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

Final Report

ANNEXES

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Annex 1: Evaluation Questions Matrix

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.

Table 1: 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 movement	• 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	**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	Literature review Survey of healthcare providers Interviews of EC 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
		responsibilities regarding CBHC; clarity of reimbursement rules on CBHC costs	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 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?	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	• 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	**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-	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

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
b. What factors hinder the provision of clear and transparent information to patients?	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)	• 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)	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.	Public consultation
4. To what extent has the information provided to patients under the Directive contributed to enhanced transparency and comparability of healthcare (regarding safety, quality, costs, waiting times, etc.) across the EU?[1] a. To what extent have Member States made the standards for quality and safety of care, applicable	JC 4.1: Transparency and comparability of 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	• Extent and clarity of information 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	**Rating of the evidence: High** As per EQ3.	Literature review Web analysis of NCPs websites Public consultation Interviews of EC officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients

[1] We have slightly amended the wording of this question. 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?"

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
standards for health professionals transparent for EU citizens?[2]	applicable standards for health professionals	healthcare safety standards, quality, costs, waiting times across the EU since the adoption of the Directive.		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 improve services provided by NCPs	• 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)
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	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	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	**Rating of the evidence: Moderate** As per EQ2. No quantitative data available on the continuity of care between MS after cross-	Literature review Survey of healthcare providers Interviews with CBHC expert group, patient organisations, healthcare

[2] 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
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?	objective, non-discriminatory and proportionate criteria JC 6.2: The Directive has ensured continuity of care between Member States after cross-border treatment	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	border treatment across the EU from 2012 to 2020; therefore the indicators was excluded.	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	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	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	**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	Subject of another commissioned study: Cross Border Patient Mobility in Selected EU Regions Literature review

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
increased cross-border cooperation in healthcare and if yes, how?	cross-border cooperation in healthcare	healthcare and how it was achieved **Indicators excluded from the analysis:** Quantitative data on cross-border cooperation in healthcare (e.g. meetings, events, exchange of information/best practices, etc.)	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 Association of European Border Regions (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".	Public consultation
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	**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-	Literature review Interviews/surveys of EC officials, national authorities (CBHC expert group), healthcare providers, healthcare insurers Case studies (including pharmacist targeted survey) Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		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	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.	

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
10. Are there specific patient groups that are particularly benefiting from the patients' rights in cross-border healthcare as set out in the Directive?	JC 10.1: There are specific patient groups that are particularly benefiting from the patients' rights in cross-border healthcare	Qualitative evidence on patient groups that have benefited more / less from the 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	**Rating of the evidence: Moderate** No quantitative data available on the use of the 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.).	Literature review Interviews of CBHC expert 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;	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	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	**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 EC 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
what kind of reimbursement mechanism would be adequate for similar situations?	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 complex diseases, including through virtual consultation panels, can be improved	- 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 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 andthe 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	**Rating of the evidence: High** Triangulation of evidence collected from the different data collection tools (desk research, surveys, interviews, public consultation, workshop) and stakeholders	Literature review Data providedby the EC Survey of ERN members

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		- 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 HCP 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 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	provides high confidence on the validity of results obtained.	Interviews of ERNs patient representatives, industry, researchers Public consultation Virtual workshop

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		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 Qualitative evidence on impact of ERNs on research on rare and low prevalence and complex diseases	**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
		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

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
15. How effectively has the Commission supported Member States in cooperating in the development of diagnosis and treatment of rare diseases by making health 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?	JC 15.1: The Commission has supported cross-border cooperation in the development of diagnosis and treatment of rare diseases by 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?	Quantitative data on actions undertaken by the EC 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 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 EC 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	**Rating of the evidence: Moderate** Limited evidence on concrete actions undertaken by the EC 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 patients to other Member States. This limitation was addressed through stakeholder consultation, including the ERNs targeted survey which addressed that specific question.	Literature review Targeted survey of ERNs Interviews of ERNs, CBHC expert group, patients, researchers, industry Public consultation Virtual workshop

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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 EC 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 achieved/benefits obtained?	JC 17.1: The costs are proportionate to and justifiable considering the identified benefits/achievements of the Directive.	Quantitative data on: - reimbursement claims received and granted for healthcare provided in 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	**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, EC 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.	Literature review Interviews of EC officials, national authorities (CBHC expert group), patients, healthcare providers, healthcare insurers, ERNs Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		- 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	These limitations have been addressed through qualitative data collected in interviews and through desk review of available literature including the EC'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.)	

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
18. How proportionately were the costs of the Directive borne by different stakeholder groups considering the distribution of the associated benefits?	JC 18.1: The costs of implementing the Directive were proportionately borne by different stakeholder groups considering the benefits experienced by each group.	Comparison of qualitative data on administrative costs and benefits of the Directive borne by different stakeholder groups, including: - 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	**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 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).)	Literature review Interviews of EC officials, national authorities (CBHC expert group), patients, ERNs
19. If there are significant differences in costs (or	JC 19.1: There is significant variability in levels of costs	Analysis of quantitative and qualitative data relating to	**Rating of the evidence: Low**	Literature review Interviews of EC officials, national authorities (CBHC

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
benefits) between Member States, what is causing them? How do these differences link to the intervention?	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	administrative costs per Member State Qualitative data on factors that influence the costs and benefits achieved by MS (see EQ20)	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).)	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? To what extent were these factors linked to the Directive?	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 factors relate to the Directive. JC 20.3: The results achieved were enhanced or limited by	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 specific admin burden)	**Rating of the evidence: Low** The limited cost data available for MS, EC 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 EC officials, national authorities (CBHC expert group), patients, healthcare providers, healthcare insurers, ERNs

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
To what extent were there external factors that influenced the results?	other factors not directly related to the Directive.	- 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:** EC 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 assessment (see EQ 17).	
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?	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.	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	**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 EC 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
What administrative burdens still exist for patients? Where is there room for simplification?	JC 21.3: Certain types of administrative burdens still exist in relation to specific aspects of the Directive. JC 21.4: There is scope to increase efficiency through simplification of current processes.	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 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)	**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	Literature review Data provided by the EC Interviews of EC officials, national authorities (CBHC expert group), patients, ERNs, researchers, industry Survey of ERNs Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		Stakeholders perceptions on balance of costs and benefits of the ERN system	center co-fund 40% of the EU funding)	
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 to another MS and receiving healthcare there?	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 required.	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
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	**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 EC officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients, Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		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		Virtual workshop
25. Are there new developments (technological[3], policy, etc.) since the Directive's entry into force, which have implications on patients' rights to cross-border healthcare? How do they impact on the Directive's relevance?	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 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	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 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	**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 EC officials, national authorities (CBHC expert group), ERNs, healthcare providers/ professionals, healthcare insurers, consumer organisations, researchers, industry Public consultation
26. Has the Directive had any effects beyond its scope, for example on the	JC 26.1: The Directive has had effects beyond its scope	**Answer to JC 26.1 combined with EQ 16**	**Answer to the first part of the question (i.e., has the Directive had any effects**	Literature review

[3] We note that evaluation question 29 focuses on technological developments. Therefore, we will not address these in this evaluation question.

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
reimbursement of cross-border health care provided by foreign doctors treating patients in the state of the patients' insurance affiliation?	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	**Indicators excluded from the analysis:** Quantitative and qualitative data on foreign doctors treating patients in the state of the patients' insurance affiliation	**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.	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 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	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 - consistency in the approach taken by NCPs across the MS - that NCPs add value to the landscape of other information providers in the 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.	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
	provide support and the type of support that they provide.	- 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 addressed by the Directive JC 28.3: It is possible to define specific issues / situations /systemic / historic	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 EC 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
	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 complex diseases	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 **Indicators excluded from the analysis:**	**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 Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		Gaps in rare diseases and complex conditions not covered by the ERNs		
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 Association of European Border Regions (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

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
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 objectives of the Directive are met.	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 and areas where more clarity is needed.	**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
33. To what extent has the application of the legal framework by Member States been coherent with regard to costs for healthcare?[4] 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	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:**	**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

[4] 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
	have resulted in problems for patients	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		
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' rights?	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 institutions on how to apply these rules	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 Coordination Regulations interact with each	**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 EC officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients Virtual workshop Public consultation

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		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		
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	**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 EC officials, national authorities (CBHC expert group), healthcare providers/ professionals, healthcare insurers, patients Virtual workshop Public consultation

