiting times etc.) been enhanced across the EU?"

[153] In the ToR, this sub-question was presented as part of EQ3. However, the study team considered it was more appropriate to answer it together with EQ4.

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	improve services provided by NCPs			
6. With regard to administrative procedures for cross-border healthcare and reimbursement has – and how – the Directive proven to be effective to ensure that these are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved? a. To what extent did the Directive ensure continuity of care between Member States after cross-border treatment?	JC 6.1: There are several ways in which the Directive has contributed to ensuring that administrative procedures for cross-border healthcare and reimbursement are based on objective, non-discriminatory and proportionate criteria JC 6.2: The Directive has ensured continuity of care between Member States after cross-border treatment	Quantitative data on: prior authorisation procedures per MS; prior vs non-prior authorisations requests per MS (received, refused, and authorised); processing time for reimbursement of costs; citizens/patients' access to/satisfaction with information available on waiting times for cross-border healthcare requests. Qualitative evidence on administrative procedures followed by MS for cross-border healthcare and reimbursement (e.g. waiting times, assessment criteria, etc.); criteria applied by MS in administrative procedures for cross-border healthcare and reimbursement; ways in which procedures and criteria applied changed since the adoption of the Directive; extent to which citizens/patients are provided with information on waiting times; extent to which continuity of care has been ensured by MS after cross-border treatment **Indicators excluded from the analysis:** Quantitative data on the continuity of care between MS after cross-border treatment across the EU from 2012 to 2020	**Rating of the evidence: Moderate** As per EQ2. No quantitative data available on the continuity of care between MS after cross-border treatment across the EU from 2012 to 2020; therefore the indicators was excluded.	Literature review Survey of healthcare providers Interviews with CBHC expert group, patient organisations, healthcare providers/professionals, healthcare insurers Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
7. To what extent have Member States applied the system of voluntary prior notification on the amount to be reimbursed and the cost of treatment and did it reduce the administrative burden? What was the patient experience?	JC 7.1: A number of Member States have applied the system of voluntary prior notification on the amount to be reimbursed and the cost of treatment JC 7.2: The system of voluntary prior notification has reduced the administrative burden on patients, healthcare providers and health insurers	Quantitative data on the application of the system of voluntary prior notification (number of MS having introduced the system) Stakeholders' perceptions on the effects of the prior notification system on the administrative burden of patients, healthcare providers and health insurers **Indicators excluded from the analysis:** Quantitative data on prior notifications (where implemented) per MS on the amount to be reimbursed and the cost of treatment Qualitative evidence on the effects of the prior notification system on the administrative burden of patients, healthcare providers and health insurers	**Rating of the evidence: Low** Very limited quantitative data available relating to the use and effects of the system of voluntary prior notification on administrative burden and patient experience (two indicators had to be excluded from the analysis for this reason). To the extent possible, the answer to this EQ was based on stakeholders' perceptions collected through interviews with representatives from MS applying the system of prior notification.	Literature review Interviews of national authorities (CBHC expert group)
8. To what extent has the Commission encouraged cooperation in cross-border healthcare between neighbouring countries and border regions as provided by the Directive? Can the Directive be credited with increased cross-border cooperation in healthcare and if yes, how?	JC 8.1: The Commission has encouraged cooperation in cross-border healthcare between neighbouring countries and border regions JC 8.2: There are several ways in which the Directive has contributed to increased cross-border cooperation in healthcare	Qualitative evidence on the Commission's actions to encourage cooperation in cross-border healthcare and results of these actions Evidence on the extent to which there is increased cooperation in cross-border healthcare and how it was achieved **Indicators excluded from the analysis:** Quantitative data on cross-border cooperation in healthcare (e.g.	**Rating of the evidence: Moderate** Limited data available on concrete actions implemented to encourage cross-border cooperation in healthcare, as well as important data gaps on patient mobility and the use of the Directive compared to the Regulations and other parallel mechanisms in border regions (see EQ2). These limitations were addressed by using evidence from the public consultation and the findings of the AEBR research project on Cross Border Patient Mobility as well as with broader literature review such as Bobek, J. et al. (2018)	Subject of another commissioned study: Cross Border Patient Mobility in Selected EU Regions Literature review Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		meetings, events, exchange of information/best practices, etc.)	study on Cross-Border Cooperation "Capitalising on existing initiatives for cooperation in cross-border regions".	
9. How effective were the Directive and the Implementing Directive 2012/52/EU to regulate the recognition of prescriptions across EU borders? a. What factors, if any, continue to prevent the recognition of prescriptions in another Member State?	JC 9.1: The Directive and the Implementing Directive were effective in regulating the recognition of prescriptions across EU borders JC9.2: There are factors that continue to prevent the recognition of prescriptions in another MS	• Quantitative data on: - The number of foreign prescription presented in the EU - the recognition rate of prescriptions across EU borders • Qualitative evidence on: - ways in which the Directive and Implementing Directive regulated the recognition of prescriptions across EU borders - extent to which these rules are being applied across the EU, incl. challenges/barriers faced in applying them - factors that continue to prevent the recognition of prescriptions in another MS	**Rating of the evidence: Low** The robustness of the findings of the prescription case study is limited, as the analysis is based on a total of 158 submitted responses to the questionnaires and 948 prescription observations (compared to 996 questionnaires and 11,952 prescription observations in 2012). Despite several follow-ups sent by the national associations at the request of the PGEU to encourage a higher response rate, pharmacists' engagement was very low. This was likely due to the difficult time in which the survey was implemented. Indeed, representatives of the sector indicated that pharmacists have been under considerable pressure under the pandemic, delivering vaccines, while cross-border prescriptions are very marginal for most pharmacies. To complement the limited quantitative data, where possible, additional quantitative and qualitative data was collected via desk research (e.g., on total prescriptions dispensed across the EU and number of pharmacies). While the low response rate affect the robustness of the quantitative analysis, the case study still provides useful information on existing problems associated with the mutual recognition of prescriptions across the EU.	Literature review Interviews/surveys of the European Commission's officials, national authorities (CBHC expert group), healthcare providers, healthcare insurers Case studies (including pharmacist targeted survey) Public consultation
10. Are there specific patient groups that are	JC 10.1: There are specific patient groups	Qualitative evidence on patient groups that have benefited more / less from the	**Rating of the evidence: Moderate** No quantitative data available on the use of the	Literature review Interviews of CBHC expert

