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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

{SWD(2022) 200 final}

Introduction

The general objective of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[1] ('the Directive') is to facilitate access to safe and high-quality healthcare in another Member State and to ensure patient mobility in accordance with the case law of the Court of Justice of the European Union ('the Court of Justice'). Member States remain responsible for the organisation and delivery of health services and medical care on their territory. Secondly, the Directive promotes cooperation on healthcare between Member States for the benefit of EU citizens, regarding prescriptions, rare diseases, eHealth, and health technology assessment. The Directive also aims at clarifying its relationship with the existing framework on the coordination of social security systems provided by Regulation (EC) No 883/2004[2] ('the Regulation') and applies without prejudice to this framework.

The Directive was due to be transposed by Member States by 25 October 2013. However, for most Member States, transposition was not completed until 2015. This is the Commission's third triennial report as required by Article 20(1) of the Directive[3]. It covers, in particular, information on patient flows, financial dimensions of patient mobility, the implementation of both Article 7(9) on Member State limitations on the rules of reimbursement and Article 8 on healthcare that may be subject to prior authorisation, and on the functioning of the European reference networks and national contact points.

This report takes into account assessments of the Directive by the European Parliament, the Council, the European Committee of the Regions and the European Court of Auditors, and Court of Justice case law interpreting certain provisions of the Directive. It takes the Fit For Future Platform opinion on patients' rights[4] into consideration.

A decade after the Directive's adoption in 2011, the Commission evaluated the Directive in 2021. This report includes a summary of its conclusions, a table of follow-up actions and a technical analysis in the attached staff working document.

1. Implementation

The Commission has systematically checked compliance of national transposition measures with the Directive's provisions, focusing on the four priority areas that have the greatest potential to act as barriers to patients if left unaddressed: systems of reimbursement, prior authorisation, administrative procedures, and charging of incoming patients. The Commission is continuing its structured dialogues with the Member States to achieve the best possible implementation of the

[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] 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).
[3] COM(2015) 421 final and COM(2018) 651 final.
[4] 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

Directive. This intensive work has led to changes in national legislation for the benefit of patients. However, as this report and the evaluation findings demonstrate, further efforts are necessary.

To support its assessment of the practical implementation of the Directive, the Commission carried out a study that, among other issues, mapped healthcare made subject to prior authorisation and the administrative requirements for cross-border healthcare in EU and EEA EFTA States[5].

1.1. Systems of reimbursement

Under Article 7(4) of the Directive, the 'costs of cross-border healthcare shall be reimbursed or paid […] up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual cost of the healthcare received.' Article 7(9) permits Member States to limit application of the rules on reimbursement of cross-border healthcare for overriding reasons of general interest. Under Article 7(11), such limitations must be 'necessary and proportionate, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services.' Furthermore, Member States are required to notify the Commission of any decision to apply limitations under Article 7(9).

The Commission has received no specific notifications under Article 7(9). However, certain transposition measures could be questioned as limiting the level of reimbursement for cross-border healthcare and undermining patients' rights. Concerning the reference point for reimbursement of cross-border healthcare costs under the Directive, three Member States[6], with varying conditions and to varying extent, use the lower reimbursement level applicable to healthcare received from private/non-contracted healthcare providers compared with the public healthcare system. As a result, the Commission initiated proceedings against those Member States for failing to fulfil obligations under the Directive[7].

1.2. Prior authorisation

Under Article 8, Member States may make the reimbursement of costs for healthcare received in another Member State subject to prior authorisation. In light of Court of Justice case law, such a requirement is a restriction to the free movement of services[8]. Therefore, as a rule, Member States should not make reimbursement of cross-border healthcare costs subject to prior authorisation[9]. However, Article 8(2)(a) allows Member States to use a system of prior authorisation for healthcare that is subject to planning requirements to ensure access to high-quality treatment or to control

[5] 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
[6] Netherlands, Austria, Finland.
[7] 2016 April infringements' package: key decisions, available here: https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_16_1452; 2019 January infringements' package: key decisions, available here: https://ec.europa.eu/commission/presscorner/detail/EN/MEMO_19_462
[8] Judgment of 23 September, *WO*, C-777/18, EU:C:2020:745, paragraph 58 and the case law cited therein.
[9] Recital 38 to the Directive.

costs, and if this healthcare: (1) involves overnight hospital stay for at least one night; or (2) requires use of highly specialised and cost-intensive medical infrastructure or equipment. Therefore, no prior authorisation could be required for a medical consultation in another Member State[10]. Under Article 8(7), Member States 'shall make publicly available which healthcare is subject to prior authorisation.'

The Court of Justice has clarified that applications for prior authorisation have to be assessed in line with the Charter of Fundamental Rights[11]. Therefore, a Member State may refuse to grant the patient an authorisation for medical treatment in another EU country, but only if such refusal is necessary and proportionate to the objective to be achieved, such as maintaining treatment capacity or medical competence[12]. Moreover, the Court of Justice has clarified that national legislation that excludes reimbursement without prior authorisation of 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[13].