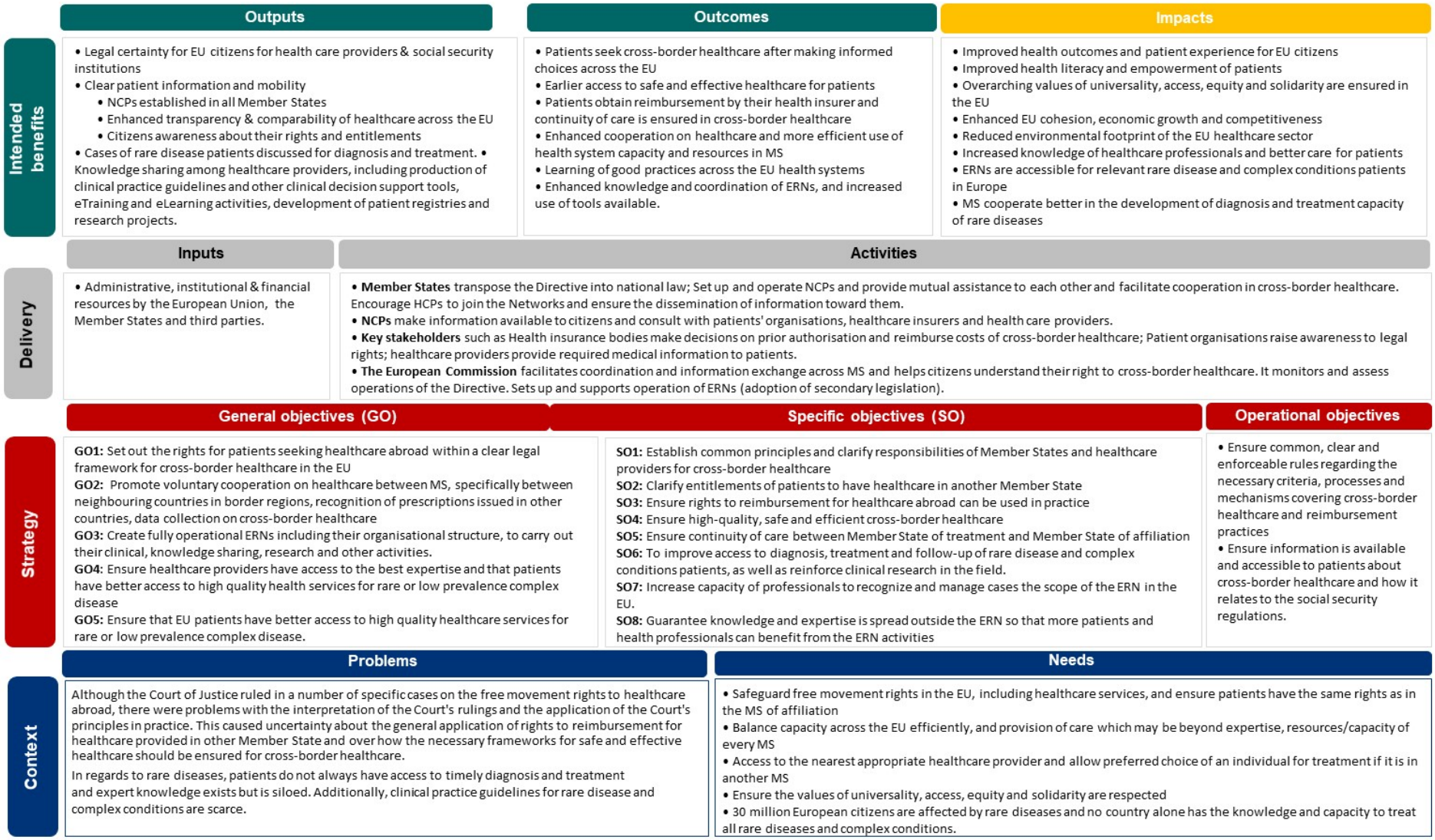
EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
		Stakeholders' perceptions on how patients' choices and MS' responses are influenced by the existing overlaps between the Directive and the Social Security Coordination Regulations		
36. To what extent is the Directive coherent with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector?	JC 36.1: The Directive aligns well to the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector	Qualitative evidence on (mis)match between the provisions of the Directive and those of the Directive on the recognition of professional 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 .	**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 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	Literature review Interviews with national authorities (CBHC expert group), healthcare providers/ professionals

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
			examples in national contexts.	
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 with other	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	**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
	activities in the field such as the Orphanet database	such as the Orphanet database		
39. To which extent does the Directive enhance and complement other existing European structures such as the European Civil Protection Mechanism in line with its objectives?	JC 39.1: The Directive enhances and complements other existing European structures such as the European Civil Protection Mechanism	Qualitative evidence on synergies/ complementarities between the objectives of the Directive and of other existing European structures such as the European 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 EC 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	JC 41.1: The Directive set the necessary provisions to facilitate cooperation between Member States in cross-	Quantitative and qualitative evidence on extent of cooperation between MS in cross-border healthcare at	**Rating of the evidence: High** Triangulation of evidence collected from the different	Evidence collected in previous EQs Interviews of EC officials, national authorities,

EVALUATION QUESTION	JUDGEMENT CRITERIA	INDICATORS	QUALITY OF THE EVIDENCE	DATA SOURCES
local level since its entry into force?	border healthcare at regional and local level	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)	data collection tools (desk research, interviews, public consultation) and stakeholders provides high confidence on the validity of results obtained.	healthcare providers/professionals, healthcare insurers, patients, consumer organisations, researchers, industry Public consultation
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	Evidence collected in previous EQs Interviews of EC 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 EC officials, national authorities, healthcare providers/professionals, healthcare insurers, patients, consumer organisations, researchers, industry Public consultation

Annex 2: Intervention logic



Annex 3: Bibliography list and secondary sources

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• Toolbox for Cross-border Healthcare: https://ec.europa.eu/health/cross_border_care/toolbox_en

- Responses to the consultation accompanying the evaluation roadmap: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights/feedback_en?p_id=18840338
- Meeting minutes
  - CBHC expert group and NCPs subgroup: https://ec.europa.eu/health/cross_border_care/events_en#anchor0
  - ERN Board of Member States: https://ec.europa.eu/health/ern/latest_updates_en

Annex 4: Factual summary report of the Public Consultation

INTRODUCTION

The Directive on patient rights in cross-border healthcare[5] aims to facilitate access to safe and high quality healthcare in another EU country. Thanks to the Directive, patients can claim reimbursement from their national health system or their health insurance provider and prescriptions are recognised anywhere in the EU. The EU Directive also aims to facilitate European cooperation in healthcare through the European Reference Networks[6] for rare and low prevalence complex diseases (ERNs). The Directive was adopted on 24 April 2011, however due to its late transposition into national law compliance checks are still ongoing.

APPROACH TO THE CONSULTATION

The public consultation was carried out using the EU Survey[7] tool and was available in all EU languages. It was accessible via the **Have Your Say[8]** portal of the Commission. It was carried out between 4 May and 27 July 2021. The public consultation had the objective to gather a wide set of views on the functioning of the Directive among patients, health authorities, other stakeholders and citizens. Given the number of responses and the self-selected sample of respondents, the public consultation results are not statistically representative. The questionnaire had five sections: (1) information about the respondent; (2) patients' rights in cross-border healthcare; (3) collaboration on rare diseases and the ERNs; (4) healthcare cooperation between regions and the impact of COVID-19 on cross-border healthcare; and (5) additional information and/or upload documentation.

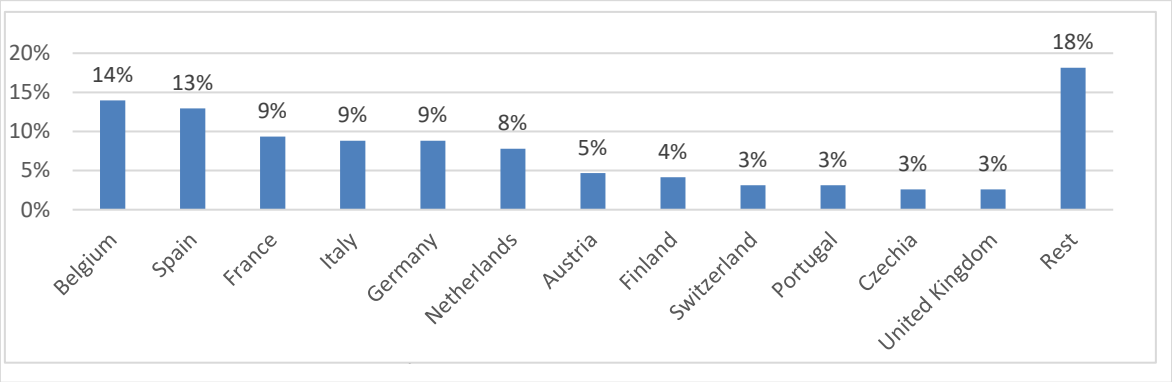
The Commission promoted the consultation through its available communication channels, as well as carried out the following communication activities: email communication announcing the launch of the consultation; reminders in the European Commission's Health and Food Safety Newsletter; posts in Twitter; webinars and meetings with key stakeholders. An information sheet was also sent to stakeholders invited to participate in targeted consultations.

OVERVIEW OF RESPONSES

The public consultation received **193 responses**. Over half of the responses were provided by stakeholders in Belgium,[9] Spain, France, Italy, and Germany. No answers were moderated and therefore all contributions were taken into account in the analysis.

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0024
[6] https://ec.europa.eu/health/ern_en
[7] https://ec.europa.eu/eusurvey/home/welcome
[8] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights_en
[9] This number includes the European and international organisations based in Belgium.

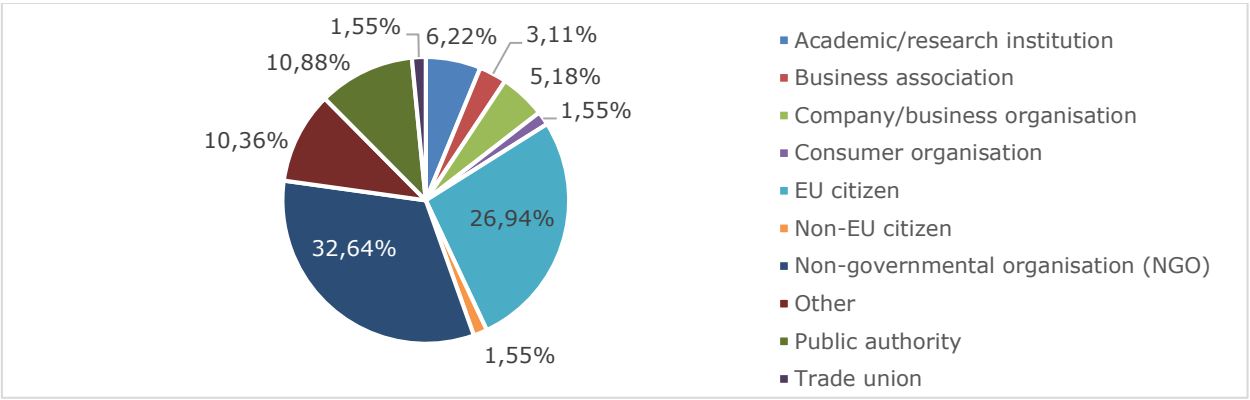
Figure 1: Responses received by country (countries with over 3% of responses)



The rest of the stakeholders were from Croatia, Romania, Slovakia, Greece, Sweden (each 2%) and Cyprus, Hungary, Luxembourg, United States, Bosnia and Herzegovina, Bulgaria, Estonia, Ireland, Latvia, Lithuania, Malta, Norway (each 1%).

In relation to the categories of stakeholders, almost 33% were non-governmental organisations, 28.5% were citizens,[10] 10% public authorities, 6% academic and research institutions, 5% companies or business organisations, and 3% business associations. The remaining categories (consumer organisations, trade unions) were less than 2%, except for the "other" category that represented 10% of the respondents.