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
particularly benefiting from the patients' rights in cross-border healthcare as set out in the Directive?	that are particularly benefiting from the patients' rights in cross-border healthcare	patients' rights in cross-border healthcare since the adoption of the Directive and reasons for this. Stakeholders' perceptions on why / how specific patient groups have benefited more / less from the patients' rights in cross-border healthcare. **Indicators excluded from the analysis:** Quantitative data on patient groups benefiting from cross-border healthcare across the EU from 2012 to 2020	Directive by different patient groups. This limitation was addressed through the triangulation of qualitative data collected during interviews, the public consultation and the review of existing and/or related literature on the topic (i.e. SOLVIT survey, ANEC survey, EXPH study, EPHA report etc.).	group, healthcare providers/ professionals, healthcare insurers, patient Public consultation
11. How effective was the Directive to support the diagnosis and treatment of patients with rare and complex diseases, including through virtual consultation panels? To what extent is the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and on the care for these patients? How can the situation be improved; what kind of reimbursement mechanism would be adequate for similar situations?	JC 11.1: There are several ways in which the Directive has supported the diagnosis and treatment of patients with rare and complex diseases JC 11.2: The absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) has impacted on the provision of virtual panels and on the care for patients with rare and complex diseases JC 11.3: There are ways in which support for the diagnosis and treatment of patients with rare and	Quantitative data on: - ERNs established, members and affiliated partners represented in them - Rare/complex diseases covered by ERNs - MS with healthcare providers in ERNs - Patients treated by members of ERNs - ERN virtual consultation panels - healthcare professionals participating in ERNs - Hospitals and healthcare providers participating in ERNs (total and per MS) - ERN registries established Evidence on: - ways in which the Directive has supported the diagnosis and	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, surveys, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity results obtained.	Literature review Data provided by the European Commission's Survey of ERN members Interviews of ERNs patient representatives, industry, researchers Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	complex diseases, including through virtual consultation panels, can be improved	treatment of patients with rare and complex diseases - extent of participation of healthcare professionals in cross-border virtual consultation panels, and factors that enable/hinder participation - ways in which the cross-border diagnosis and the effects of the absence of reimbursement on the provision of virtual panels		
12. How effective was the knowledge sharing on rare and complex diseases among EU healthcare professionals thanks to ERNs?	JC 12.1: Knowledge sharing activities organised by ERNs have supported healthcare professionals (at least within the networks) in diagnosing and treating patients with rare and complex diseases	Quantitative data on: - Number of educational activities accruing educational credits, aimed at healthcare professionals organised by the ERN - Number of new clinical practice guidelines written by the ERN - Number of educational activities not accruing credits aimed at healthcare professionals delivered by the ERN coordination team or healthcare provider members of the ERN - Number of congresses/ conferences/ meetings at which the ERN activities and results were presented - Number of accepted peer-reviewed publications in scientific journals regarding diseases within the scope of the ERN and which acknowledge the ERN reviewed publications	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, surveys, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained.	Literature review Data provided by the European Commission's Survey of ERN members Interviews of ERNs patient representatives, industry, researchers Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		Qualitative evidence on if / how the knowledge sharing activities have supported healthcare professionals in diagnosing and treating patients with rare and complex diseases Stakeholders perceptions on the effects of the knowledge sharing activities on healthcare professionals' diagnosis and treatment of patients with rare and complex diseases (e.g. in terms of enhanced knowledge among healthcare professionals)		
13. What has been the impact of the ERNs on the research on rare and low prevalence and complex diseases?	JC 13.1: There ERNs have had an impact on the research on rare and low prevalence and complex diseases	Quantitative data on: - Number of Clinical Practice Guidelines and other types of Clinical Decision Making Tools adopted for diseases within the scope of the ERN - Number of new clinical practice guidelines written by the ERN - Number of Clinical Decision Making Tools (clinical consensus statements or consensus recommendations) - Number of clinical trials and observational prospective studies within the ERN - Number of accepted peer-reviewed publications in scientific journals regarding diseases within the scope of the ERN and which acknowledge the ERN reviewed publications	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews of ERNs patient representatives, industry, researchers Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		Qualitative evidence on impact of ERNs on research on rare and low prevalence and complex diseases Stakeholders perceptions on the impact of the ERNs on the research on rare and low prevalence and complex diseases (e.g. in terms of volume, quality and coverage of research, and importance of ERNs registries)		
14. To what extent is the use of ERNs and knowledge sharing effective to allow patients with rare diseases to receive diagnosis and treatment they need, including potentially healthcare in another EU Member State?	JC 14.1: The use of ERNs and knowledge sharing have allowed patients with rare diseases to receive diagnosis and treatment they need, including potentially healthcare in another MS	Quantitative data on the use of ERNs and knowledge sharing activities by healthcare professionals (see quantitative indicators in EQ12) Qualitative evidence on ways in which the use of ERNs and knowledge sharing activities have allowed patients with rare and complex diseases to receive diagnosis and treatment they need, including potentially healthcare in another MS Stakeholders' perceptions on the impact of ERNs and knowledge sharing activities on granting patients with rare diseases with the diagnosis and treatment they need	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews of ERNs patient representatives, industry, researchers Public consultation Virtual workshop
15. How effectively has the Commission supported Member States in cooperating in the development of diagnosis and treatment of rare diseases by making health	JC 15.1: The Commission has supported cross-border cooperation in the development of diagnosis and treatment of rare diseases by	Quantitative data on actions undertaken by the European Commission to increase health professionals' awareness of tools and rules applicable to cross-border cooperation in the development of diagnosis and treatment of rare diseases, as well as	**Rating of the evidence: Moderate** Limited evidence on concrete actions undertaken by the European Commission in supporting MS in cooperating in the development of diagnosis and treatment of rare diseases by making health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of	Literature review Targeted survey of ERNs Interviews of ERNs, CBHC expert group, patients, researchers, industry Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
professionals aware of tools available to them at Union level (in particular the Orphanet database and the ERNs) and the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?	making health professionals aware of: - tools available to them at EU level (e.g. Orphanet database and ERNs) - possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?	data on the health professionals' awareness and use of the tools and the referral of patients to another MS Qualitative evidence on ways in which the European Commission has made healthcare professionals aware of the tools available at Union level Stakeholders' perceptions on the level of awareness and use of healthcare professionals of the tools available for the diagnosis and treatment of rare diseases	patients to other Member States. This limitation was addressed through stakeholder consultation, including the ERNs targeted survey which addressed that specific question.	
16. Has the Directive triggered any unexpected or unintended effects?	JC 16.1: The Directive has had some unexpected or unintended effects	Quantitative data collected for other EQs on patients' mobility across the EU and cross-border healthcare (e.g. EQ2) Qualitative evidence on any unexpected or unintended effects of the Directive (vis-à-vis the objectives it was meant to achieve) Stakeholders' perceptions on any unexpected or unintended effects of the Directive	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews/surveys of European Commission's officials, national authorities (CBHC expert group), ERNs, healthcare providers/ professionals, healthcare insurers, researchers, industry Public consultation
Efficiency				
17. To what extent are the costs justified and proportionate given the effects observed/objectives	JC 17.1: The costs are proportionate to and justifiable considering the identified	Quantitative data on: - reimbursement claims received and granted for healthcare provided in	**Rating of the evidence: Low** Limitations of the patient mobility data (see EQ2) Limited quantitative data on the administrative costs related to applying the Directive for MS,	Literature review Interviews of European Commission's officials, national authorities (CBHC

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
achieved/benefits obtained?	benefits/achievements of the Directive.	another MS - aggregate amount reimbursed per MS per year (for CBHC with and without prior authorisation) - administrative waiting times to process requests for prior authorisation and reimbursement - patient complaints about administrative procedures Stakeholders' perceptions on: - administrative burden on patients, healthcare providers and healthcare insurers (n.b. administrative burden to be defined as additional to national situations) **Indicators excluded from the analysis:** Quantitative data on: - administrative costs (FTEs) for handling applications for prior authorisation, and reimbursement (incl. translation costs, assimilation to health system and calculation of amount to be reimbursed) - other administrative costs (FTEs) re. compliance, monitoring and reporting - incoming and outgoing patients per MS per year	European Commission and other stakeholders. There have been several concurrent research activities on this topic area (or in related topics), which may have led to some stakeholder fatigue. These limitations have been addressed through qualitative data collected in interviews and through desk review of available literature including the European Commission's report on patient mobility ("Trend report reference years 2018-2020") and Ecorys and Spark 2021 Mapping and Analysis of Administrative Procedures (Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.)	expert group), patients, healthcare providers, healthcare insurers, ERNs Public consultation
18. How proportionately were the costs of the Directive borne by different stakeholder groups	JC 18.1: The costs of implementing the Directive were proportionately borne by	Comparison of qualitative data on administrative costs and benefits of the Directive borne by different stakeholder groups, including:	**Rating of the evidence: Low** The limited data available did not allow to calculate or estimate aggregate costs across different cost categories for the different	Literature review Interviews of European Commission's officials, national authorities (CBHC

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
considering the distribution of the associated benefits?	different stakeholder groups considering the benefits experienced by each group.	- national authorities (including NCPs) - patients **Indicators excluded from the analysis:** Quantitative data on administrative costs of the Directive borne by different stakeholder groups Degree of proportionality of costs and benefits by stakeholder group	stakeholder groups and thus prevented the assessment of whether the costs of the Directive were proportionate to the associated benefits for each stakeholder group. This limitation was addressed through interviews with stakeholder groups and desk review of available literature including EPHA report on the Implementation of the Cross-border Healthcare Directive and Ecorys and Spark 2021 Mapping and Analysis of Administrative Procedures (Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).)	expert group), patients, ERNs
19. If there are significant differences in costs (or benefits) between Member States, what is causing them? How do these differences link to the intervention?	JC 19.1: There is significant variability in levels of costs and benefits by Member State. JC 19.2: The reasons why significant differences (should they exist) can be identified, as well as how they link to the intervention	Analysis of quantitative and qualitative data relating to administrative costs per Member State Qualitative data on factors that influence the costs and benefits achieved by MS (see EQ20)	**Rating of the evidence: Low** Limited quantitative data on administrative costs related to applying the Directive for MS and on patient mobility (see EQ2) These limitations were addressed through qualitative data collected in interviews and desk review of available literature including the Commission's report on patient mobility ("Trend report reference years 2018-2020.") and Ecorys and Spark 2021 Mapping and Analysis of Administrative Procedures (Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).)	Literature review Interviews of European Commission's officials, national authorities (CBHC expert group), patients, healthcare providers, healthcare insurers, ERNs
20. Which factors influenced the cost side and which ones influenced the benefit side and to what extent?	JC 20.1: It is possible to identify main cost drivers and factors that enhanced or limited the benefits JC 20.2: The identified cost drivers and limiting	Quantitative and qualitative evidence of factors related and unrelated to the Directive and their level of significance on costs, i.e. - Estimated MS costs (treatment costs, compliance costs and	**Rating of the evidence: Low** The limited cost data available for MS, European Commission and patients did not allow to quantitatively identify the main cost drivers in cross-border healthcare. In turn, the extent of the contribution of the Directive and other	Literature review Interviews of European Commission's officials, national authorities (CBHC expert group), patients, healthcare providers,