Only seven Member States and one EEA EFTA State[14] have no prior authorisation system in place, thus giving patients the freedom to choose a healthcare provider abroad and reduces administrative burden.

All other countries have a prior authorisation system, primarily for the protection of their healthcare systems. The Directive's effect on the systems was uncertain at the time of transposition and the use of prior authorisation was a means to monitor this effect[15].

The Commission remains highly concerned that national systems of prior authorisation must meet the criteria of Article 8(2) of the Directive and comply with the principle of proportionality. As described in Section 3 below, patient mobility remains very low and its impact on national healthcare budgets marginal, which does not generally point to a need for extensive prior authorisation systems to protect healthcare planning. Two Member States therefore decided to remove prior authorisation[16].

Where prior authorisation is considered justified, patients have the right to know which treatments are subject to prior authorisation[17]. For this purpose, exhaustive and well-defined shortlists of treatments should be prepared and made publicly available, so that patients are able to identify easily the applicable rules. However, the lists of healthcare subject to prior authorisation differ significantly across Member States in the extent to which healthcare is specified.

The evaluation findings confirm that extensive use of prior authorisation and the lack of transparency over its application is a major barrier to cross-border healthcare, hampering the Directive's effectiveness for the benefit of patients.

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[10] Judgment cited in footnote 8, paragraph 79.
[11] Judgment of 29 October 2020, *A*, C-243/19, EU:C:2020:872, paragraph 83.
[12] *Ibid*, paragraph 85.
[13] Judgment cited in footnote 8, paragraph 85.
[14] Cyprus, Czechia, Estonia, Finland, Latvia, Lithuania, Sweden and Norway. The Netherlands has not introduced a prior authorisation system in its national legislation, but where persons insured under its social security system have access to cross-border healthcare, prior authorisation seems to be required by the health insurers.
[15] See the study referred to in footnote 5.
[16] Cyprus and Latvia.
[17] Guiding principles for information provision on prior authorisation systems across Member States, available here: https://ec.europa.eu/health/system/files/2022-02/crossborder_enhancing-implementation_info-provision_en.pdf

The Commission therefore urges Member States to assess whether, 10 years after the adoption of the Directive, prior authorisation remains justified for the purposes of the Directive, and whether their lists of healthcare subject to prior authorisation could be reduced, not least to ensure legal certainty for patients and transparency of the prior authorisation systems.

1.3. Administrative procedures

Under Article 7(7), the Member State may impose, on a patient seeking reimbursement of costs of cross-border healthcare, the same conditions, eligibility criteria and regulatory and administrative formalities as it would impose if this healthcare were provided in its territory. However, no conditions, criteria or formalities can be discriminatory or constitute an obstacle to the free movement of patients, unless they are justified by planning requirements.

Likewise, Article 9(1) requires Member States to ensure that administrative procedures for the use of cross-border healthcare are based on objective, non-discriminatory criteria that are necessary and proportionate to the objective to be achieved.

Following these principles, the Commission urges Member States to assess whether the procedures for prior authorisation and reimbursement of cross-border healthcare costs could be made less burdensome for patients, for them to fully benefit from the Directive's rights.

Evidence gathered for the evaluation confirms that cumbersome and disproportionate administrative procedures undermine citizens' rights to cross-border healthcare in some Member States. Particular attention should be given to ensuring that patients are only required to submit information they can easily access, and which is strictly necessary for handling prior authorisation or reimbursement requests in line with the Directive. Patients should not be required by health insurers to provide the estimated cost of expected healthcare nor a doctor's assessment of the effectiveness of the treatment received. Moreover, Member States should avoid requesting information from patients that is normally held by the health insurance body assessing the request, such as waiting times for a particular treatment. Neither should the patient be responsible for proving that there is no reason on which prior authorisation may be refused, for example, to provide evidence that the healthcare provider abroad does not raise serious, specific concerns as regards quality of care and patient safety.

Finally, in assessing the proportionality of the administrative requirements, Member States should take into account the costs associated with submitting requests for cross-border healthcare. In particular, the requirement for patients to provide a certified translation of the documentation may represent a disproportionate obstacle to free movement of services[18].

1.4. Fees for patients from other Member States

Article 4(3) requires Member States to observe the principle of non-discrimination with regard to patients from other EU countries. It also notes that, under certain circumstances, Member States

[18] See the study referred to in footnote 5.

may adopt measures on access to treatment. However, such measures must be justified, proportionate and necessary and they must be publicly available in advance[19].

Member States may set fees for the delivery of healthcare in their territory. However, under Article 4(4), they have to ensure that healthcare providers apply the same scale of fees to patients from other EU countries as they do for domestic patients in a comparable medical situation. If there is no comparable price for domestic patients[20], Article 4(4) obliges providers to charge a price calculated according to objective, non-discriminatory criteria. These requirements, however, are without prejudice to national legislation that allows healthcare providers to set their own prices, so long as they do not discriminate against patients from other EU countries.