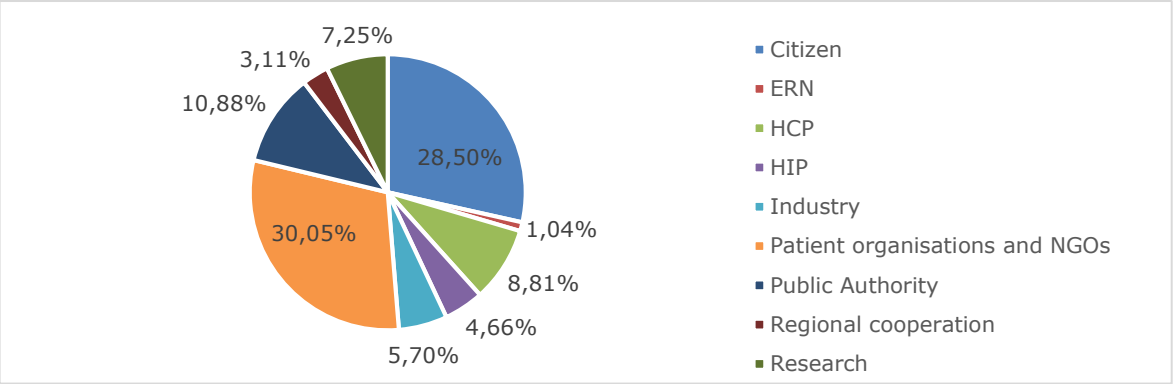
Figure 2: Percentage of responses by category of stakeholder



The respondents have been recategorised to reflect the stakeholder categories in the Commission's consultation strategy for the ex-post evaluation of the Diretive. The new categories used were: individual citizens, patient organisations and NGOs representing specific groups (consumers, older people, people with disabilities, LGBTIQ people, socio-economically disadvantaged groups), public authorities (national, regional and local, including National Contact Points for cross-border healthcare (NCPs)), healthcare providers (HCP), health insurers (HIP), industry, research organisations, organisations or projects promoting regional cooperation and ERNs.[11]

[10] EU citizen (26,94%) and non-EU citizens (1,55%).
[11] In some cases, health providers and health insurers are also public authorities. However, for the purpose of the analysis, we followed the classification that stakeholders selected when answering the profling questions (i.e. NGO, EU citizen, public authority, academic/research institution, company/business organisation, business association, consumer organisation, non-EU citizen, trade union, and other).

Figure 3: Percentage of responses as per recategorisation of stakeholder groups



ANALYSIS OF THE RESPONSES

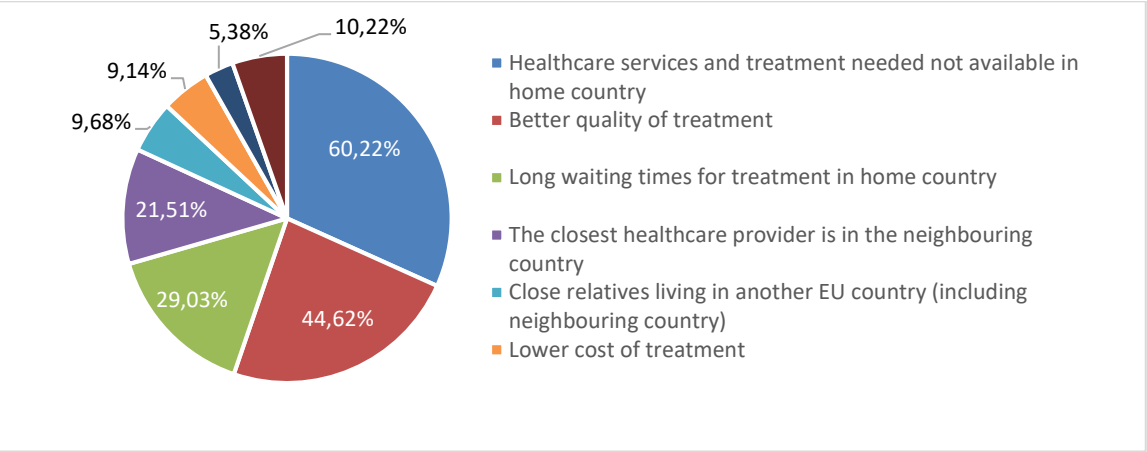
Questions on patients' rights (Q1-Q20)

Seven in ten respondents said that they were **informed about their rights to seek healthcare in another EU country**. However, only 15% responded that they were *completely* informed about it, indicating that information gaps remain. The vast majority of the respondents (81%) also indicated that they were aware that patients can get healthcare costs incurred in another EU country reimbursed under the Directive and/or the EU rules on social security coordination. Nevertheless, 71% of respondents also indicated that they were aware of problems resulting from both EU schemes.

Respondents were also of the opinion that **the EU schemes for reimbursement do not fully meet patients' needs** on accessing healthcare in another EU country, and gaps persist. A third of participants believed needs were met to some extent (33%), a quarter believed it was met to a limited extent (25%), and 4% that it was not met at all. An additional 13% did not provide an answer. Respondents considered the financial problems generated by the two schemes and the fear of an incomplete reimbursement one of the main problems resulting from the EU schemes (mentioned by 55 out of 106 respondents). The lack of access to information for patients about their rights was considered the second most important problem (31 out of 106 respondents). A third problem was the administrative burden and slow authorisation procedures (27 out of 106 respondents).

Respondents were also asked to provide their views on **reasons for seeking healthcare abroad**. The main reasons mentioned were: healthcare services and treatment needed not available in home country (selected by 60% of respondents); better quality of treatment (45%); long waiting times for treatment in the home country (29%); and the closest healthcare provider being in the neighbouring country (22%) .

Figure 4: Main reasons for seeking healthcare abroad (n=186)



Half of the respondents were aware of **patients' experiences with healthcare providers abroad** (52%) while 32% were not aware and 16% did not know. The majority of those who were aware of patients' experiences with healthcare providers abroad, indicated that providers recognise medical documents and tests from the home country (60% completely/to a great extent/to some extent) and issue clear final invoices for reimbursement by the patient´s health insurer (52% completely/to a great extent/to some extent) at least to some extent. Additionally, 46% of respondents indicated that healthcare providers transfer medical records or a patient summary to the healthcare provider back home and healthcare providers give clear information on prices at least to some extent. Furthermore, more than half (54%) responded that they were unaware of any administrative problems for patients receiving follow-up care at home after treatment abroad, while 46% were aware of such issues.

More than half of respondents agree that there are **barriers to cross-border healthcare** either completely (13%) or to a great extent (40%). A third of participants (33%) responded that there are barriers to some extent, 5% answered that there are barriers only to a limited extent and 2% responded that there are no barriers at all. The remaining 7% did not provide an answer. The main barriers experienced in accessing healthcare abroad are: patients have to pay upfront for treatment costs and then seek reimbursement from their own health insurer (mentioned by 117 out of 174 respondents); lack of information on patients' rights to healthcare abroad (107 out of 174 respondents); and language barriers (88 out of 174 respondents).

Respondents were divided between those who knew about the **existence of NCPs** (54%) and those who did not (46%). Among those who know about them, nearly three quarters (73%) reported that they had contacted an NCP or checked its website for information, compared to a 27% who did not. Moreover, respondents were asked to evaluate the information provided in three different categories: completeness, quality and clarity. Regarding clarity, 40% of respondents who had contacted a NCP or checked its website rated it as high (4/5 out of 5 points), 13% as average (3 out of 5) and 39% as low (1/2 out of 5). With reference to the completeness, 31% rated it as high (4/5 out of 5), 18% as average (3 out of 5) and 45% as low (1/2 out of 5). When it comes to quality, 40% rated it as high (4/5 out of 5), 18% as average (3 out of 5) and 36% as low (1/2 out of 5). Overall, 5% (on average)did not know how to rate the information provided by NCPs or had no opinion on it.

Moreover, over a quarter (28%) of respondents who had contacted an NCP or checked its website for information considered it not suitable for **people with disabilities** and a quarter (25%) that it was suitable. The rest of respondents (47%) did not provide an opinion on this. Many (39%) did not provide an opinion either on whether the

information was available in a **minority language** in their country. But 37% said it was not available and a quarter (24%) said it was. Nearly two thirds (64%) of respondents also did not provide an answer on whether the information covered the **LGBTIQ community**. 30% said it did not cover this and 6% said it did.

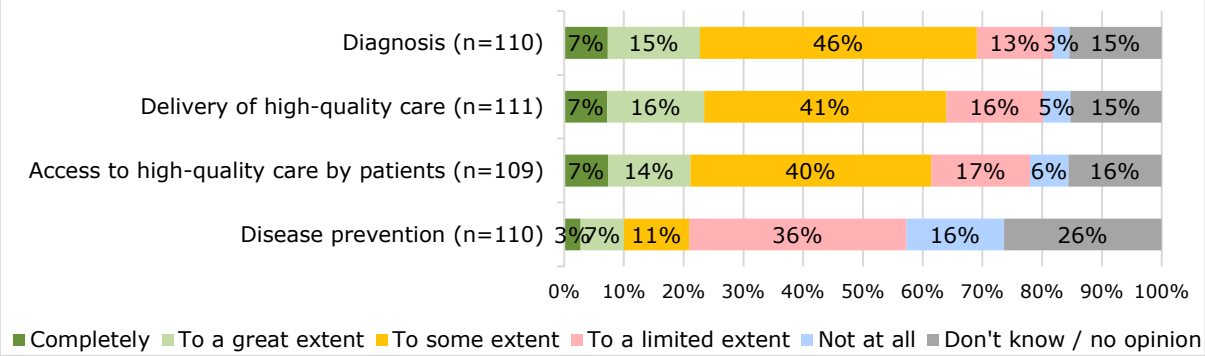
Finally, 60% of respondents were aware of the possibility of having **medical prescriptions** recognised by a pharmacist in another EU country. Opinions were mixed in relation to awareness about problems related to the non-recognition of prescriptions. Over a third of respondents (38%) were aware of problems with pharmacists in another EU country not recognising prescriptions. However, about a third (31%) were not aware of these problems, and another 31% were unable to provide an opinion. The most common problems experienced included: refused prescriptions in general, a pharmacist's inability to verify the prescription, language problems and unavailability of the prescribed medicine.