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
To what extent were these factors linked to the Directive? To what extent were there external factors that influenced the results?	factors relate to the Directive. JC 20.3: The results achieved were enhanced or limited by other factors not directly related to the Directive.	specific admin burden) - Estimated patients' costs (non-reimbursable costs and admin burden), Qualitative feedback on factors that enhanced or reduced the benefits achieved, in relation to treatment benefits, patient benefits, social benefits, benefits for MS and other stakeholders. **Indicators excluded from the analysis:** European Commission's costs to support the Directive Costs for other stakeholders	influencing factors over costs could not be assessed. These limitations were addressed, where possible, through desk research, qualitative findings and by means of estimations and assumptions in the cost-benefit analysis (see EQ17).	healthcare insurers, ERNs
21. How significant is the administrative burden for specific stakeholders caused by the Directive compared to the situation before it came into force? Has the Directive led to a reduction in administrative burdens on patients in relation to cross-border healthcare and reimbursement of costs? What administrative burdens still exist for patients? Where is there room for simplification?	JC 21.1: The level of administrative burden is significant for different stakeholders when compared with the situation before the Directive. JC 21.2: There is evidence of increased efficiency / simplification over time for patients using cross-border healthcare and seeking reimbursement of their costs. JC 21.3: Certain types of administrative burdens	Quantitative evidence confirming improved availability/access to information, increased speed of reimbursement of costs / handling complaints. Patient associations, NCPs/ CBHC expert group, health insurers, etc. confirm main sources of persistent administrative burden for patients and. Qualitative feedback confirm main sources of simplification and opportunities to increase efficiency. **Indicators excluded from the analysis:** Comparative analysis of data on costs	**Rating of the evidence: Low** Lack of data on cost and administrative burden (same limitations and measures to address these limitations as under EQ 18, 19 and 20).	Literature review Interviews of European Commission's officials, national authorities (CBHC expert group), patients, healthcare providers, healthcare insurers, ERNs, researchers, industry Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	still exist in relation to specific aspects of the Directive. JC 21.4: There is scope to increase efficiency through simplification of current processes.	and benefits per specific stakeholder group (as identified in EQ 18) with equivalent data from the 2008 Impact Assessment		
22. To what extent are the costs of ERNs system and their tools justified and proportionate given the objectives achieved and benefits obtained?	JC 22.1: The costs of providing a comprehensive ERN system supported by a range of tools are appropriate to the level of additional benefit that has been achieved	Costs for the European Commission for implementation, development of tools and annual allocation. Quantitative data on administrative costs (FTEs) re. establishment and running of ERNs, monitoring and reporting. Quantitative data on results/benefits of the ERN system collected for the EQs on effectiveness (e.g. EQ13, EQ14) Stakeholders perceptions on balance of costs and benefits of the ERN system	**Rating of the evidence: Moderate** Limited data on the funding that ERNs received from coordinating centres, private donors/patients organisations, and from MS. To address these limitations, both qualitative and quantitative evidence were used to assess the costs of ERNs. In addition, the funding form the coordinating centers was estimated based on the EU funding (i.e. coordinating center co-fund 40% of the EU funding)	Literature review Data provided by the European Commission Interviews of the European Commission's officials, national authorities (CBHC expert group), patients, ERNs, researchers, industry Survey of ERNs Public consultation
23. To what extent is the model of ERNs allowing rare disease patients to receive diagnosis and treatment without physically transporting the patient to another Member State (thanks to the virtual consultations, knowledge sharing, development of clinical guidelines, etc.) more (or less) cost-effective as compared to patients being physically transported	JC 23.1: The direct and indirect costs associated with ERN's virtual diagnosis and treatment are lower than would be required to performance physical consultations. JC 23.2: There are specific circumstances when the provision of virtual diagnosis and treatment is not cost-effective because physical presence is	Quantitative data on administrative costs collected in EQ 22 Stakeholders' perceptions on: - costs and benefits associated with physical consultations - Other cost-saving elements	**Rating of the evidence: Moderate** Limited quantitative data on the costs associated with patients being physically transported to another member State and receiving healthcare there as well as on the cost of ERNs (see EQ 22) This limitation was addressed through qualitative feedback from stakeholders' consultation as well as quantitative estimates.	Literature review Interviews of national authorities (CBHC expert group), ERNs, researchers, industry Survey of ERNs

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
to another MS and receiving healthcare there?	required.			
Relevance				
24. How well do the Directive's specific objectives still correspond to the current and future needs of EU citizens for cross-border healthcare? Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?	JC 24.1: EU citizens continue to need and seek planned healthcare and access to healthcare in other MS now and in the future under the common principles and entitlements set out in the Directive JC 24.2: Citizens/patients have been enabled to select their preferred treatment in another Member States	Extent that common principles and responsibilities of MS and healthcare providers for cross-border healthcare correspond to current and future needs Extent of the clarify of entitlements of patients to have healthcare in another MS Extent that rights to reimbursement (under certain conditions) for healthcare abroad can be used in practice Extent that high-quality, safe and efficient cross-border healthcare is ensured Ensure that continuity of care between Member State of treatment and Member State of affiliation is ensured	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews/surveys of the European Commission's officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients, Public consultation Virtual workshop
25. Are there new developments (technological[154], policy, etc.) since the Directive's entry into force, which have implications on patients' rights to cross-border healthcare?	JC 25.1: Changes in healthcare policies, systems, and capacity, also in the light of Covid-19, have had implications on patients' rights to cross-border healthcare	Evidence on new/changed health insurance /provision policies /Covid-19 influencing access to and take up of CBHC and influencing the needs addressed by the Directive Qualitative feedback on the introduction of new technologies in the	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews of the European Commission's officials, national authorities (CBHC expert group), ERNs, healthcare providers/ professionals, healthcare insurers, consumer

[154] EQ29 focuses on technological developments. Therefore, these were not addressed in this evaluation question.

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
How do they impact on the Directive's relevance?	JC 25.2: Identified changes enhance or reduce the relevance of the Directive JC 29.2: There are other new technological developments which are expected to influence cross-border healthcare in the future	provision of cross-border healthcare Quantitative and qualitative evidence that identified new technologies made it easier for patients to take up their rights to cross-border healthcare		organisations, researchers, industry Public consultation
26. Has the Directive had any effects beyond its scope, for example on the reimbursement of cross-border health care provided by foreign doctors treating patients in the state of the patients' insurance affiliation?	JC 26.1: The Directive has had effects beyond its scope JC 26.2: The Directive has had effect on the reimbursement of cross-border health care provided by foreign doctors treating patients in the state of the patients' insurance affiliation	**Answer to JC 26.1 combined with EQ 16** **Indicators excluded from the analysis:** Quantitative and qualitative data on foreign doctors treating patients in the state of the patients' insurance affiliation	**Answer to the first part of the question (i.e., has the Directive had any effects beyond its scope, JC2.1) is provided under EQ16.** **Rating of the evidence for JC26.2: Very low** No evidence was found regarding the reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients' insurance affiliation.	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/ professionals patients, healthcare insurers
27. Are the National Contact Points still relevant for meeting patient information needs? What could be improved as regards NCPs?	JC 27.1: Patients continue to refer to NCPs for information and to support their access to cross-border healthcare JC 27.2: NCPs have capacity to consistently and adequately respond to all patient enquiries	Quantitative data confirming numbers and type of enquiries Qualitative data and stakeholder feedbacks confirmed that: - types of patients' information needs being met by NCPs - expectations and possible improvements to delivery channels	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews of national authorities (CBHC expert group), healthcare providers/professionals, healthcare insurers, patient Public consultation Analysis of NCP websites

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	received JC 27.3: There are ways to further enhance how NCPs provide support and the type of support that they provide JC 27.4: NCPs have capacity to consistently and adequately respond to all patient enquiries received. JC 27.5: There are ways to further enhance how NCPs provide support and the type of support that they provide.	- consistency in the approach taken by NCPs across the MS - that NCPs add value to the landscape of other information providers in the MS - accessibility of NCP information by disadvantaged groups - need to broaden the role of the NCPs, for example, into advocacy services for their own patients Evidence that information materials in the public domain and levels and types of accessibility/delivery channels meet patients' expectations also regarding social media **Indicators excluded from the analysis:** Quantitative data and stakeholder feedback on whether there is a conflict of interest if the NCP is a payer organisation		
28. Which provisions have proven to be significant for the Directive's relevance and which are less adequate to meet the needs of cross-border patients? Which factors explain this?	JC 28.1: There is demand for additional/revised provisions in the Directive JC 28.2: Patients and/or those involved in the provision of healthcare experience persistent problems not fully	Evidence of significant variation in demand for and provision of healthcare relating to specific provisions of the Directive Stakeholders' perceptions on areas of most relevance, as well as aspects which could be reinforced and or reasons / situations which influence the adequacy of provisions in the Directive	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained	Literature review Interviews of the European Commission's officials, national authorities (CBHC expert group), healthcare providers/ professionals, patients Virtual workshop Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	addressed by the Directive JC 28.3: It is possible to define specific issues / situations /systemic / historic and cultural reasons, which explain variations in the relevance of different provisions of the Directive (should these exist)			
29. Are there any technological developments which have implications for the Directive since its entry into force?	JC 29.1: New technology has been integrated to enhance the organisation, provision and access to cross-border healthcare JC 29.2: There are other new technological developments which are expected to influence cross-border healthcare in the future	**Answer combined with EQ25**	N/A	N/A
30. Are the ERNs still relevant for meeting the needs of patients with rare and complex diseases?	JC 30.1: ERNs improve the diagnosis and treatment of rare and complex diseases JC 30.2: There are factors that limit the extent that ERNs can enhance the diagnosis and treatment of rare and	Relevance of ERNs for meeting patient needs Quantitative data on the number of patients benefiting from ERNs (including data on the number of patients treated in the CPMS) Factors that enhance / limit supply and demand for services	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Desk review of available reports studies and statistics on ERNs Interviews with national authorities (CBHC expert group), ERNs, patient representatives, industry, researchers Survey of ERNs