During the conformity check, the Commission did not identify that healthcare providers are setting, or are allowed to set, discriminatory prices for patients from other Member States, which would contradict the above principles. However, the Fit for Future Platform[21] notes the findings of the European Committee of the Regions report[22] that a scale of medical fees charged on patients is not readily available in all Member States. Its opinion therefore calls for improving information on applicable fees for treatments in Member States.

2. Reports by other EU institutions and bodies

The **European Parliament** analysed shortcomings in the implementation of the Directive and concluded[23] that action is needed, for example, to simplify administrative procedures and to improve information provided by national contact points (NCPs) set up specifically for the purpose.

The **European Court of Auditors** concluded[24] that the Commission had monitored the transposition of the Directive into national law and its implementation by the Member States well. While EU actions improved cooperation between Member States, the impact on patients was rather limited at the time of the audit. Its recommendations call for greater support for NCPs, the deployment of cross-border exchanges of health data, and strengthening EU actions in the field of rare diseases and the European reference networks. The Commission continues to follow up on these recommendations.

[19] As part of their annual reporting under Article 20 of the Directive, Denmark, Estonia, Romania, Iceland and UK (England and Wales) indicated having put in place such measures.
[20] This might be the case where public/contracted healthcare providers in a Member State providing healthcare to insured persons under the benefits-in-kind system cannot act in private capacity.
[21] See the opinion referred to in footnote 4.
[22] 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
[23] European Parliament Resolution on the implementation of the Cross-Border Healthcare Directive, 2018/2108(INI), 12.2.2019.
[24] ECA Special Report 7/2019 *EU actions for cross-border healthcare: significant ambitions but improved management required*, 4.6.2019.

The **Council's** conclusions[25] echoed the Court of Auditors report and encouraged the Commission to support NCPs to improve the information provided to patients about their rights to cross-border healthcare, including information on the European reference networks.

The **European Committee of the Regions** supported[26] the use of prior authorisation where necessary to protect health systems, and promoted the use of prior notification to provide patients with clarity on their healthcare costs and to support authorities in complying with their obligations under the Directive.

3. Data on patient mobility

Under Article 20 of the Directive, Member States are asked to contribute to Commission reports on patient mobility by providing information on NCPs, limitations for patient flows, healthcare with or without prior authorisation, requests for information about healthcare, reimbursements made and reasons for which healthcare was reimbursed or not.

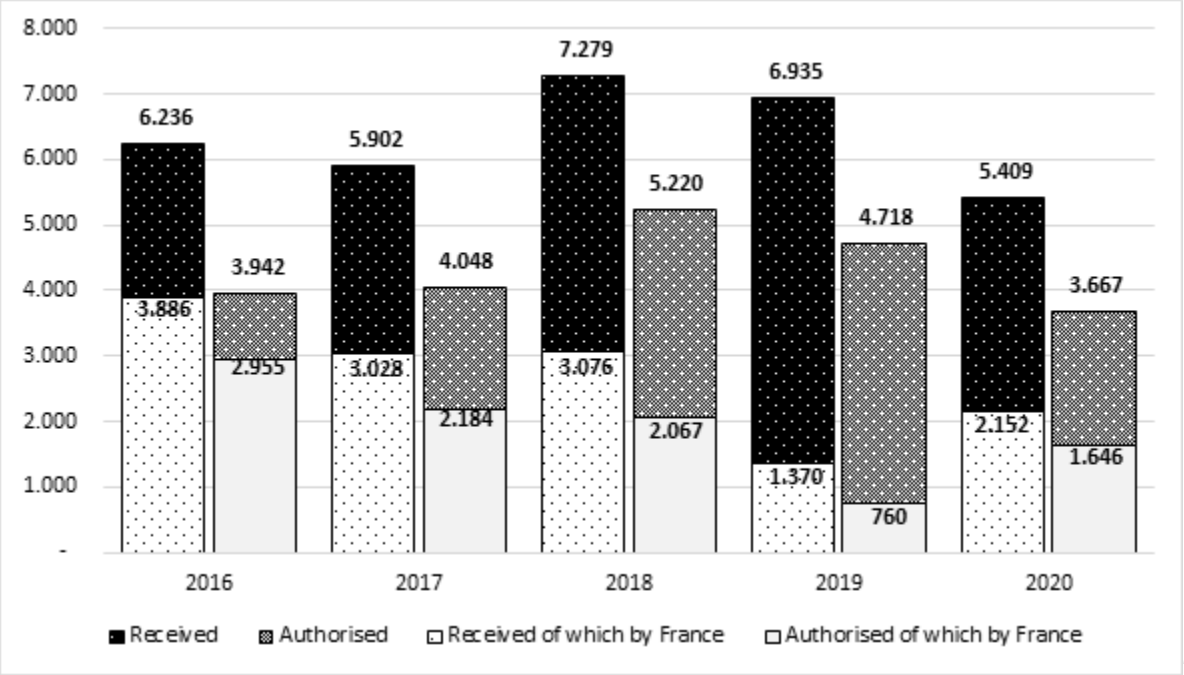
This report gives a high-level overview of the data received for the three-year period 2018-2020 and includes data for 2016 and 2017 for comparison purposes. The number of Member States[27] and EEA EFTA States that provided data are not the same for each reference year. In addition, many countries have been able to provide only limited information. Nor was it possible in some countries to separate data for cross-border healthcare under the Directive and the Regulation from other parallel schemes[28].