Questions on rare diseases and ERNs (Q21-Q28)

Nearly two thirds of participants were aware of **the existence of ERNs** and their purpose (63%), while 37% were not. Among those who were aware of the ERNs, almost half believed that the ERNs helped health professionals provide diagnosis and treatment options for patients with rare and complex diseases to at least some extent (6% completely, 21% to a great extent and 48% to some extent). In addition, 79% of respondents believed to at least some extent that the ERNs helped generate knowledge and contribute to research on rare and complex diseases in the EU (9% completely, 23% to a great extent and 47% to some extent).

Regarding the extent to which **ERNs have helped achieve their objectives**, contributors identify diagnosis as the top-scoring area with 69% responding this goal was achieved at least to some extent (7% completely, 15% to a great extent and 46% to some extent). Second-tier areas include the delivery of high quality care, with 64% responding that the goals were achieved to at least some extent (7% completely, 16% to a great extent and 41% to some extent) and access to high quality healthcare by patients, with 61% responding this goal was achieved at least to some extent (7% completely, 14% to a great extent and 40% to some extent). Respondents provided a more negative opinion in relation to disease prevention, with 36% of respondents considering that ERNs have helped to a limited extent and 16% saying that ERNs have not helped at all.

Figure 5: Q.26 To what extent have ERNs helped achieve the objectives in the following areas



Respondents generally indicated that **Member States have helped develop ERNs at national level** mainly by supporting the participation of national centres in ERNs and connecting their national centres of expertise. There were more mixed views in relation to disseminating information on ERNs to healthcare providers and disseminating

information on ERNs to patients. When asked about the biggest barriers that healthcare providers and patients face in accessing the expertise of ERNs, the respondents indicated that for healthcare providers these were: non-interoperable IT systems (60%); administrative burden (53%); and the insufficient integration of ERNs in the national health system and lack of support for their activities by the national authorities (49%). For patients, the barriers were: lack of awareness/information (62%); language (60%); issues related to reimbursement of the health services provided (49%); and absence of a clear pathway to refer patients to ERNs (41%).

Cooperation between regions and the impact of COVID-19

Contributors were asked to identify to what extent the Directive has supported **cross-border cooperation in healthcare between neighbouring countries and in the border regions** over the past 5 years. Six in ten respondents believe that the Directive supported exchanges of information (21% to a great extent and 39% to a limited extent) and exchanges of good practices (19% to a great extent and 40% to a limited extent). Less than half believed that the Directive supported agreements in cooperation in healthcare provision (18% to a great extent and 27% to a limited extent).

Among the barriers facing hospitals, health authorities and health insurers in cooperation across border regions, respondents pointed mainly to the differences in health systems and resources as the most common ones. According to four in ten contributors, the Directive could help health systems tackle a possible backlog of postponed treatments arising from the COVID-19 pandemic to a great extent (28%) or completely (12%), with 20% believing it could help to a limited extent and 11% not at all. Three quarters of contributors believe that the restrictions on free movement during the pandemic had an impact on access to healthcare in another EU country (23% completely, 35% to a great extent and 17% to some extent).

POSITION PAPERS

Twenty one (21) respondents uploaded additional information as part of their reply. The majority of these documents were position papers. Few organisations also included reports, as well as research papers, which they had published outside of the context of the ongoing evaluation, but which were relevant to it. Annex 1 provides an overview of the organisations, position papers and reports received.

The types of organisations submitting documentation included EU and international umbrella organisations; national/regional authorities, academia and healthcare professionals' associations/networks; companies working in the field of pharmaceuticals and medical technologies; national and EU organisations working in the fields of patients' rights, rare diseases or disabilities.

All position papers acknowledged the importance of the Directive for patients' rights in cross-border healthcare. However, these documents pointed out a number of downfalls and current practical limitations when it comes to cross-border healthcare, including the following main issues: (1) lack of awareness of citizens of their rights to cross-border health care; (2) a number of technical and financial barriers to getting healthcare, including a lack of guidance on how to access healthcare abroad, as well as issues with the reimbursement of costs; (3) obstacles to cross-border healthcare when it comes to diagnosing and treating rare and low prevalence complex diseases and citizens with disabilities; (4) challenges and limitations in relation to information provision by the NCPs and to what ERNs can deliver and achieve.

APPENDIX 1: OVERVIEW OF POSITION PAPERS

Table 2: Overview of Position Papers

TITLE	ORGANISATION
Öppet samråd om EU:s patientrörlighetsdirektiv 2011/24/EU	Sveriges Kommuner och Regioner
Overdruksyndroom Tarlovcysten	SOSNL
Soins de santé au-delà de la frontière : les barrières et opportunités dans le Benelux	Secrétariat général de l'Union Benelux
Specific comments on ERNs	Pro Rare Austria
ANEC Contribution to the EC Consultation on the evaluation of Directive 2011/24/EU on patients' rights in cross-border healthcare	ANEC (The European consumer voice in standardisation)
Annex to City of Helsinki answers to public hearings on: "Digital health data and services – the European health data space" &" Cross-border healthcare – evaluation of patients' rights"	City of Helsinki
ARM recommendations on cross-border and regional access to Advanced Therapy Medicinal Products (ATMPs) in Europe	Alliance for Regenerative Medicine (ARM)
Impact of cross-border healthcare on persons with disabilities and chronic conditions	International Federation for Spina Bifida and Hydrocephalus
Cross-Border Healthcare–Evaluation of Patients' Rights	COTEC
EDF's recommendations for the European Commission's evaluation of patient rights in cross-border healthcare	European Disability Forum (EDF)
EFN Position Statement on Continuity of Care	European Federation of Nurses Associations (EFN)
Elekta's feedback on the public consultation on the Evaluation of patient rights in cross-border healthcare	Elekta
Comment rendre l'action de l'UE pour les maladies rares mieux adaptée aux besoins des patients et de leurs proches ? Des avancées locales et transfrontalières aux solutions européennes	EMRaDI
Cross-border healthcare for rare diseases patients: what can be done?	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
EUREGHA's contribution to the evaluation of the patients' rights in cross-border healthcare directive	European Regional and Local Health Authorities (EUREGHA)
An empty promise: accessing cross-border healthcare for people living with a rare disease	EURORDIS (Rare Diseases Europe)
Patient directive – position paper EPECS, July 2021	EPECS
Orchard Therapeutics position on cross-border healthcare in the EU: Experience-based contribution to cross-border healthcare evaluation.	Orchard Therapeutics
Posicionamiento de federasistencia sanitaria transfronteriza	FEDER
Rare Cancers Europe	RCE
Universal Health Coverage "Leave No Child Behind"	PEDIATRIA Polska

Annex 5: Analysis of NCP websites

Introduction

This section presents the results of the analysis of the NCP websites conducted as part of the present study. For this analysis, the methodological approach adopted was the approach used in the 2015 *Evaluative study on the cross border healthcare Directive (2011/24/EU)* and the 2018 *Study on cross-border health services: enhancing information provision to patients*. The website analysis was based 48 Specific Analytical Items (SAI), that were developed as a structure to analyse the website design, its functionalities, its ease of access, and gauge whether a citizen would be able to find the information required under the cross-border healthcare Directive. In total, the NCP websites of 30 countries were analysed, equating to 31 websites as two NCPs from Sweden were included in the analysis. All EU Member States were included in the analysis, as well as Norway, Iceland and Liechtenstein.

As described by the 2018 Study, the analysis was divided into three sections as shown in Figure 6. First, the individual NCP websites were analysed, then the results of individual websites were aggregated to reflect the overall performance of websites per SAI category and a comparative analysis of the aggregated results, using stars and spider diagrams was conducted. Recommendations were then formulated highlighting areas of improvement.

Figure 6: NCP Web analysis process

As in 2018, this new iteration of the web analysis focused on Specific Analytical Items (SAI) distributed among nine key areas (SAI Categories), three of which focused on the website and six that focused on the content of the website. Information provided in the websites was analysed in English and in the national languages using the Google Translate tool offered by the Internet browser. The key areas of assessment were:

1. **Technical elements** which assessed areas such as independence of the NCP's address; presence of background information about the website and the presence of NCP e-mail address.

2. **Accessibility** which assessed areas such as order in search (Google) for: "NCP + the name of the MS"; order in search (Google) for: "NCP + healthcare + the name of the MS"; and which website opens when clicking on the EU DG Sanco NCP's contact list;

3. **Usability of the website** which assessed areas such as the presence of most visited pages, the presence of frequently asked questions and the presence of an internal search engine.

4. **General Information** which assessed areas such as the information provided for inbound patients and information provided for outbound patients.

5. **Healthcare providers** which assessed areas such as information on the health system in the NCP country; information on health providers and the provision of contact details of national healthcare providers.

6. **Patient rights** which assessed areas such as information on the definition of waiting time, information on paients' rights in case of undue deay and information on patients' rights in the event of harm.

7. **Prior authorisation** which assessed areas such as presence of information on which treatment require prior authorisation, presence of list of treatments requiring prior authorisation and information on procedures to obtain reimbursements.

8. **Quality and safety standards** which assessed areas such as information on national legislation and policies regarding patient safety; information on the national quality strategy and information on quality measurements/indicators for healthcare providers.

9. **Entitlement for reimbursement of costs** which assessed areas such as information on which treatments are reimbursed; information on which treatments are not to be reimbursed; and information on requirements for the recognition of invoices/clinical information.

A full breakdown of the Web analysis criteria can be found in Table 3. The average scores across all NCP websites in relation to the nine key areas are presented in Figure 7. The 2021 analysis results show that overall, the average scores achieved across all NCPs varied greatly with the highest average being 82% and the lowest being 37%. However, France and Finland were found to achieve the highest overall averages of 82% and 80% respectively.

Positively, when comparing the 2018 and 2021 average scores as reflected in Figure 8, improvements between 2018 and 2021 can be seen for each of the nine categories except technical elements, where the 2021 average score is slightly lower than 2018.