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	complex diseases	**Indicators excluded from the analysis:** Gaps in rare diseases and complex conditions not covered by the ERNs		Public consultation
31. Is there any difference in relevance and adequacy of the Directive's provisions depending on territorial dimension (i.e. for border regions)?	JC 31.1: The provisions under the Directive meet patients' cross-border health needs consistently irrespective of where they reside and/or where they seek healthcare support JC 31.2: Cross-border healthcare provision between border regions has the same/different requirements than provision between non-bordering Member States/regions	Evidence on levels of cross-border healthcare provision Stakeholders' perceptions related to the territorial dimension	**Rating of the evidence: Moderate** Limited data available on concrete actions implemented in terms of cross-border cooperation since the Directive's adoption (see EQ 8) and important data gaps on patient mobility and the use of the Directive compared to the Regulations and other parallel mechanisms in border regions (see EQ 2). These limitations were addressed with the findings of the AEBR research project on Cross Border Patient Mobility as well as with broader literature review such as Bobek, J. et al. (2018) study on Cross-Border Cooperation "Capitalising on existing initiatives for cooperation in cross-border regions"	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/ professionals
Coherence				
32. To what extent have the specific objectives of the Directive translated unambiguously into legal provisions to apply patients' rights in cross-border healthcare? Identify where more clarity is necessary.	JC 32.1: The specific objectives of the Directive translated unambiguously into legal provisions to apply patients' rights in cross-border healthcare. JC 32.2: There is a need to enhance clarity of legal provisions to ensure that the specific	Qualitative evidence on the application of the provisions of the Directive across the EU Qualitative evidence on the alignment between the specific objectives and legal provisions of the Directive and reasons underlying any identified misalignments/divergences/gaps Stakeholders' perceptions on extent to which the legal provisions of the Directive address its specific objectives	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	objectives of the Directive are met.	and areas where more clarity is needed.		
33. To what extent has the application of the legal framework by Member States been coherent with regard to costs for healthcare?[155] Identify inconsistencies and resulting problems for patients.	JC 33.1: The application of the legal framework by Member States has been coherent with regard to costs for healthcare JC 33.2: Inconsistencies in the application of the legal framework by Member States have been identified which have resulted in problems for patients	Qualitative evidence on the relationship between the legal application of the Directive by MS and the costs for healthcare, as well as any identified inconsistencies **Indicators excluded from the analysis:** MS quantitative data relating to treatment costs, number of claims/forms received and issued, and amounts reimbursed by MS Quantitative evidence on the application of the provisions of the Directive across the EU Stakeholders' perceptions on the extent to which the application of the Directive by MS has been coherent with regard to costs for healthcare, including any inconsistencies identified	**Rating of the evidence: Moderate** Limitation in the data available in regard to treatment costs, number of claims/forms received and issued, and amounts reimbursed by MS.	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers
34. Has the Directive sufficiently clarified its relationship with the existing framework on the coordination of social security systems (the Social Security Coordination Regulations) with a view to application of patients'	JC 34.1: The Directive is sufficiently clear on how it interacts with the existing framework on the coordination of social security systems, leaving no room to uncertainty to patients, health providers and social security	For the purpose of consistency and to avoid overlap, EQ34 and EQ35 have been combined. Quantitative evidence on patients' application for cross-border healthcare under the Directive and the Social Security Coordination Regulations Qualitative evidence on how the Directive and the Social Security	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained	Literature review Interviews with the European Commission's officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients Virtual workshop

[155] The wording of this question has been modified. The original question in the ToR read: "To what extent have Member States applied the legal framework been coherent with regard to costs for healthcare? Identify inconsistencies and resulting problems for patients."

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
rights?	institutions on how to apply these rules	Coordination Regulations interact with each other, from both a legal and practical perspective Stakeholders' perceptions on extent to which the patients, health providers and Social Security bodies understand the relationship between the Directive and the Social Security Coordination Regulations and how to apply them in practice		Public consultation
35. To what extent is there overlap between the Directive and the Social Security Coordination Regulations and how has this influenced the patients' choice for reimbursement of healthcare costs and the response by the Member State of affiliation?	JC 35.1: There is a certain degree of overlap between the Directive and the Social Security Coordination Regulations which influences patients' choices and the response of MS.	For the purpose of consistency and to avoid overlap, EQ34 and EQ35 have been combined. Qualitative evidence on: - how the Directive and the Social Security Coordination Regulations interact with each other, from both a legal and practical perspective - reasons for patients' choice of each scheme for the reimbursement of cross-border healthcare costs - MS' responses to the reimbursement of cross-border healthcare costs under the different schemes Stakeholders' perceptions on how patients' choices and MS' responses are influenced by the existing overlaps between the Directive and the Social Security Coordination Regulations	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation, workshop) and stakeholders provides high confidence on the validity of results obtained.	Literature review Interviews with the European Commission's officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients Virtual workshop Public consultation
36. To what extent is the Directive coherent with the Directive on the recognition of professional	JC 36.1: The Directive aligns well to the Directive on the recognition of	Qualitative evidence on (mis)match between the provisions of the Directive and those of the Directive on the recognition of professional	**Rating of the evidence: Moderate** Limited information to assess the extent to which the Directive is coherent with the Directive on the recognition of professional qualifications with	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
qualifications with regard to the regulated professions in the healthcare sector?	professional qualifications with regard to the regulated professions in the healthcare sector	qualifications with regard to the regulated professions in the healthcare sector Stakeholders' perceptions on: - extent to which the provisions of the Directive and those of the Directive on the recognition of professional qualifications are aligned.	regard to the regulated professions in the healthcare sector. This limitation was addressed to the extent possible through stakeholder consultations (who did not raise any points of incoherence between the two Directives, or stated that they were not aware of any problems) and desk review of available literature such as Ecorys 2017 study on cross-border health services, which examines the free movement of healthcare providers in practice through specific examples in national contexts.	professionals
37. Have there been any problems with regard to the application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision), i.e. difficulties related to determining which rules apply or how to access the professional's liability insurance?	JC 37.1: The application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision) is clear and has not generated any difficulties	Qualitative evidence on the application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision), incl. any identified difficulties in applying the rules Stakeholders' perceptions on: - how the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision) are being applied in practice, incl. any difficulties identified in applying the rules	**Rating of the evidence: Low** Insufficient information available to assess whether there have been any problems with regard to the application of the professional rules for the health service providers (in the context of a temporary and occasional cross-border service provision), i.e. difficulties related to determining which rules apply or how to access the professional's liability insurance	Literature review Interviews with healthcare providers/ professionals
38. To what extent did the Directive contribute to activities on rare diseases in particular taking into account relevant legislation and the Orphanet database?	JC 38.1: The activities on rare diseases under the Directive are coherent with other relevant legislation (e.g. data protection in relation to the CPMS) JC 38.2: The activities on rare diseases under the Directive are coherent	Qualitative evidence of the Directive coherence with other EU policies and activities Stakeholders' perceptions on the extent to which activities on rare diseases under the Directive are coherent with other activities in the field such as the Orphanet database	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, and interviews) and stakeholders provides high confidence on the validity of results obtained	Literature review Interviews of national authorities, ERNs, researchers, industry