3.1. Patient mobility numbers

The aggregated reported data, on the number of requests for prior authorisation and for reimbursement requests without prior authorisation, show that patient mobility under the Directive remains very low, with a significant drop in 2020 due to the COVID-19 pandemic and restrictions on free movement (see Figure 1 for healthcare subject to prior authorisation).

[25] Council conclusions in response to the ECA Special Report 7/2019, 12913/19 FIN, 23.10.2019.
[26] ECR Opinion *Implementation and future perspectives for cross-border healthcare*, CDR 4597/2019, 14.10.2020.
[27] As the Directive still applied to the UK during the transition period until 31 December 2020, this report includes UK data.
[28] This is especially the case for France, which reports relatively high numbers of patient mobility. In light of this, the numbers for France are highlighted specifically in Figures 1 and 2.

Figure 1 Number of prior authorisation requests received and granted for all countries that provided data, 2016-2020



The totals for prior authorisations, excluding the UK, are as follows: in reference year **2016**, 6 009 requests received and 3 822 granted; in **2017**, 5 471 requests received, 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.

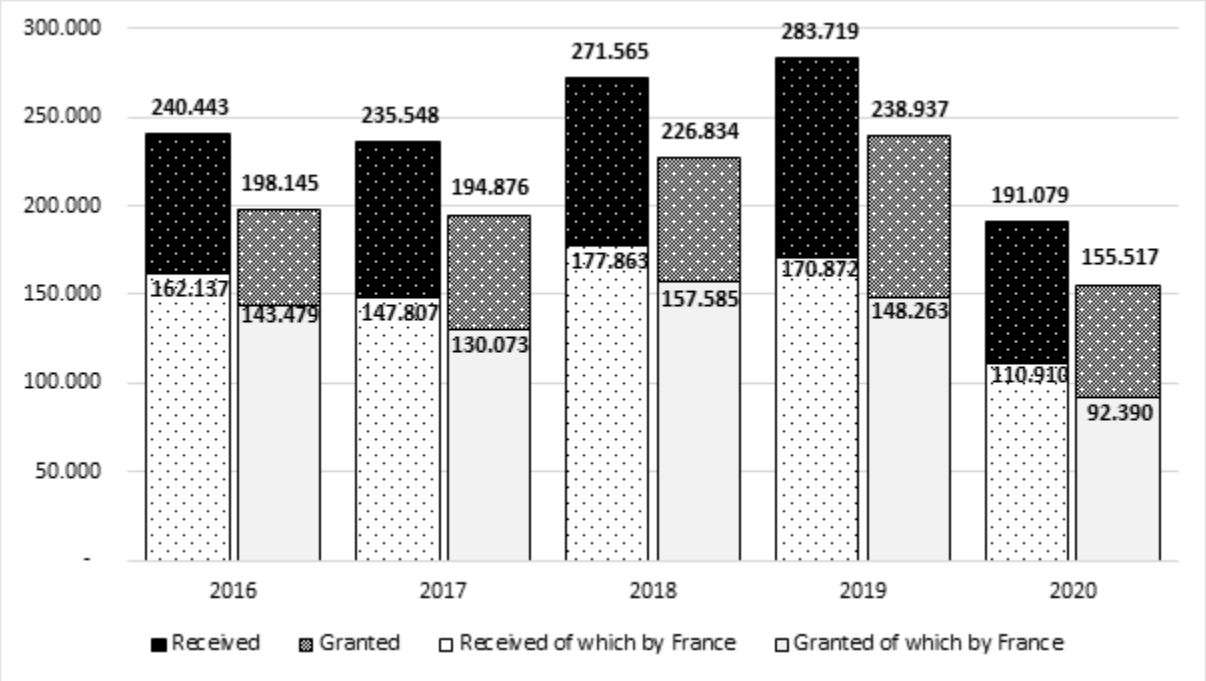
Source Questionnaires on Directive 2011/24/EU reporting on patient mobility

In the countries that provided data for all reference years 2016-2020[29], the number of prior authorisation requests received and granted peaked in 2018. There was an increase in the number of requests received during this period, notably in Ireland, Luxembourg and Slovakia. However, for most countries, the number of requests received and granted has declined over the years. This was especially the case in Belgium, Bulgaria, Italy and Poland.

The number of reimbursement requests without prior authorisation is notably higher than the number of prior authorisation requests (Figure 2).

[29] This concerns 15 Member States and the UK.

Figure 2 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 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

In those countries that provided data for all reference years 2016-2020[30], the number of requests for reimbursement received and granted also peaked in 2018 before declining in 2019 and 2020. In most of these countries, there was a decrease in patient mobility in the period of 2016-2020. However, some countries, notably Czechia, Ireland, Slovakia and the UK, saw an increase in the number of requests for reimbursement received.