Figure 7: 2021 Average scores of the NCP websites

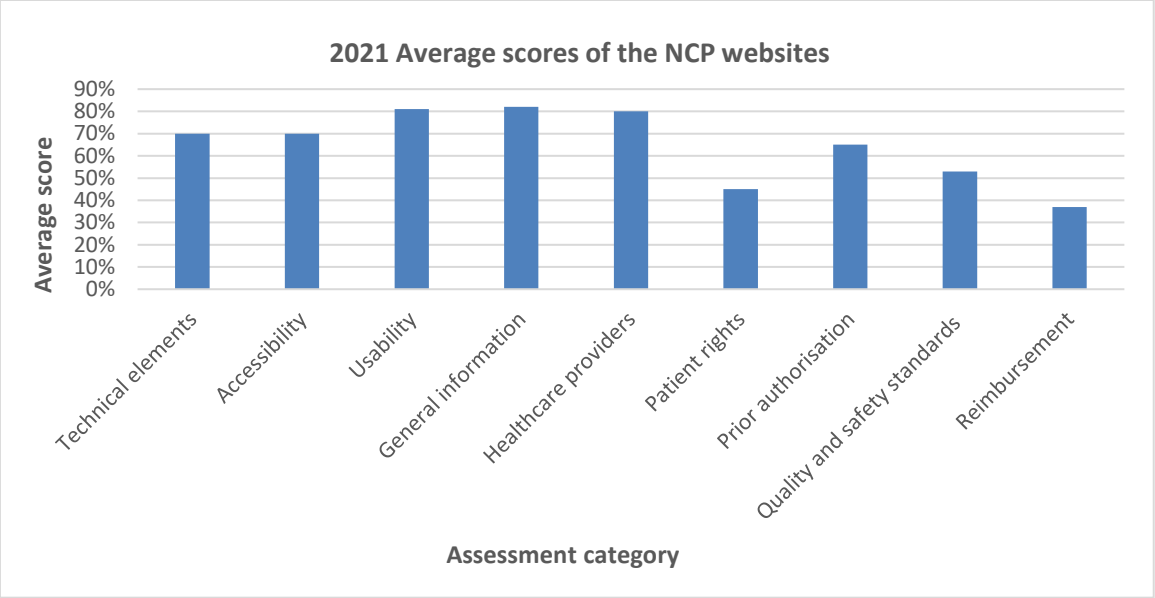
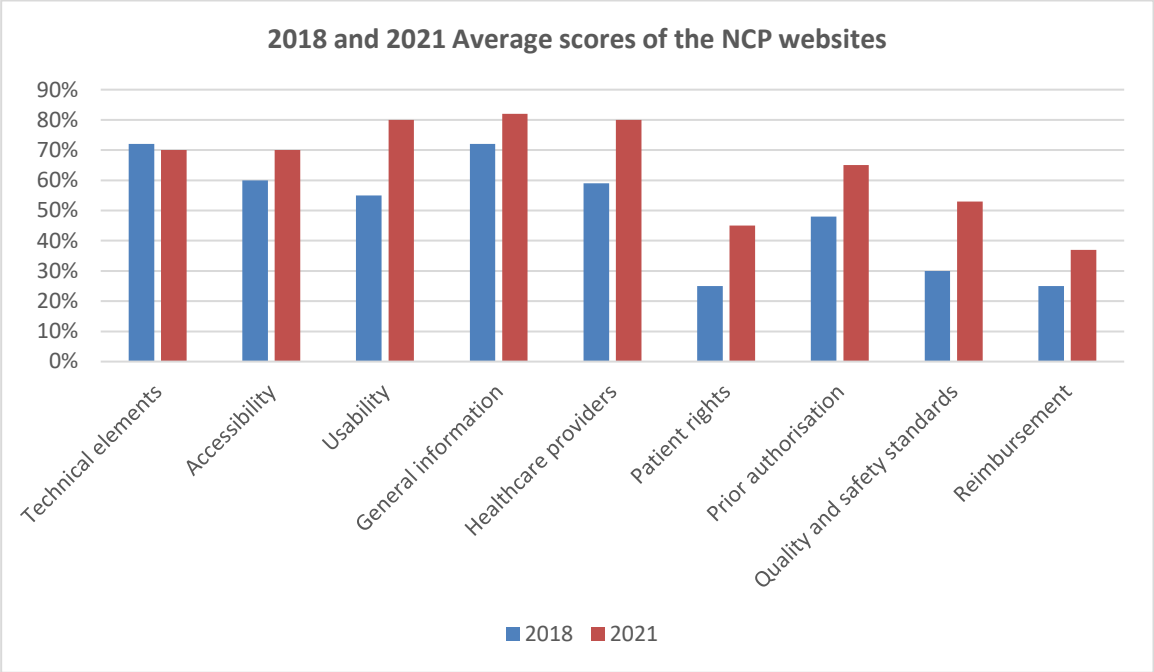


Figure 8: Comparison of 2018 and 2021 average scores of the NCP websites



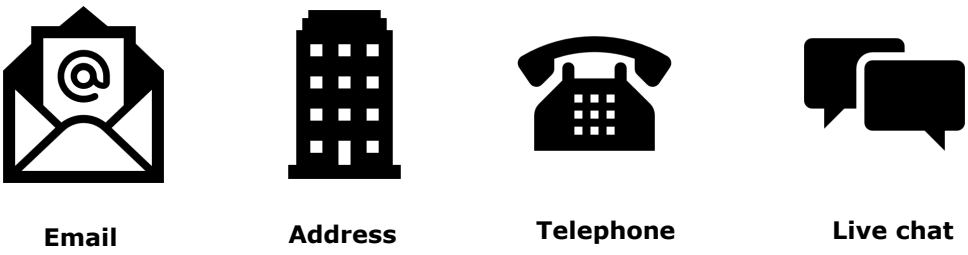
Subsequent sections elaborate in detail on each of the nine categories.

Technical elements of the website

This category focused on whether the NCP websites included elements such as an independent website, background information i.e., the organisation responsible for the website, contact details for the NCP and other NCPs, and alternative communication channels.

In relation to the technical elements of the website, overall, the NCP websites analysed scored relatively well with an average of 70% with 19 out of 31 NCP websites scoring 75% or above. A majority of the NCPs developed an independent website to cater to the needs of citizens seeking information on cross-border healthcare, and included at least one contact mechanism, though the contact mediums varied across the NCPs. All analysed country NCP websites, except Norway included at least one form of contact information (phone number, email address and/or office address). Only 50% provided citizens with other options to communicate with the NCP, including live popup chats and social media channels such as Facebook and Twitter. 29 out of the 31 analysed NCP websites provided contact information for other NCPs, either by providing their direct contact details or by redirecting web users to the NCP list developed by the European Commission. In this area, however it was found that there was room for improvement as some of the websites did not link directly to European Commission's list, and therefore were either out of date or needed to be manually updated regularly with NCP contact details. Countries receiving the highest score for this category (87.5%) and thus seen as "best practices" were Finland, Malta, Latvia, Ireland, Croatia and Luxembourg.

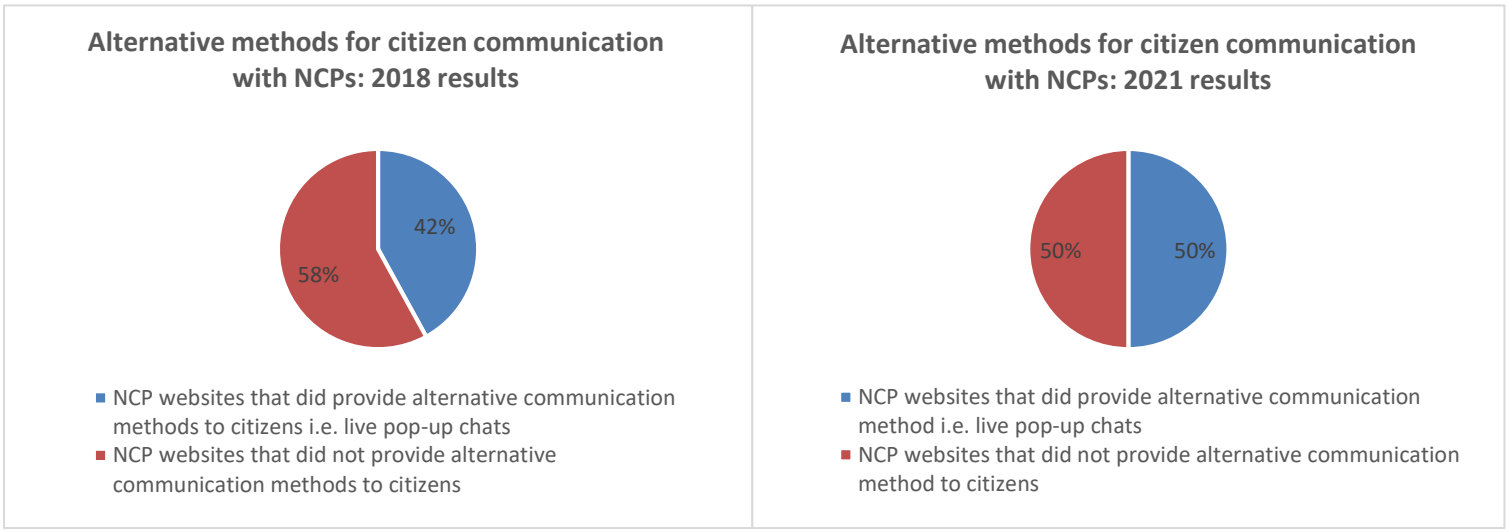
Figure 9: Communication methods available via NCP websites



Comparing results to previous studies

When comparing our findings to the results from the 2015 Evaluative study[12] and the 2018 study by the Commission[13], results found were similar though there are signs of a slight improvement in that there has been an increase in the amount of NCP websites offering citizens alternative methods to communicate with NCPs such as live pop-up chats and social media channels. This is reflected in Figure 10.