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
	with other activities in the field such as the Orphanet database			
39. To which extent does the Directive enhance and complement other existing European structures such as the Civil Protection Mechanism in line with its objectives?	JC 39.1: The Directive enhances and complements other existing European structures such as the Civil Protection Mechanism	Qualitative evidence on synergies/ complementarities between the objectives of the Directive and of other existing European structures such as the Civil Protection Mechanism	**Rating of the evidence: Low** Beyond discussion on the Social Security Coordination Regulations, stakeholders were less engaged with or aware of relevant existing structure impacting on and/or impacted by the Directive	Literature review Interviews national authorities (CBHC expert group), healthcare providers/ professionals
EU added value				
40. In what ways has the Directive provided added value in terms of patient rights in cross-border healthcare and patient choice of healthcare services in the EU compared to what could reasonably have been expected from the Member States acting in the absence of the Directive?	JC 40.1: The achievements of the Directive in terms of patient rights in cross-border healthcare and patient choice of healthcare services in the EU are additional to what could have occurred from the MS acting in the absence of the Directive	Quantitative and qualitative evidence on the achievements of the Directive collected for other EQs Stakeholders' perceptions on the benefit of support provided by the EU to patients with regard to CBHC	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Evidence collected in previous EQs Interviews with the European Commission's officials, national authorities (CBHC expert group), ERNs, healthcare providers/ professionals, healthcare insurers, patients, consumer organisations, researchers, industry Public consultation
41. How effective was the Directive in facilitating cooperation between Member States in cross-border healthcare at regional and local level since its entry into force?	JC 41.1: The Directive set the necessary provisions to facilitate cooperation between Member States in cross-border healthcare at regional and local level	Quantitative and qualitative evidence on extent of cooperation between MS in cross-border healthcare at regional and local level (collected for other EQs) Stakeholders' perceptions on ways in which the Directive has facilitated cooperation between MS at regional and local level (collected for other EQs)	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Evidence collected in previous EQs Interviews of the European Commission's officials, national authorities, healthcare providers/professionals, healthcare insurers, patients, consumer organisations, researchers, industry

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
42. In what ways the Directive (and therefore the ERNs established by the Directive) provide an added value for patients with rare and complex diseases compared to the national situation alone?	JC 42.1: The achievements of the Directive in terms of patients with rare and complex diseases are additional to what could have occurred from the MS acting in the absence of the Directive	Quantitative and qualitative evidence on the achievements of the Directive collected for other EQs, particularly in relation to rare and complex diseases Stakeholders' perceptions on the added value the ERNs have beyond national actions by MS	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained	Public consultation Evidence collected in previous EQs Interviews of the European Commission's officials, national authorities, healthcare providers/professionals, healthcare insurers, patients, consumer organisations, researchers, industry Public consultation
43. What would be the most likely consequences of repealing the Directive's provisions on patients' rights in cross-border healthcare?	JC 43.1: The Directive is unique/fundamental in setting out the rights for patients in cross-border healthcare JC 43.2: Effects of repealing the Directive	Quantitative and qualitative evidence of the achievements (and gaps, if any) of the Directive collected for other EQs Stakeholders' perceptions on the effects of repealing the Directive on patients' rights in cross-border healthcare	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	Evidence collected in previous EQs Interviews of the European Commission's officials, national authorities, healthcare providers/professionals, healthcare insurers, patients, consumer organisations, researchers, industry Public consultation

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS

		Citizens/Consumers/[156]		Businesses[157]		Administrations[158]		Others: ERNs	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Costs									
Administrative costs Reimbursement procedures and reimbursement costs	Recurrent		Reimbursement procedures to access care and prior authorisation perceived as impediments; no data available on administrative costs Cross-border reimbursements average processing time: 3 weeks to 6 months without prior authorisation; one to 6 months with prior authorisation[159]		*N.A.*	EU contribution over 5 years from CHAFEA/HADEA via the Third Health Programme; EUR 30.932.113,11 EU contribution over 3 years from Connecting Europe Facility EUR 12.003.969,00			

[156] Including patients.
[157] Including healthcare professionals and hospitals (public and private).
[158] Including national public authorities, insurance (public and private).
[159] 9 countries have not introduced prior authorisation. See Commission study "Enhancing the Implementation of the Directive 2011/24/EU, analytical report on "mapping administrative procedures", February 2022.

Compliance costs Cost of implementing necessary systems to administer cross-border healthcare and provide information to patients Implementation and operational costs of the ERNs	One-off & recurrent					Estimate cost of at least EUR 12.4 million in co-funding (2017-2020)	Compliance costs estimated to be minor by MS: most NCPs have between 1 and 3 FTE staff		
Compliance costs of the ERNs	Recurrent								
Enforcement costs	Recurrent		N.A.		N.A.		N.A.		
Benefits									

Direct benefits Estimated number of patients benefiting from healthcare abroad	Recurrent		329,589 patient mobility cases estimated across 30 countries Patients in particular profiting: patients living in border regions and patients with some specific condition Less than 1% of citizens on a waiting list benefit from faster treatments; no data available on the reduction of waiting times						
Estimated number of patients with rare diseases benefiting from ERNs			1.7 million patients treated by ERN members 2,100 virtual expert panels opened in the CPMS Patients participated to 732 clinical trials within the ERNs		Almost 1500 ERN members (hospital units) and more than 200 ERN affiliated partners across EU and Norway				

Indirect benefits Reduction of inequalities in access to healthcare	Recurrent		Social impacts of the Directive could not be determined quantitatively. Only anecdotal qualitative evidence is mixed						
Potential beneficiaries from ERNs	Recurrent		Potential future patients: Patients profiting from treatments tested in the 732 clinical trials						
Increased efficiencies in care pathways	Recurrent				Costs saved from avoiding misdiagnosis or inefficient treatment of rare disease patients thanks to ERNs		Costs saved from avoiding misdiagnosis or inefficient treatment of rare disease patients thanks to ERNs		
Research and knowledge generation, exchange of knowledge and best practice	Recurrent				Better understanding of diagnosis and of treatment options by healthcare professionals: ERNs results and activities presented at 1183 congresses/ conferences/ meetings; 583 educational activities				162 new clinical practice guidelines written by the ERN 143 Clinical Decision Making Tools developed by ERNs 732 clinical trials (before

					aimed at healthcare professionals organised by the ERN; 1,446 educational activities aimed at healthcare professionals delivered by the ERN coordination team or HCP members of the ERN				medicine/treatment is approved and on the market) conducted within the ERNs 405 observational prospective studies (once medicine/treatment is approved and on the market) conducted within the ERN

ANNEX V. STAKEHOLDERS CONSULTATION – SYNOPSIS REPORT

INTRODUCTION

This synopsis report provides an overview of the results of the consultation of stakeholders that was conducted as part of the study supporting the evaluation of the Directive 2011/24/EU. The report is structured as follows:

- Consultation strategy (Section 1);
- Consultation results (Section 2).

1. CONSULTATION STRATEGY

1.1. Overview of consultation activities

In line with the European Commission's stakeholder consultation strategy, the study entailed the following consultation activities:

- public consultation launched by DG SANTE in May 2021;
- in-depth interviews with stakeholders at EU and national level;
- targeted surveys, questionnaires and information requests to stakeholders;
- online survey of pharmacists conducted in the context of a case study on the recognition of medical prescriptions in four countries;
- presentations of study progress and preliminary findings to ERN coordinators group and the Cross-border Healthcare expert group; and
- virtual workshop with stakeholders, held on 9 November 2021.

The study engaged a total of **287 stakeholders** through these activities. Further details on the specific groups of stakeholders who provided data, views and experiences for the ex-post evaluation of the Directive are provided below.

The study then conducted a quantitative and qualitative analysis of data gathered through the different consultation activities. The quantitative analysis included a descriptive statistical analysis of the results of the public consultation and targeted surveys. Furthermore, all views provided in the interviews and the open questions of the public consultation were analysed using qualitative data analysis techniques. Where answers were provided in languages other than English, these were translated to English and integrated to the evidence base for coding and analysis.

The analysis of the evidence from consultation activities was conducted first at the level of individual data collection tools. Then, the contractor triangulated the data, and contrasted it with data coming from the literature review, to produce the answers to the study's evaluation questions and developing overarching conclusions and recommendations. These were presented in the study's (draft) final report.

1.2. Stakeholders consulted

Table "Stakeholders engaged per consultation activity" provides an overview of stakeholders consulted as part of the study. The breakdown of stakeholders evidences that the consultation aimed to collect different perspectives on the issues under assessment. A choice was made so that the most relevant consultation tool was selected for each stakeholder group and that the topics of the consultation reflected the profile, knowledge, experience, and interest of each group.

Stakeholders engaged per consultation activity

Consultation activity	Stakeholder group	Nr of stakeholders targeted	Nr of stakeholders responding	Level of engagement
Public consultation	Non-governmental organisations (NGOs); EU and non-EU citizens; public authorities; academic/research institutions; company and business organisations; business associations; consumer organisations; trade unions; other	N/A	193 responses and 21 position papers	Medium
Exploratory interviews	Commission DGs (SANTE and EMPL); EU-level representatives of health insurers and pharmacists; external contractors of previous studies on cross-border healthcare	8	8	High
Interviews or written contributions	EU-level representatives of healthcare providers/professionals; insurers; health industry; research and consumers	12	9	High
	National health authorities	11	9	High
	National-level healthcare providers/professionals	8	8	High
	Patients	12	12	High
	National-level health insurers	8	4	Low
	ERN representatives (coordinators and Board of Member States)	10	8	High
	ERN patient representatives	3	3	High
Targeted surveys,	Healthcare providers/ professionals	N/A	7	Low
	Patient ombudsmen	12	7	Medium
	Pharmacists (case study – dispensers' online survey)	250 (50 per study country)	72 (PL); 55 (FR); 26 (NL);	High in PL and FR;

Consultation activity	Stakeholder group	Nr of stakeholders targeted	Nr of stakeholders responding	Level of engagement
			4 (DE); 1 (DK)	Medium in NL; Low in DE and DK
	ERNs	N/A	64	Medium[160]
Virtual workshop	Stakeholders from all groups	117 (registered)	84	High
Feedback on the evaluation roadmap	NGOs; EU and non-EU citizens; business associations; company/business organisations; trade unions; public authorities; research institutions	N/A	63	Medium

1.3. Consultation challenges

Some challenges emerged during the consultation activities. 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. For instance, response rates from healthcare providers to a targeted questionnaire, from pharmacists in some countries to the dispensers' online survey, and from national health insurers invited to participate in interviews were particularly low. This was mainly due to some stakeholder fatigue (as several concurrent research activities were taking place at the time of the study) and unavailability because of the Covid-19 pandemic (many stakeholders of the health sector were occupied in the response to the pandemic and were less available).