3.2. Financial implications of patient mobility

In 2018-2020, the total reimbursed amount reported was EUR 243 million (EUR 73.4 million in 2018, EUR 92.1 million in 2019 and EUR 77.5 million in 2020[31]).

In those countries that were able to provide data in all relevant reference years for healthcare with and without prior authorisation[32], the total reimbursed amounts increased every year from 2016 to 2019, followed by a significant drop in 2020.

[30] This concerns 17 Member States, the UK and Norway.
[31] The totals excluding the UK amounted to EUR 65.7 million in 2018, EUR 82.3 million in 2019 and EUR 74.9 million in 2020.
[32] This concerns 17 Member States, the UK and Norway.

In 2019[33], for the EU-28 Member States, of the total government expenditure of EUR 7.5 trillion, around EUR 1.2 trillion went to health. In those countries that were able to provide information on the overall amount reimbursed for healthcare with and without prior authorisation in 2019, the total healthcare spending amounted to EUR 882 billion. Therefore, the share of the amount reimbursed under the Directive of total government expenditure on healthcare amounted to 0.01% (= EUR 92.1 million/EUR 882 billion).

Cross-border healthcare in general remains very limited[34] and the impact on national healthcare budgets arising from patients wishing to access cross-border healthcare under the Directive appears marginal. This is true for all countries, no matter whether they set up a prior authorisation system or not.

3.3. Direction of patient mobility

Looking at flows of patients, the patterns have not changed significantly over the period 2018-2020. Most patient mobility is still primarily taking place between neighbouring countries. This would suggest that patients prefer to receive healthcare near their home where possible, and that if they do choose to travel, they prefer to travel to a neighbouring country. A similar conclusion was reached on cross-border healthcare under the Regulation[35].

The highest flows of patients travelling abroad after receiving prior authorisation from their health insurer was from Ireland to the UK, France to Germany, and France to Spain in 2018, from Ireland to the UK, the UK to Ireland, and Luxembourg to Germany in 2019 and, in 2020, from Ireland to the UK, France to Spain, and France to Germany.

The highest flows of patients seeking healthcare without prior authorisation were from France to Portugal, Belgium and Spain. The next highest flows go from Denmark to Germany, Poland to Czechia, Sweden and Norway to Spain. The latter two flows illustrate a visible trend of patients from Nordic states using cross-border healthcare services in Spain.

It is interesting to note that some countries authorise more than 90% of requests for prior authorisation for treatment in a specific country, e.g. Ireland for treatment in the UK, Slovakia for treatment in Czechia, Bulgaria for France, and Austria for Germany. Similarly, for healthcare not subject to prior authorisation, a high share of reimbursement requests relates to one specific country of treatment, e.g. in Ireland for treatment in the UK, in Poland for treatment in Czechia, and in Finland for treatment in Estonia.

4. Information to patients

[33] Eurostat [GOV_10A_EXP]. Although data for 2020 is already available at the time of publication of this report, it does not include the UK data.
[34] Cross-border healthcare under the Regulation amounted to roughly 0.3%-0.4% of total healthcare spending in 2019 and 2020 (Cross-border healthcare in the EU under social security coordination – Reference year 2019 and Reference year 2020, available here: https://ec.europa.eu/social/BlobServlet?docId=23780&langId=en and 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).
[35] *Ibid*.

National contact points (NCPs) play an essential role in enabling patients to make use of their rights to cross-border healthcare under the Directive and the Regulation. As the evaluation showed, people often struggle where to find information and to understand the rules that apply. While there has been gradual improvement in information to patients, major gaps remain in terms of the availability, completeness and clarity of information and in terms of accessibility for people with disabilities. In addition, information on the European reference networks (ERNs) and rare diseases is only provided by 14 NCPs. The evaluation revealed this as a key concern for patient organisations, and for the European Disability Forum.

To address this, and in cooperation with Member States, in 2018, the Commission produced Guiding Principles for the practice of NCPs[36]. These are designed to assist NCPs in their daily task of providing clear, accurate and high-quality information on the main aspects of cross-border healthcare. Most importantly, the information must always be patient-oriented. The evaluation found that NCP websites are not always digitally accessible to patients with disabilities, as required under the Web Accessibility Directive[37], and that only 30% of websites provide information on the physical accessibility of healthcare facilities[38]. Under the principle of inclusion, NCPs are invited to recognise and support the right of people with disabilities to have equal access to information to healthcare in other EU countries, as required under Article 6(5) of the Directive.

In 2021, Member States approved additional Guiding principles for information provision on prior authorisation systems[39]. This is intended, among other things, to guarantee that patients are provided with clear and complete information about their rights to cross-border healthcare subject to prior authorisation.

The Commission's multilingual Toolbox for Cross-Border Healthcare[40], which includes a Manual for Patients, aims to help patients navigate the different pathways to cross-border healthcare. Most NCPs have posted the Manual for Patients on their websites and others are encouraged to do so. The EU's Single Digital Gateway can help people seeking medical assistance to connect with NCPs through the Your Europe Portal[41].