Figure 10: 2018 and 2021 results on NCP provision of alternative methods for communication with NCPs



Accessibility of the website

This category assessed how easily the website could be found and used, taking into account users with decreased sensory functioning. Overall, an average of 70% was scored across all the NCP websites analysed indicating a good score with room for improvement. None of the websites were the first hit when "NCP + the name of the MS" was searched using Google. All NCPs except Italy came 6th or after. However, when the search was extended to "NCP + healthcare + the name of the MS" only Ireland, Estonia and the Netherlands became the first hit. Positively, all of the websites were described as easy to open by the researchers and 29 of

[12] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf
[13] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients', Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

the 31 NCPs analysed provided information or a version of their website in both their national language and English. As this analysis adopted the methodology of the 2015 and 2018 study, there was no assessment of the provision of websites in the language of the neighbouring country in the context of border regions. This is beneficial in increasing accessibility to incoming patients (patients from another MS). Only Portugal and Luxembourg's websites were found to be only in their national languages. However, a significant area for improvement was the fact that only 11 of 31 websites were found to provide options for people with decreased sensory functions, for example read-out-loud, other text-to-speech functionality add-ons; increased text size, different colour mode, which would greatly affect the accessibility of the website. As shown in Figure 11, across the 11 websites offering accessibility options the most common accessibility option was the use of increased text size, followed by options for changes to colour and contrast. Additionally, most websites only offered one accessibility option.

Overall, best practice NCPs were Finland, Malta, Spain, Hungary, Italy, Slovenia, Estonia and Germany as they received the highest score (86%).

Figure 11: Breakdown of accessibility options on NCP websites

NCP Website	Options for people with decreased sensory functions				
	Read out loud	Increased text size	Help page	Different colour/contrast mode	Video options
NCP Website 1		x			
NCP Website 2		x			
NCP Website 3			x	x	
NCP Website 4	x				
NCP Website 5	x				
NCP Website 6		X		x	
NCP Website 7		x		x	
NCP Website 8		x			
NCP Website 9		x		x	x
NCP Website 10			x		
NCP Website 11		x			

Comparing results to previous studies

2021 findings were similar to the findings of the 2015[14] and 2018 analysis results[15], though significantly fewer websites were found as first hit when "NCP + healthcare + the name of the MS" were used as a search on Google during the 2021 web analysis. This indicates that though NCP websites are functional and provide basic information, there is room for improvement especially in terms of making the website more accessible for those with decreased sensory functioning as there has been a slight decrease from 38% to 35% between 2018 and 2021 in the number of NCP websites providing options for people with decreased sensory functioning.

Usability of the website

In assessing the usability of the website, the study team focused on elements that made it easier for visitors to navigate their website and identify the information they needed most. This included aspects such as the presence of most visited pages, frequently asked questions, an internal search engine and a media library which contained videos on cross-border healthcare. The overall visual appeal and layout of the website was also assessed. The average score for usability across all NCPs was 80% with 24 out of 31 NCPs scoring 83% or more. However, seven NCPs scored 67% indicating room for improvement in this area. It should be noted that based on the analysis, none of these websites had a media library, however, as only seven countries in total had a media library, their lower scores are likely to have been due to the absence of one or more of the other key components assessed. For example, all seven were found to have limited visual appeal in relation to the use of menus, subheadings, illustrations, and overall attractiveness, three of the seven NCP websites also did not have a frequently asked questions page.

Comparing results to previous studies

When comparing the 2021 findings to the results from the 2015 Evaluative study[16] and the 2018 study by the Commission[17], there is a notable improvement in the usability of websites. The average score achieved in 2021 analysis in this area is 25% higher when comparing the average score achieved by websites in the 2018 analysis. Nonetheless as highlighted above, there is room for improvement.

General information on cross border healthcare

The following sub-sections focus on the NCP websites' content and completeness. Under this category, the study team assessed the presence of information on both the Regulation and the Directive, particularly in relation to their differences. The analysis also looked at information provision for both inbound and outbound patients and the presence of information on patient rights. In this category, the average score across all NCP websites was 82%, however there was large disparity with the scores as the highest was 100% while the lowest was 0% as reflected in Figure 12. Overall, 27 out of 31 NCP websites scored 75% or above, and all but three were found to provide information for incoming patients on the EU Regulation 883/2004 and the EU Directive 2011/24 legislation. Furthermore 29 of the 31 websites provided general information on patients' rights. However, 14 out of 31 were found to provide information on

[14] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf

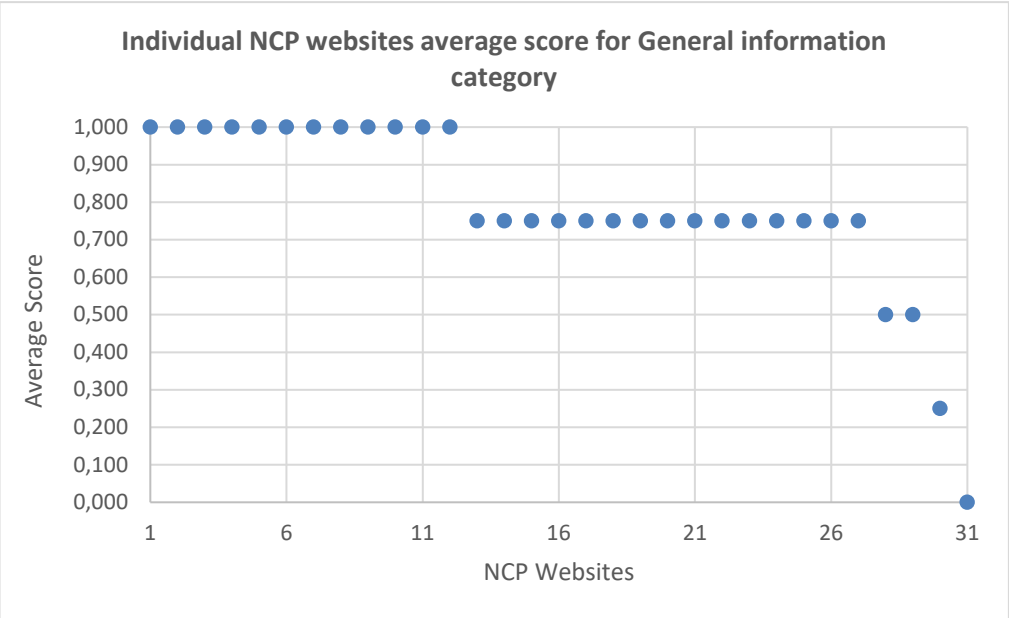
[15] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients,' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

[16] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf. For the evaluative study on the cross-border healthcare Directive, 32 NCPs of the EU Countries were included with an available website.

[17] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients'. Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

the distinction between both the Directive 24/2011 and the Regulation (EC) 883/2004. In terms of the highest scores, multiple countries scored 100%. Spain, Italy. Estonia, Germany, France, Greece, Belgium, Luxembourg, Austria, Cyprus, Bulgaria, Slovakia were seen as 'best practice'. The subsequent sections will assess the information provided in more detail.

Figure 12: Average scores for General informaton category



Comparing results to previous studies

When comparing the 2021 findings to the results 2018 study by the Commission[18], results were found to be similar. Though the scores achieved in the 2015 Evaluative study[19] were higher in some areas for example the number of NCP websites providing a distinction between the EU Regulation 883/2004 and the EU Directive 2011/24 legislation, as stated in the 2018 Commission study[20], this may be due to the definition and interpretation of each of the scoring criteria.

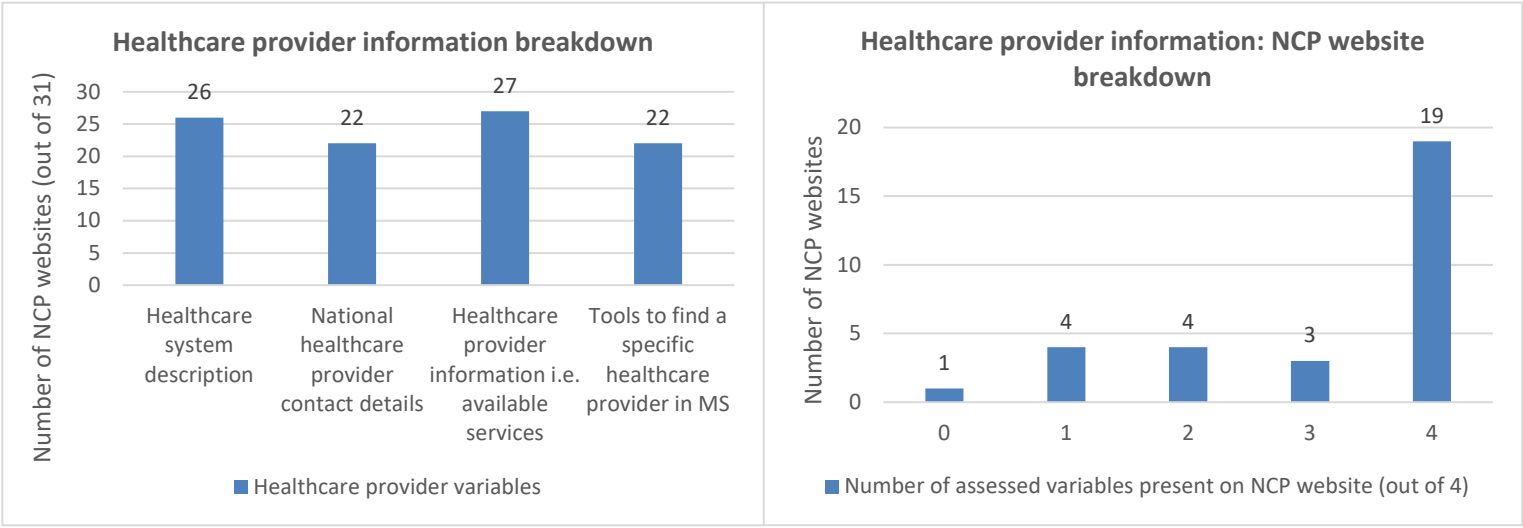
Information on healthcare providers

This category assessed whether websites included a description of the healthcare system, information on healthcare providers, contact details of national healthcare providers and tools to find a specific national healthcare provider in another Member State (MS). Overall, the combined average score of NCPs was 80%, and it was shown that across the board, there was still room for improvement. Given that nine of the assessed NCPs scored 50% or less, five of which scored 25% or lower, it was evident that information provision in this area within some countries was very low. Particular areas for improvements included the provision of contact details of national healthcare providers and the presence of tools to find a specific national healthcare provider in MS. Overall, 19 out of 31 NCP websites scored 100% and were seen as best practice. These included Spain, Austria, Greece, Finland, Czechia and the Swedish website

[18] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf,
[19] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)'. Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf
[20] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients'. Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

for EU citizens. The horizonal axis of the bar charts in Figure 13 show the assessed components. The NCP websites scoring 100% in this area and seen as best practice were found to have all four components present on their website. Those that scored 75% had three out of four components, while those scoring 50% had two of the components, 25% had one and those scoring 0 had none of the assessed components. The first bar chart similar results across the components, while the second shows the variation in NCPs that had one, two, three or four of the assessed components.