- **Analysis of public consultation results**: The reasons mentioned above are likely to have affected responses to the Commission's public consultation also. 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.

[160] The evaluation team targeted all 24 ERNs and ask them to respond to a questionnaire in the most suitable way to them, either providing responses from coordinators or the wider ERN. Although the number of individual responses was high, the ERNs responding to the survey were seven; therefore, it was considered a medium-level of engagement.

- **Evidence provided by stakeholders**: Stakeholders were not always knowledgeable of the issues under evaluation and/or reported that no data was available on certain topics. As a result, the consultation activities produced limited evidence on some issues including: the functioning of the system of prior notification; cross-border cooperation in healthcare (incl. in diagnosis and treatment of rare diseases); 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.

The challenges emerging from the public and targeted consultations were addressed by discussing and validating the study findings with experts and stakeholders. For instance, the preliminary findings of the study were presented in different fora such as a virtual workshop with stakeholders organised by the study team, a meeting of the ERN coordinators group, and a meeting of the cross-border healthcare expert group. In these other consultations, stakeholders indicated that they agreed with most of the results, which they considered to be in line with their knowledge and views on the performance of the Directive.

2. CONSULTATION RESULTS

The results of the various stakeholder consultation activities are presented below per overarching question.

2.1. 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?

The first part of this question refers to the relevance of the Directive in relation to the needs of patients. According to stakeholders across all sectors, the Directive continued to be relevant to the cross-border healthcare needs of EU citizens, and in particular of patients with rare diseases. However, some needs remained unaddressed, which constituted barriers for traveling abroad for healthcare.

Stakeholders at EU and national level, including national authorities, healthcare providers, insurers, and patients, recognised that the Directive provided a clear common framework to guarantee patients' rights to cross-border healthcare. Moreover, for ERN representatives (including patient representatives), the objectives of the Directive corresponded to the current and future needs of patients with rare and complex diseases. Adding to this, over half of public consultation respondents who were aware of the possibility of getting reimbursed for healthcare costs incurred in another EU country under the existing EU schemes (i.e., the Directive and the rules on Social Security Coordination) believed that the EU schemes met patients' needs either completely (4%),

to a great extent (20%), or to some extent (33%). The perspective of the receivers of the healthcare services (citizens, patient organisations and NGOs representing specific groups[161]) was more negative though, than that of the organisers/providers/payers of the services: while 51% of the latter believed that patients' needs were met either completely or to a great extent, just 19% of the former agreed. Six in ten of these felt that needs were met either to some extent (36%) or to a limited extent (24%).

Stakeholders referred to some financial, mobility, language and specific needs of patients with rare diseases that remained unaddressed and that constituted barriers for traveling abroad for healthcare. Stakeholders across all sectors highlighted financial needs as a key barrier to being able to access healthcare abroad. For instance, 69% of public consultation respondents identified the need to pay upfront for treatment costs as the main barrier to cross-border healthcare. Stakeholders representing people with disabilities referred to the fact that the Directive contained no specific obligatory provisions to support the needs for those less able to travel (for example, elderly people) or people with disabilities. Language barriers were identified as one of the five biggest barriers to cross-border healthcare by 52% of respondents to the public consultation. In relation to patients with rare diseases, representatives of patients and workshop participants noted that there were delays in securing prior authorisation for these patients given that the doctors may not have the knowledge on rare conditions required to perform the clinical evaluation.

In terms of future needs, it is worth noting that six in ten public consultation respondents agreed that the Directive could help health systems tackle a possible backlog of postponed treatments arising from the pandemic, either completely (12%), to a great extent (28%) or to some extent (20%).

The second part of this overarching question looks at patients' awareness of their rights to cross-border healthcare. In the public consultation, the receivers of the healthcare services were significantly less positive about this than the organisers/providers/payers of the healthcare services. While just over a quarter of the receivers (27%) considered that they were informed completely or to a great extent about their rights to seek healthcare abroad, this was three quarters (74%) among the organisers/providers/payers of the healthcare services. Moreover, citizens were significantly less likely to know about the reimbursement possibilities under the two existing EU schemes (Directive and Social Security Coordination Regulations) than respondents representing organisations with an EU/international or national scope of work (65% said they were aware of this, while this was 97% and 85% in the other two groups). Most respondents (52%) also reported that patients did not receive information from their healthcare provider on treatment options in another EU country. From the patients and patient organisations consulted, there was evidence that many citizens did not know their rights and may either go abroad without

[161] Consumers, elderly, disabled, LGBTIQ, and socio-economically disadvantaged groups.

checking the procedures for reimbursement and amounts first with NCPs or their health insurance or not even apply for reimbursement after being treated abroad.

Key to patients' awareness of their rights are the NCPs; however, awareness of NCPs remained low among citizens, as revealed in the public consultation[162] and other targeted consultations. In the public consultation, the receivers of the healthcare services tended to be much more negative about the completeness, clarity and quality of the information provided by NCPs, and generally considered it more difficult to find information, than the organisers/providers/payers of the services. In general, patients, patients' representatives and organisations representing specific groups pointed to the need of enhancing completeness and accessibility of the information provided by NCPs, as well as the provision of information in a suitable format for people with disabilities and covering the LGBTIQ community. ERNs representatives and NCPs who participated in the workshop also noted the lack of readily available information on ERNs services targeted at patients with rare diseases and doctors treating these patients.

National authorities were more positive about the performance of NCPs though, indicating that NCPs had received an increasing number of queries and that in general patients recognised them as the agency responsible for cross-border healthcare in their country. National authorities also stressed that information provision on patients' rights by NCPs had improved significantly in the last years. However, other stakeholders, including patients/citizens, considered that information on aspects such as safety and quality standards, treatment prices and waiting times had not been provided systematically or in a comparable format across NCPs. In particular, healthcare providers noted that information on these aspects (and especially information on treatment costs) could not always be provided to patients given that in many Member States this was not even available at central level.

2.2. How effectively does the Directive operate in practice and what barriers remain to patients seeking cross-border healthcare?

The first part of this question refers to the practical implementation of the Directive. In the interviews and additional targeted consultations, stakeholders across all sectors agreed that the Directive had brought improvements for patients to make their preferred choice for treatment. They considered that the Directive had contributed to removing some obstacles to accessing healthcare in another Member State, including for patients with rare and complex diseases patients. For them, the clear legal framework had made an important contribution to facilitate access to cross-border healthcare. Also, the fact that patients did not need, for the most part, approval to receive care abroad or that they

[162] 69% of those responding to the public consultation as citizens said they were not aware of the NCPs, compared to 74% of people representing EU/international organisations who said they were aware.

were able to access private care were mentioned by most national authorities consulted as facilitators of cross-border healthcare.

In relation to the system of voluntary prior notification, which enables the patient to receive a written confirmation of the amount to be reimbursed based on an estimate, national authorities and health insurers from the Member States that have applied this system[163] considered the system to be positive as it reduced patients' uncertainty regarding reimbursement amounts. They noted that, although the system did not provide definite assurance of the cost for the patient, it provided certainty that the treatment abroad was covered by the national healthcare system and that an amount of the costs would be reimbursed, therefore reducing the financial risk for the patient. This was considered by stakeholders to be of great importance for patients.

Another aspect of the practical implementation of the Directive is the recognition of prescriptions across EU borders. For national authorities, the mutual recognition of prescriptions was an example of where the Directive had worked to decrease barriers. However, pharmacists and representatives of pharmacists also highlighted some persisting issues on this matter. They stated that in some Member States, rules on recognition of prescriptions had not yet been duly integrated into national legislation, and in countries where they had, pharmacists occasionally faced difficulties to ascertain the authenticity and validity of prescriptions issued by a prescriber in another Member State. Language was identified as another barrier accounting for non-dispensation. Adding to this, four in ten public consultation respondents (38%) said that they were aware of problems with pharmacists in another EU country not recognising prescriptions.