5. Cooperation between health systems

5.1. Recognition of prescriptions

Under Article 11(1) of the Directive, Member States, under certain conditions, must make sure that prescriptions for medicinal products or medical devices issued in another Member State for a named

[36] https://ec.europa.eu/health/system/files/2019-12/2019_ncptoolbox_ncp_guiding_principles_crossborder_en_0.pdf
[37] Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).
[38] European Disability Forum (2021), *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.
[39] Referred to in footnote 17.
[40] https://ec.europa.eu/health/cross-border-healthcare/toolbox-cross-border-healthcare_en
[41] https://europa.eu/youreurope/index_en.htm

patient can be dispensed on their territory. Implementing Directive 2012/52/EU[42] gives effect to the principle of mutual recognition of prescriptions. The Court of Justice has clarified that the Directive (2011/24/EU) does not require a pharmacist to recognise order forms issued by a health professional in another Member State that do not contain the name of the patient concerned[43].

The evaluation found that, while the recognition of prescriptions has considerably improved, patients continue to experience issues in relation to the recognition of prescription in another EU country, mainly due to problems with verification of authenticity and language.

5.2. European reference networks

The ERNs[44] are virtual, voluntary cross-border networks, bringing together highly specialised healthcare providers across Europe to help diagnose and treat patients suffering from rare or low prevalence complex diseases that require highly specialised healthcare and a concentration of knowledge and resources. They act as key focal points for knowledge generation and dissemination, health professional training, and education and research in the area of rare or low prevalence complex diseases.

Launched in 2017, 24 ERNs are now working on a wide range of thematic issues including rare cancers. They have expanded significantly since then, reinforcing the EU's capacity to provide the best expertise and life-saving knowledge for patients with rare and low prevalence complex diseases. As of 1 January 2022, 620 new members joined the network bringing the total number of ERN members to 1 466 and extending its geographical coverage to all 27 Member States and Norway. By the end of 2020, ERNs also included 289 affiliated partners (228 associated national centres plus 61 centres belonging to 4 national coordination hubs). The four rare-cancer ERNs will play an important role in Europe's Beating Cancer Plan[45] and the EU Mission on Cancer[46] linking into the future Network of National Comprehensive Cancer Centres.

In November 2017, the Commission-funded Clinical Patient Management System[47] became operational. This dedicated IT platform supports the virtual expert panels of ERN health professionals, from different centres of expertise across the EU, who convene to share their expertise for the diagnosis and treatment of patients with rare and low prevalence complex disease. By June 2021, almost 2 000 expert panels had been opened, with the number growing steadily. The Commission is working on an improved version of the system to enhance its functioning.

To facilitate the exchange of information on rare disease patients and to support the ERNs to collect and share information, the Commission also set up the European Platform on Rare Disease Registration (EU RD Platform)[48] in 2019.

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[42] 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).
[43] Judgment of 18 September 2019, *VIPA*, C-222/18, EU:C:2019:751, paragraph 47.
[44] https://ec.europa.eu/health/european-reference-networks/networks_en
[45] https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/cancer-plan-europe_en
[46] https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/cancer_en
[47] https://cpms.ern-net.eu/login/
[48] https://eu-rd-platform.jrc.ec.europa.eu/_en

The Commission provided the ERNs with considerable support through the EU's Third Health Programme and, since 2021, the EU4Health programme. These include a wide range of activities, such as the development of ERN clinical practice guidelines and clinical decision support tools, the development and maintenance of ERN patient registries to facilitate the provision of care, a short-term mobility and exchange programme for ERN health professionals, and the assessment, monitoring and evaluation of the ERNs[49]. The ERN clinical research activities are co-financed under the EU's research and innovation programmes. With funding from Horizon 2020, the ERNs are major beneficiaries of the European Joint Programme on Rare Diseases[50] and of the ERICA[51] project, which will create a platform that integrates all ERN research and innovation capacity improving access to therapies.

5.3. eHealth

The eHealth Network, set up under Article 14 of the Directive, is a voluntary network composed of national authorities responsible for eHealth. It works towards interoperable applications and enhanced continuity of, and access to, care.

The Commission adopted a legislative proposal on the European Health Data Space[52], drawing on a separate evaluation of Article 14. The evaluation concludes that the effectiveness and efficiency of the eHealth Network has been limited, mainly due to the voluntary nature of the collaboration. Since 2018, its activities focused on increasing the use and exchange of health data for the provision and continuity of care and setting up the MyHealth@EU infrastructure. The number of Member States connected to MyHealth@EU is expanding and most Member States are expected to implement MyHealth@EU platform by 2025. So far, ten Member States are connected through national contact points for eHealth and have started to exchange patient summaries and ePrescriptions to ensure continuity of care for cross-border patients. Support for additional data contents is being added to the MyHealth@EU infrastructure, including laboratory test results, hospital discharge reports and medical images.

Following the outbreak of the COVID-19 pandemic in 2020, the eHealth Network gave priority to the public health crisis. It helped to quickly develop and implement two important initiatives to protect public health and ensure the free movement of people: the interoperability at EU level of contact tracing and warning apps, and the EU Digital COVID Certificate[53].