Figure 13: Breakdown of presence of healthcare provider information on NCP websites and further breakdown of components per NCP site.

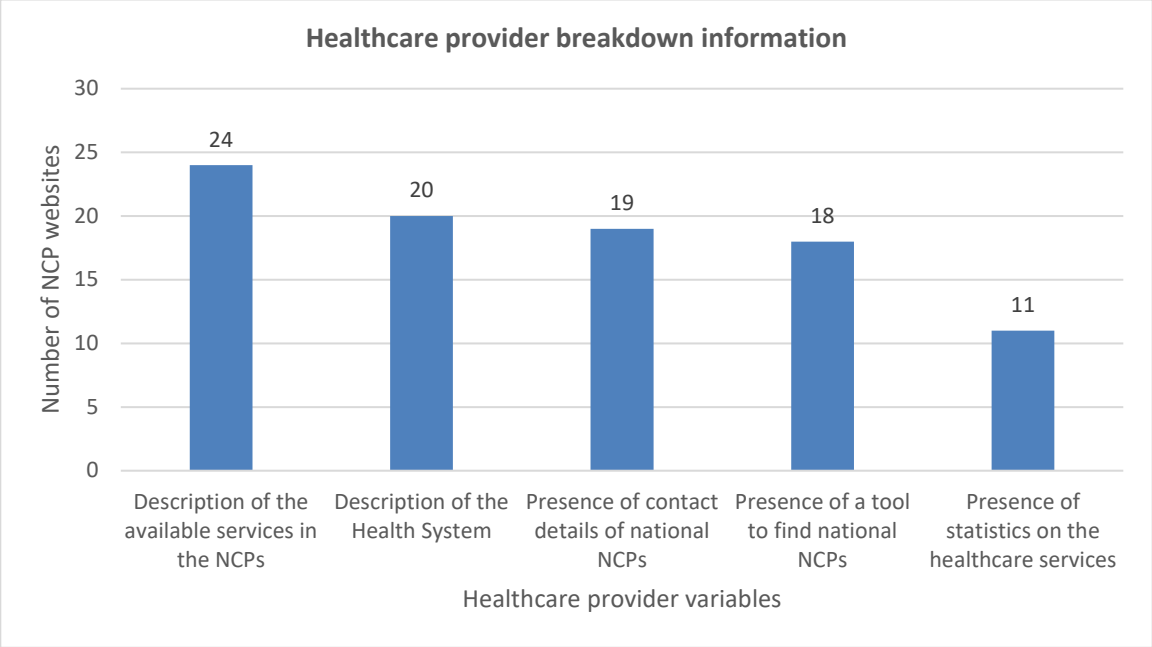


Comparing results to previous studies

When comparing the results from the 2015 Evaluative study[21] and 2018 study by the Commission[22] to the 2021 analysis findings, it seems that information provision on healthcare providers in this area on NCP websites has increased slightly which is positive. A breakdown for each component was not available for the 2018 web analysis, but the increase is reflected through findings such as the inclusion of a tool to find specific heathcare providers in 18 out of 32 websites in 2018 and 22 out of 31 websites in 2021. Nonetheless, a breakdown can be found in the 2015 Web analysis[23] report which shows improvements between 2015 and 2021.

[21] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf
[22] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf
[23] 32 NCP websites were assessed in the 2015 web analysis.

Figure 14: 2015 Web analysis Healthcare provider information breakdown



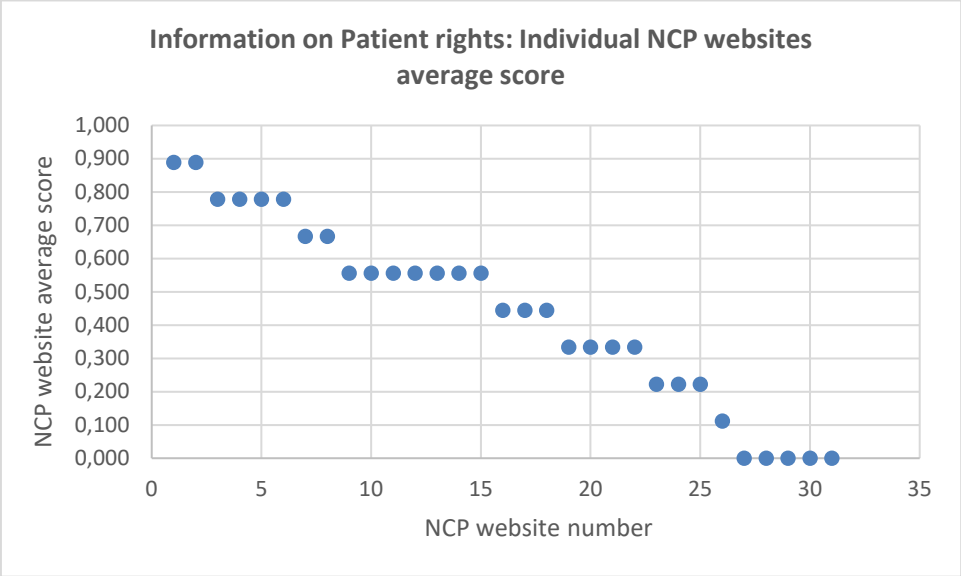
Information on patient rights

The category for patient rights assessed nine components. Components included the presence of information on the patients' rights in cases of harm; information on access to hospitals for patients with disabilities; information on how to access to electronic medical records and Information on rare diseases for patients with a rare disease without references to ERNs (European Reference Networks). Surprisingly, the presence of information on undue delay was only assessed in one instance. All NCPs were assessed on their provision of information on the definition of waiting time.

Overall, the average score for this category was very low at 45%. The data suggested that information on patient rights was generally lacking as only six NCPs scored over 70%, 23 scored 56% or lower, with some countries scoring as low as 22% and 0%. Figure 15 below shows varying average scores achieved by NCP websites. Identified areas of specific concern was information provision on patient's rights in cases of harm and information on complaint procedures. Only 50% of NCPs provided information on both, though a higher number of NCPs provided information on at least one (22 out of 31 provided information on harm and 16 provided information on complaint procedures). Quite detrimentally, none of the websites however were found to provide information on undue delay.

Generally, all websites could be improved; though Latvia and Slovenia were particularly strong websites as they received a score of 89% while France, Belgium, Finland and Malta received a score of 78%.

Figure 15: Average scores achieved by individual NCP websites in relation to Information on Patient rights



Comparing results to previous studies

When comparing the results from the 2015 Evaluative study[24] and 2018 study by the Commission[25] to the 2021 findings, the 2021 analysis shows an improvement between the 2018 and 2021 results as indicated by the increase in the average score for NCPs from 25% to 45%. More similarities in results can be found between the 2021 and 2015 Evaluative study, though it should be noted that the 2015 Evaluative study assessed the National and English websites without distinguishing both versions which may have affected the findings.

Information on prior authorisation

Another important aspect of cross-border healthcare is prior authorisation. Information provision is particularly important in this area given that prior authorisation may be a pre-requisite for patients to receive reimbursement for their healthcare costs, depending on the treatment. Overall, the average score for NCPs was 65%, with only two NCPs scoring 100% and half of the websites scoring 80% or more. Positively, 27 of the 31 websites included information on how to obtain reimbursement and 25 provided information on the importance of prior authorisation for planned healthcare and whether and which treatments require prior authorisation, while 17 provided a specific list of treatments requiring prior authorisation. Just over half (17/31) of the NCP websites provided forms for obtaining reimbursement, though one country within this group was found to only provide this form in the national language. The lowest number of points was in relation to the provision of information on the time period for prior authorisation requests to be dealt with, which is quite important information for patients to know. Overall, Sweden's website for patients abroad and Romania were seen as best practice as they scored 100%.

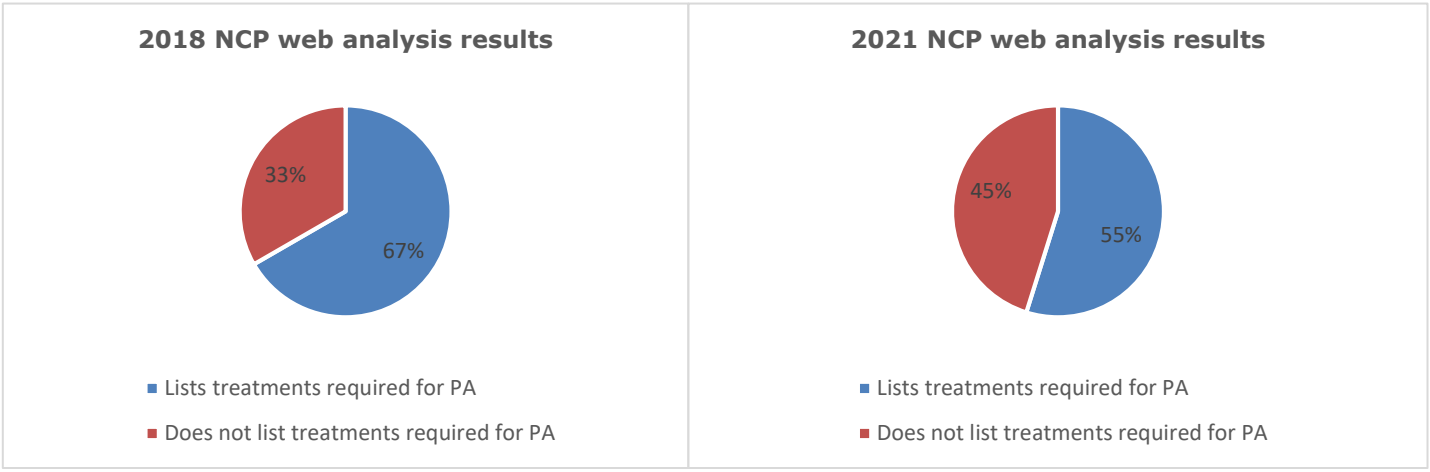
[24] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf

[25] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

Comparing results to previous studies

When comparing the results from the 2015 Evaluative study[26] and 2018 study by the Commission[27] to the 2021 findings, overall there is an improvement in the provision of information on prior authorisation, especially in relation to the provision of information on how to obtain reimbursement. It is worth noting that our web analysis adopted the same methodology as the previous studies which assessed each NCP website regardless of whether or not prior authorisation was applied in the country. There are some countries which, according to Ecorys' 2021 study "clearly have not implemented a PA-system or decided to remove it"[28]; however some still provide information on procedures for obtaining reimbursement and forms for prior authorisation.