Last, in relation to the establishment of ERNs, representatives of ERNs, national authorities, representatives of patients with rare diseases, health professionals and, in general, stakeholders from the rare diseases sector agreed that the Directive, through the ERNs, had been effective in supporting the diagnosis and treatment of patients with rare and complex diseases. Moreover, in the ERNs targeted survey, 81% of respondents agreed that ERNs had effectively impacted research and knowledge sharing on rare and complex diseases among EU healthcare professionals. According to stakeholders, effective knowledge sharing was one of the areas where the objectives of the ERNs were being best achieved. ERNs had proceeded at different pace on this but most of them now had regular webinars, education sessions, seminars, etc. where they spread knowledge and had high attendance rates. Generally, stakeholders consulted indicated that the effectiveness of ERNs varied between ERNs and that many were still at an early stage of development.

[163] DK, EE, EL, IE, IT, PL, SE and NO.

The establishment of the virtual consultation panels through the Clinical Patient Management System (CPMS) was generally positively assessed by stakeholders and was highlighted as being increasingly used for the diagnosis and treatment of patients with rare diseases. As highlighted by representatives of ERNs, patient registries had an enormous potential in improving patients' care and were raising the interest of the pharmaceutical industry, as they allowed to create cohorts of patients necessary for research on new therapies. Several stakeholders also stressed that ERNs' patient registries were being developed in a much harmonised way to ensure their interoperability. Moreover, nearly six in ten respondents to the public consultation indicated that ERNs had helped to increase professional training, to at least some extent. Representatives of ERNs noted that this was particularly relevant for junior physicians interested in the treatment of rare diseases.

The second part of the questions refers to barriers which prevent patients from seeking healthcare abroad. Over half of public consultation respondents agreed that there were persisting barriers to patients seeking healthcare in another EU country, with 53% that either completely agreed or agreed to a great extent with this. For instance, stakeholders reported that there were gaps in relation to the availability of information for patients to make an informed choice on cross-border healthcare (as discussed in the previous question). Patients' representatives and health insurers mentioned that there was a persisting confusion of patients on how to access care under the Directive and the Social Security Coordination Regulations. Moreover, healthcare providers indicated that the most common areas where information was lacking were in relation to prior authorisation, treatment prices, and quality and safety standards.

Language barriers were also identified as one of the main barriers to cross-border healthcare by respondents to the public consultation. Patients, patient representatives, and health insurers reported that in some cases patients were required to provide certified translations of healthcare documentation in order for their healthcare systems to process their reimbursements (as discussed below). Workshop participants highlighted that certified translations of medical records were justified in many cases, as they had financial risks for the national healthcare systems providing the reimbursement, as well as clinical risks for the doctors that had to interpret the document. Certified translation therefore mitigated this risk.

Stakeholders across all sectors highlighted financial barriers as a key barrier to being able to access healthcare abroad. They referred to the need to pay upfront, as well as travel costs. Moreover, national authorities and representatives of healthcare providers at EU level highlighted the discrepancy in tariffs for medical services between countries, meaning that patients from countries with lower tariffs for services (primarily in Eastern Europe) would have to pay the difference from their own pocket if travelling to countries with higher tariffs.

Other barriers highlighted by public consultation respondents included: the difficulties in transferring medical records between systems; the lack of follow-up care in the home country; uncertainty about prices and reimbursements; difficulties in accessing public healthcare providers/treatment options abroad; the translation of medical documents and invoices required by health insurer; and difficulties in accessing healthcare and insufficient support for those with disabilities, including the lack of information on the accessibility of hospitals.

National authorities and health insurers also noted that patients generally preferred to receive care close to home and most were not eager to go abroad even if they could afford it. They agreed with other stakeholders that going abroad was difficult as there were language barriers, costs associated with travel, patients may not have relatives or friends to rely on while they are abroad, or they may not have a place to stay.

Last, national authorities, health providers and health insurers mentioned that patients may face challenges in continuity of care, often arising from differences between the healthcare system of the country of treatment and of affiliation. For example, one health insurer noted that difficulties could arise if a particular medical service required as part of the follow-up care was not available in the country of affiliation. One representative of health providers noted that continuity of care also raised issues of professional liability, as different healthcare professionals and systems are responsible for the treatment and the aftercare. Challenges could arise also from the application of standards of care between the two countries or if the patient comes back to his home country with a device that was not used there. In the public consultation, almost half of respondents (46%) reported that they were aware of administrative issues for patients receiving follow-up care at home. In a targeted questionnaire, healthcare providers said that they did provide follow-up treatments to patients who had been treated abroad and that they ensured continuity of care, but that there were still some challenges (as outlined above).

In relation to barriers pertaining to ERNs, representatives of ERNs mentioned that the virtual panels were quite burdensome regarding the amount of information that needed to be entered for each patient and that it took time to set up and use the CPMS. However, they also acknowledged that a simplification of the CPMS was already ongoing and the expectation was that it would increase its use considerably. They also noted that there was a weak integration of ERNs in the national health systems and a lack of care pathways of referring patients to the ERNs was not clear. In the absence of referral routes and considering a general lack of awareness among professionals outside the field of rare diseases on how to access the ERNs, the stakeholders consulted demanded increased teamwork between NCPs and ERNs in relation to provision of information to patients and practitioners. Another issue reported which was affecting the effectiveness of the ERNs was the fact that hospitals were not reimbursed for the time that their healthcare professionals spent treating foreign patients on virtual panels. Thus, when doctors allocated time to virtual consultations, they did it outside of their working hours and/or

take time away from their national patients. Last, in the public consultation, respondents referred to some additional barriers including the non-interoperable IT systems and administrative burden.

2.3. 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?

The first part of the question addresses the efficiency of the Directive. Stakeholders across all sectors generally agreed that the impact of the Directive on national health budgets arising from patients wishing to access cross-border healthcare was marginal. Some national authorities pointed out that there was a concern before the Directive's adoption that it would cause a large flow of financial resources to finance cross-border healthcare services. However, they considered that, in practice, the financial impact had been modest so far. No stakeholder reported that complying with the Directive created any excessive or disproportionate costs for public authorities and national insurance bodies or other health insurance providers.

National authorities and health insurers explained that the Directive states that patients have the right to be reimbursed for the care received abroad, up to the value of the same care in their home health system. For them, this provision of the Directive was key to limiting the costs arising from the Directive for Member States, particularly for Eastern European countries where tariffs were lower than in other parts of Europe. Moreover, they stressed that the burden or cost of applying the Directive was comparable to that of the Social Security Coordination Regulations, under which in most cases, Member States reimbursed each other for the entire cost incurred by the Member State of treatment.

Furthermore, stakeholders agreed that with the limited number of patients accessing cross-border healthcare via the Directive, the benefits of the Directive had also likely been modest across the Member States. National authorities and health insurers mentioned that the Directive could, in theory, contribute to greater efficiency in healthcare provision across the EU.

In terms of benefits, there was agreement across all stakeholder groups that patients with rare or complex diseases were a clear patient group benefiting from the Directive, given the improvements in the diagnosis and treatment of rare diseases made possible through the establishment of the ERNs.

Stakeholders of the rare diseases sector considered that the establishment of the ERNs had entailed a relatively small investment from the European Commission, compared to the size of the network and the number of healthcare providers that were involved. Representatives of ERNs indicated that they could finance most of the activities with the

existing funding; however, they also mentioned that more financial resources were needed to ensure the sustainability of the ERNs. ERNs representatives emphasised that the system relied on experts dedicating part of their working hours or overtime to work on ERN activities, without appropriate compensation mechanisms. They pointed to some "hidden costs" to the participation of experts, which are borne by their employers or by themselves.

For ERN representatives, there was considerable administrative burden coming from their participation in the networks. They mentioned that ERNs had been operating under different grants, which meant they had to deal with different applications, reporting obligations, and numerous deadlines. Moreover, they pointed to the significant time spent in inputting data into the CPMS and setting up the system for virtual consultations, which was not accounted for anywhere.

ERN representatives welcomed the announced changes to the grant system which they understood would entail a 100% of funding. There was agreement across stakeholders from the rare diseases field that integrating the ERNs to the national health system would help to increase sustainability, as well as professionalise the participation of experts in the ERNs.

ERNs representatives also considered there was room to improve the network's cost-effectiveness in the future. Some ERN tools, for example, the CPMS had still not shown the extent to which it can be a more cost-effective solution than the physical movement of patients to specialised centres. According to them, the ERNs had lot of potential to produce cost-savings in the future. Collaboration and virtual consultations could not only avoid transportation costs but could also help to minimise the risk of misdiagnosis, which in rare diseases was very high. On stakeholder provided an example: a misdiagnosed pediatric kidney cancer could cost up to EUR 2 million.