5.4. Health technology assessment

[49] https://www.nivel.nl/en/project-amequis-2020-ongoing
[50] https://www.ejprarediseases.org/
[51] https://erica-rd.eu/
[52] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, COM (2022) 197 final.
[53] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 1).
On 18 October 2021, the Commission published the first report on the implementation of the EU Digital COVID Certificate system COM(2021) 649 final.

Article 15 provided a legal basis for promoting European cooperation in health technology assessment (HTA), an important part of evidence-based decision-making on health. On 31 January 2018, the Commission adopted a proposal for a Regulation on HTA aimed at strengthening and making sustainable European cooperation in this area[54]. The new Regulation was adopted on 15 December 2021 and entered into force on 12 January 2022[55]. It deleted Article 15 of the Directive. In parallel with the negotiation on the Commission's proposal, the HTA network activities continued and were complemented by the technical work of the EUnetHTA Joint Action 3[56]. At the onset of the COVID-19 pandemic in 2020, the EUnetHTA Joint Action 3 developed and published its 'rolling collaborative reviews' for several pharmaceutical and non-pharmaceutical therapies for COVID-19.

5.5. Cross-border and regional cooperation

The Directive requires Member States to provide mutual assistance and to facilitate cooperation in cross-border healthcare between neighbouring countries and that the Commission should encourage Member States in this cooperation.

The EU supports cooperation and integration of health systems in border regions through its Interreg programme. This acted as a catalyst for a number of regional partnerships in healthcare to improve local access to care as well as joint facilities and services. However, complex invoicing and reimbursement procedures for healthcare services across different health systems remain a problem. This can significantly affect the well-being of people living in border regions where over 40% of the EU population resides. The evaluation found some evidence that the Directive provides an additional instrument to facilitate healthcare in border regions as prior authorisation for cross-border healthcare is not necessary for routine outpatient treatments. The Association of European Border Regions concluded that the reimbursement mechanism under the Directive is usually not the preferred option, as the upfront payment of costs for cross-border healthcare acts as a disincentive[57].

Several regional agreements in healthcare offer models of cooperation to overcome financial and administrative barriers[58]. A user-friendly manual for patients[59] developed by the Upper Rhine region serves as a model of good practice in cooperation between NCPs and health insurers to provide clear information to meet the specific needs of the patient.

The COVID-19 pandemic has raised the importance of cross-border regional cooperation. Several EU regions played a vital role during the COVID-19 crisis by providing over 300 intensive care places and treatment to relieve over-burdened hospitals across the border. The Commission's Guidelines on EU Emergency Assistance in Cross-border Cooperation in Healthcare put in place an EU-wide coordination mechanism and drew attention to patients' rights to reimbursement, the transfer of medical records, the continuity of care, and the recognition of prescriptions when receiving healthcare abroad. The evaluation found that the Directive could help to reduce the huge

[54] COM(2018)51 final.
[55] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (OJ L 458, 22.12.2021, p. 1).
[56] https://www.eunethta.eu/
[57] 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
[58] C(2020) 2153 final.
[59] https://www.trisan.org/fr/outils/guide-de-mobilite-des-patients

backlog of postponed routine non-urgent treatment arising from the COVID-19 pandemic when spare healthcare capacity may exist across the border.

6. Evaluation findings

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 brought additional legal clarity on the rights of patients to use healthcare services anywhere in the EU and it remains relevant for safeguarding the free movement of healthcare services as interpreted by the Court of Justice.

The evaluation has shown that the Directive has enshrined important 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; however, some problems with the language, verification and authenticity of prescriptions persist.

The Directive's potential for improving access to cross-border healthcare continues to be hampered by some issues. These include, in particular: the low level of awareness over patients' rights to cross-border healthcare; inadequate patient information; disproportionate administrative burdens; and uncertainty over healthcare costs abroad and reimbursement. Patient organisations, in particular, criticise the requirement for patients to pay upfront for treatment abroad, arguing this creates inequalities in access to healthcare. However, under the Directive, patients have to pay costs upfront as it is the only viable way to empower the patient to choose public or private healthcare in another EU country without prior approval, while also giving the patient the right to reimbursement of costs, up to a certain level, by their health insurer. It provides the patient with an additional option to cross-border healthcare over and above the rules on coordination of social security systems.

The complex legal relationship between the Directive and the Regulation is difficult for the general public to understand, and for NCPs and health insurers to communicate to patients. At the same time, the responsibility for choosing the route that is more beneficial is often left to patients, with uncertain financial implications. This raises doubts as to whether clarity between the Directive and the Regulation has been achieved for the benefit of patients.

The Directive has had a substantial impact in the area of rare diseases with the creation of the ERNs to support the diagnosis and treatment of rare disease patients. The ERNs facilitate knowledge generation and sharing, and support clinical research. However, to ensure their long-term sustainability, further improvements are necessary to integrate the ERNs in national health systems and to create clear pathways for patients to access the ERNs at national level. In addition, the Clinical Patient Management System supporting the virtual medical expert panels requires further technical development and the absence of a separate invoicing and reimbursement mechanism for

ERN healthcare providers participating in the virtual expert panels is an obstacle for their greater use. The EU funding streams for ERNs support were also administratively complex.