The second part of the questions refers to the administrative burdens for patients seeking healthcare abroad. According to stakeholders that replied to the public consultation, the Directive had contributed to some extent to removing obstacles to cross-border healthcare. Nevertheless, they also highlighted persisting administrative difficulties or burden, especially for patients, such as complex administrative procedures for prior authorisation and reimbursement. One stakeholder specifically noted that it could take up to 20 days for patients to receive acknowledgement from the administrative body dealing with reimbursement of receipt of the request, and even more time to process it. Other stakeholders representing healthcare providers and public authorities mentioned that often patients lacked the documents requested to be attached to their reimbursement requests and documents had to be retrieved from the healthcare provider in the treating country. In some cases, additional forms were required when the treatment exceeded certain costs (e.g., over EUR 200 for dental treatment). Patient representatives warned

that administrative burdens were a deterrent to patients and were more important than the quality and safety of the healthcare for the patient when deciding about receiving healthcare abroad.

Health insurers also pointed to persisting administrative burdens related to reimbursement claims stemming from the need to translate certain documentation, to review and process the submitted medical documentation, and to follow-up with patients who may not have all the documentation needed to process the reimbursement. The missing information may bring delays in processing the reimbursement request. Also, additional information or documentation required is sometimes difficult to obtain from healthcare providers due to privacy reasons. In some Member States, each cross-border healthcare claim required a case-by-case assessment by health insurers.

2.4. How does the Directive interact with other legislation, such as the Regulation on the coordination of social security systems?

A majority of stakeholders agreed that the Directive had brought improvements for patients to make their preferred choice for treatment. They viewed as generally positive that there is a legal framework for cross-border healthcare that includes both the Directive and the Social Security Coordination Regulations. However, they also pointed out that the two parallel EU schemes (in addition to national, bilateral, and multilateral schemes or agreements) create some confusion and it is difficult for patients to understand and providers/insurers to manage. Both patients and healthcare professionals often are unaware that different rules apply, for example for planned and unplanned healthcare, or if the care is provided by public or private providers. Moreover, some health insurers indicated that they work on a case-by-case basis, investigating which is the most appropriate or beneficial route for each individual patient seeking reimbursement of cross-border healthcare costs. Workshop participants agreed with this and emphasised that patients find the different pathways confusing. They were of the view that the responsibility for navigating these pathways should be of the healthcare authorities, rather than the patients, although patients still need information about their rights and entitlements to effectively engage with authorities' advice.

This was confirmed also in consultations of patients (and organisations representing patients). For instance, there were references to cases where patients had travelled abroad, paid up front, obtained partial reimbursement of costs and then learned that it could have been done through the Regulations with full reimbursement. Healthcare providers have also pointed out that the dual system is sometimes also confusing to them.

Adding to this, most respondents to the public consultation (81%) said they were aware of the possibility of getting healthcare costs incurred in another EU country reimbursed under the existing two EU schemes; among which 71% said that they were aware of problems resulting from them and referred to the administrative burden and slow authorisation and/or reimbursement procedures.

In the field of rare diseases, stakeholders of this sector were of the view that the activities on rare diseases under the Directive were coherent with other relevant legislation and policies and that there were no major incompatibilities. ERNs and Member States representatives, as well as researchers in the field of rare diseases, noted that ERNs were an appropriate tool that fit well with other initiatives such as the Orphanet database, the European Joint Programme on Rare Diseases, which, with support from the Commission and Member States, aimed at creating a rare diseases research eco-system in Europe and bring together researchers and practitioners. Specifically, on Orphanet, the synergies with the ERNs and the importance of their work, for example in the development of the ORPHAcodes were highlighted by stakeholders working in this field. This was also highlighted at the virtual online workshop where a participant explained the importance of adopting the ORPHAcodes as a building block for the description of rare diseases across Member States.

2.5. 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?

Stakeholders from all sectors generally agreed that the Directive had provided EU added value in cross-border healthcare by providing a framework in which to implement cross-border coordination mechanisms. They referred mainly to improvements in the provision of information to patients through the NCPs, cross-border recognition of prescriptions, mechanisms for reimbursement, and diagnosis and treatment options for patients with rare and complex diseases.

National authorities, health insurers, health providers and patient representatives saw the Directive as a very good instrument which reinforced patients' right to seek healthcare abroad. However, they were of the view that more needed to be done to realise its full potential in practice. Often as a result of low awareness among citizens and practitioners, some instruments or rights, such as NCPs or the recognition of prescriptions, were not being used as much as they could.

In relation to the EU added value of the ERNs, 85% of respondents to the ERNs targeted survey considered that the ERNs had effectively provided an added value for patients with rare diseases, compared to what could have been achieved at the national level alone. In the public consultation and interviews, stakeholders from all sectors also stressed the strong added value of the ERNs and the collaboration in rare diseases. They pointed out that through the ERNs network there was quicker access for patients to specialised advice. They also noted that the ERNs had offered EU added value by helping health professionals provide diagnosis and treatment options for patients with rare diseases, facilitating the exchange of knowledge and best practices among healthcare professionals, helping EU countries with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality, and helping to generate knowledge and contributing to research on rare diseases in the EU.

ERNs coordinators referred also to ERNs added value during the Covid-19 pandemic. They explained that thanks to the ERN structure, they were able to respond to questions from patients with rare diseases. Moreover, coordinators were able to work together and agree very quickly which patients should get priority for vaccination and for which patients vaccination would not be advisable. Without the ERNs this process would have taken much more time. Another benefit mentioned was that through the ERNs, health professionals could connect to and hold discussions with other areas outside of their expertise. To illustrate these contributions of ERNs, as well as areas for improvement, one stakeholder said: “ERNs are a diamond, but they still need to be cut and formed, to become more accessible for patients and professionals”.

ANNEX VI. EUROPEAN REFERENCE NETWORKS

Name	Description/Disease	Name	Description/Disease
Endo-ERN	European Reference Network on endocrine conditions	ERN EuroBloodNet	European Reference Network on haematological diseases
ERNICA	European Reference Network on inherited and congenital anomalies	ERN RITA	European Reference Network on immunodeficiency, autoinflammatory and autoimmune diseases
ERKNet	European Reference Network on kidney diseases	ERN eUROGEN	European Reference Network on urogenital diseases and conditions
ERN ITHACA	European Reference Network on congenital malformations and rare intellectual disability	ERN-RND	European Reference Network on neurological diseases
ERN BOND	European Reference Network on bone disorders	ERN EURO-NMD	European Reference Network on neuromuscular diseases
ERN LUNG	European Reference Network on respiratory diseases	ERN Skin	European Reference Network on skin disorders
ERN CRANIO	European Reference Network on craniofacial anomalies and ENT disorders	ERN EYE	European Reference Network on eye diseases
ERN PaedCan	European Reference Network on paediatric cancer (haemato-oncology)	ERN TRANSPLANT-CHILD	European Reference Network on transplantation in children
ERN EpiCARE	European Reference Network on epilepsies	ERN GENTURIS	European Reference Network on genetic tumour risk syndromes
ERN RARE-LIVER	European Reference Network on hepatological diseases	MetabERN	European Reference Network on hereditary metabolic disorders
ERN EURACAN	European Reference Network on adult cancers (solid tumours)	ERN GUARD-HEART	European Reference Network on diseases of the heart
ERN ReCONNET	European Reference Network on connective tissue and musculoskeletal diseases	VASCERN	European Reference Network on multisystemic vascular diseases

Source: https://ec.europa.eu/health/ern/networks_en

ANNEX VII. INFORMATION ON HEALTHCARE UNDER THE CBHC DIRECTIVE AND THE REGULATIONS ON THE COORDINATION OF SOCIAL SECURITY SYSTEMS

	Directive	Regulations
Type of healthcare provider	The Directive gives you the right to treatment by both public and private healthcare providers.	The Regulations give you the right to treatment by public healthcare providers only.
Payment for cross-border healthcare services	Under the Directive, you have to pay upfront for the healthcare services you use and you will be fully or partially reimbursed afterwards.	Under the Regulations, you are entitled to healthcare in another EU/EEA country (as well as in CH, and the UK) as if you were insured there: under the same conditions and at the same cost (free in some countries) as people insured in that country.
Reimbursement of costs for cross-border healthcare	You can claim the costs you had for healthcare services in another EU/EEA country from your health insurance institution. It will reimburse the costs up to the level that would have been paid in your country of residence (without exceeding the actual costs of healthcare received).	Costs of the benefits in kind are reimbursed under the conditions and reimbursement rates applicable in the Member State of treatment. In principle, the reimbursement procedure shall take place between the institutions of the countries involved. However, if the person has borne the cost of the treatment, s/he can request reimbursement either in the country of treatment or when returning home.
Price for healthcare	Private healthcare providers and, in certain cases, public healthcare providers are allowed to set their own prices or apply "private" prices for your healthcare as for a domestic patient. However, they cannot discriminate against patients from other EU/EEA countries.	The prices charged are the same as for persons covered by the social security system of the country where you received your treatment.

Prior authorisation	The general rule is that you do not need prior authorisation for cross-border healthcare. Your country of insurance may require prior authorisation for certain healthcare treatments and equipment. Many EU countries do, so it is important to check before going if your treatment is among treatments for which prior authorisation is necessary.	Prior authorisation is always required for reimbursement of planned healthcare. Prior authorisation for planned healthcare (PD S2) is granted by the health insurance company.