The Commission has effectively encouraged cross-border regional cooperation in healthcare with the support of the Interreg programme. While the Directive is used to complement other mechanisms for cross-border healthcare, there is limited data on its impact on patient mobility in border regions. Stakeholders saw a potential role for the Directive as a mechanism to address the growing backlogs of routine treatments.

While outside the scope of this evaluation, the Directive has 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 creation of a future European Health Data Space.

Overall, the evaluation has found that, while cross-border patient mobility remains low, the Directive has provided added-value and its objectives remain relevant to meet patient needs to access healthcare in another Member State. The Directive has been particularly successful at encouraging cooperation between health systems, particularly in the areas of rare diseases, eHealth, and health technology assessment.

However, the problems raised in the evaluation mean that the Directive's objectives are not yet being fully realised for the benefit of patients.

Conclusions and way forward

Maximising the potential of the Directive and strengthening cooperation between Member States in cross-border healthcare will be a further step in building the European Health Union.

This report and the evaluation outcomes show that important issues persist with regard to the **consistent application of the Directive in Member States**. New information gathered by the Commission requires investigation into the compliance of national measures with the Directive's provisions and its principles of proportionality and legal certainty. The Commission thus invites Member States to reassess the necessity and proportionality of national measures limiting patients' access to cross-border healthcare and causing unnecessary administrative burdens.

The Commission will continue its bilateral exchanges with Member States to ensure implementation of the Directive and, where necessary, will do all it can to ensure Member States comply with their obligations.

Moreover, the COVID-19 pandemic highlighted the importance of quality data in the effective functioning of health systems. The Commission urges the Member States to meet their legal commitment under the Directive for the provision of **data on patient mobility** necessary to monitor the implementation of patients' rights and to provide the necessary evidence to inform future policies on cross-border healthcare.

Drawing on the lessons learnt from the evaluation, **European cooperation could further support the implementation of the Directive in a number of ways**. This report sets out actions to reduce and simplify procedures through the digitalisation of healthcare, to raise awareness on patients' rights and improve information to patients, to clarify the interplay between the Directive and the

Regulation, to safeguard the sustainability of the ERNs, to further support cross-border cooperation between regions and to strengthen monitoring and enforcement of the Directive[60].

The use of digital technologies in healthcare accelerated in response to the COVID-19 pandemic. The **application of new digital tools for cross-border healthcare** – such as the digitalisation of invoices, prior authorisation and reimbursement requests – could simplify and reduce administrative burdens, making access to cross-border healthcare easier and less costly. The take-up of digital solutions will require actions at regional, national and EU level.

Building on European cooperation in eHealth, the Commission adopted a proposal for a Regulation on the **European Health Data Space**, which is expected to scale up the eHealth digital service infrastructure. This will help ensure continuity of care for EU citizens while travelling abroad. The gradual introduction of ePrescription services in Member States allows EU citizens to obtain their medication abroad more easily.

While the Directive was successful in enshrining patients' rights, for those rights to be fully enjoyed they need to be known by patients. Despite improvements by NCPs, more efforts are necessary to **enhance the user-friendliness and accessibility of information for patients including for people with disabilities.** The Commission's Manual for Patients and guiding principles provide tools to support NCPs in their work and should be widely promoted. The Commission considers NCPs should engage with patient organisations, healthcare professionals and health insurers to raise awareness on cross-border healthcare, and to join forces to reduce the administrative and emotional burden on patients seeking healthcare abroad. Moreover, providing greater **clarity on the Directive's relationship with the Regulation**, and information on how these schemes work, are a priority to improve patient choice in cross-border healthcare.

The creation of the European reference networks has mobilised substantial commitment from health professionals and investment by healthcare providers in the area of rare diseases. The ERNs have enabled the exchange of scarce knowledge to the benefit of rare disease patients. Their involvement in research on rare diseases[61] is critical to find solutions for patients encountering diagnosis difficulties or having no treatment option for one of the estimated 6000-8000 rare diseases. Safeguarding the **sustainable development of ERNs** requires action by Member States, supported by the Commission, to **better integrate ERNs into national healthcare systems**. Solutions are under development to ensure the smooth functioning of ERN virtual consultation panels so that more rare disease patients can receive the long-awaited answers about their diagnosis and treatment.

The COVID-19 pandemic has shown the importance of European solidarity across borders in times of crisis. People in border regions benefit greatly from structured regional cooperation in healthcare in emergency situations and for planned healthcare by sharing healthcare facilities. Several regions offer inspiration and **good practice examples of structured cooperation between health administrations, insurers and healthcare providers** working together across borders to overcome differences in national health systems to meet patients' needs.

[60] Annex "Follow-up actions to enhance the implementation of the Directive 2011/24/EU".
[61] https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en