Figure 16: 2018 and 2021 web analysis results comparison (prior authorisation treatments)



Information on quality and safety standards

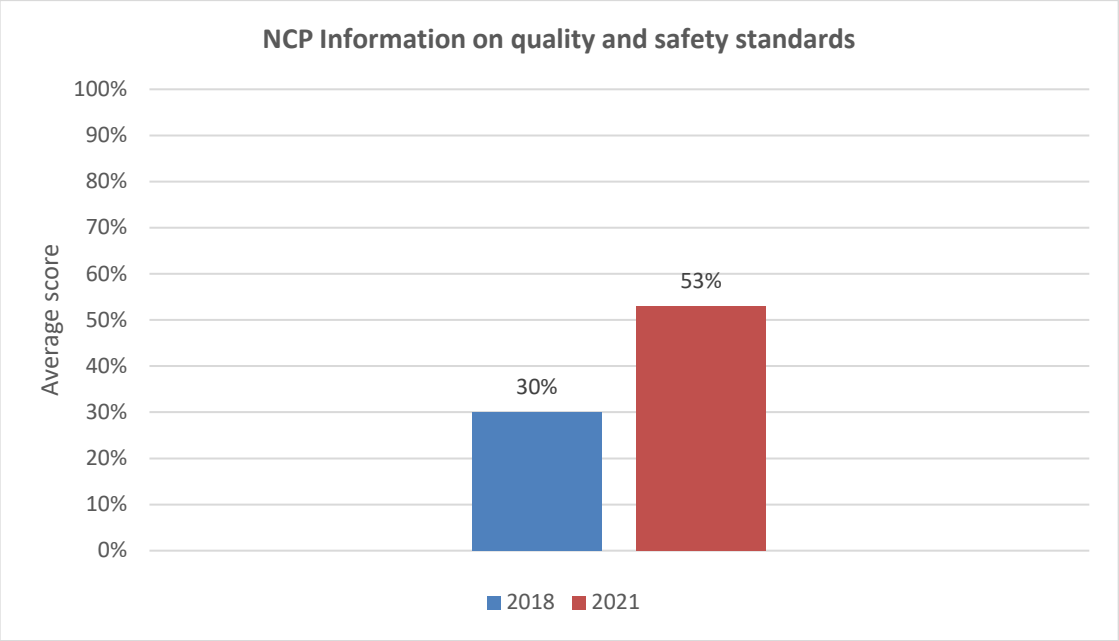
Another key aspect of cross-border healthcare is the maintenance of quality and safety standards and the ability of patients to be informed about the quality and safety standards in another MS in order to make an informed decision. The average score across NCPs was also low at 53%. Large disparities among the scores were found as only 11 NCPs scored over 80%, seven scored 60% while the remaining NCPs scored 40% or lower. It should also be noted that six NCPs scored 0. NCP websites achieving such low scores is particularly concerning given the importance of this category. 30% of the NCP websites did not provide information on national laws, regulations and policies regarding patient safety, and only 10 NCP websites provided information on quality measurements/indicators for healthcare providers. Best practice NCPs for this category were France, Finland, Austria, Latvia and the Netherlands who scored 100% and were found to provide information not only on national quality and safety policies but also quality measurements and indicators.

[26] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf.
[27] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf
[28] Ecorys, Technopolis, (2021). 'Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU'.

Comparing results to previous studies

When comparing the results from the 2015 Evaluative study[29] and 2018 study by the Commission[30] to the 2021 findings, there is an improvement in the provision of information in this area. When comparing average scores achieved in this area between 2018 and 2021, 2021 results show an increase of 23 percentage points as shown in Figure 18 below. It should be noted that though 2021 results were more similar to the 2015 results i.e. the provision of information relating to national laws, these results are most likely due to the lack of differentiation between the national and English website.

Figure 17: 2018 and 2021 NCP website average scores (Quality and safety standards)



Information on the entitlement of reimbursement costs

This category assessed components such as the presence of information on reimbursable and non-reimbursable treatments; information on requirements for the acceptance of invoices/clinical information, and the time period for reimbursement. The average score across NCPs was 37% which was the lowest average score attained on any of the nine categories assessed for the web analysis. A range of scores were attained by the NCPs as though the highest score was 83%, 27 out of 31 websites achieved 50% or less in this category. Furthermore, while 20 of the 31 websites included some information on which treatments could be reimbursed, only four NCPs provided information on non-reimbursable treatments. In addition to this, only 50% provided information on the requirements for the acceptance of invoices or clinical information which is also very key. Information on reimbursement tools and the time period for reimbursement was also scarce. Notable NCP websites in this category were Estonia, Poland and Ireland who scored 83% and provided information on 5 out of 6 of the assessed components. However, improvement is still needed across the board as neither Estonia, Poland nor Ireland provided information on treatments that were non-reimbursable. A

[29] Evaluative study on the cross-border healthcare Directive (2011/24/EU) (2015) Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.pdf.
[30] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

breakdown of the information provided per NCP Website is provided below to illustrate the variation.

Figure 18: NCP Website component breakdown (information on reimbursement)

NCP Website	Assessed information components of SAI Category					
	Reimbursable treatments	Non-reimbursable treatments	Requirements for the acceptance of invoices/clinical information	Time period for reimbursement	Payment tools for reimbursement	Type of tariffs to be applied
1	x					
2	x		x			
3					x	x
4	x		x			
5	x					
6	x	x	x			
7	x		x			x
8	x		x	x	x	x
9						
10			x	x	x	
11	x		x	x		
12	x					x
13	x		x			x
14	x					x
15		x	x	x	x	
16		x	x		x	
17						x
18						
19	x					x
20						
21	x					x
22	x		x			
23	x					
24		x				x

NCP Website	Assessed information components of SAI Category					
	Reimbursable treatments	Non-reimbursable treatments	Requirements for the acceptance of invoices/clinical information	Time period for reimbursement	Payment tools for reimbursement	Type of tariffs to be applied
25	x		x	x	x	x
26	x			x		
27	x					
28			x			
29						
30	x	x				
31			x	x		x

Comparing results to previous studies

When comparing the 2021 analysis results to the 2015 Evaluative study[31] and 2018 study by the Commission[32], there is evidence of slight improvement between 2018 and 2021. Though 2015 Evaluation Studies showed higher scores for NCPs in this area, it is difficult to compare directly with these results because it is unclear whether the findings were based on native or English websites.

Template for web-analysis

For the web-analysis we have adopted the same approach and format used by contractors in 2015, 2018 and the Commission in 2020 (for which the results have not been made public) to conduct a web analysis of NCP websites in each Member state. We will update the findings using the criteria listed below to assess each Member state individually, marking an 'x' where applicable. The web analysis will be aggregated, analysed, and presented as per the 2018 "Study on cross-border health services: enhancing information provision to patients" to assess progress made since the previous web-analysis.

[31] KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU)' Retrieved from: http://ec.europa.eu/health//sites/health/files/cross_border_care/docs/2015_evaluative_study_frep_en.Pdf.
[32] Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.' Retrieved from: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossborder_frep_en.pdf

Table 3: Website analysis criteria

Section 1: Technical elements			Section 2: Accessibility		Section 3: Usability	
• NCP address • Independence of the NCP's website address. • Presence of background information about the website (e.g. organisation responsible for the website).	• Presence of other communication channels (e.g., live pop-up chat and social media such as Twitter and Facebook). • Presence of contact details of other NCPs.	• Presence of e-mail address. • Presence of the office address. • Presence of telephone numbers. • Date of the last update of the website.	• Order in search (Google) for: • "NCP + the name of the MS" • Order in search (Google) for: • "NCP + healthcare + the name of the MS"	• Ease of opening the website (accessibility). • Language • Availability of options for people with decreased sensory functioning • By clicking EU DG SANTE NCP's contact list, it opens: Same address, other address, Page not found	• Presence of most visited pages • Presence of frequently asked questions. • Presence of internal search engine. • Media Library containing video's regarding cross-border healthcare.	• Visual appeal and layout (scored on the use of menus, (sub)headings, illustrations, and overall attractiveness).

Section 4: Completeness of content – General information			Section 5: Healthcare providers		Section 6: Patients rights		
• Information for inbound patients under the EU Regulation 883/2004 and the EU Directive 2011/24.	• Information that clarifies the differences between EU Regulation 883/2004 and the EU Directive 2011/24. • Information on patients' rights regarding cross-border care. • Information for outbound patients under the EU Regulation 883/2004 and the EU Directive 2011/24.		• Presence of a description of the Health system. • Presence of information (e.g., available services) of	• Presence of tools to find a specific national healthcare provider in MS • Contact details of national healthcare providers.	• Presence of information on the definition of waiting time • Presence of information on patients' rights in case where the patient	• Information on rare diseases for patients with a rare disease without references to ERNs (European Reference Networks).	• Presence of information on how to access to electronic medical records • Presence of information on mechanisms to settle

			healthcare providers. .		was not able to wait for the decision of the competent institution on the application for prior-authorisation, for reasons relating to his or her state of health or to the need to receive urgent treatment	• Information on ERNs for patients with a rare disease. • Presence of information on complaint procedures in case of follow up treatment issues.	disputes (e.g. reimbursement issues) • Presence of information of patients' rights in case of harm • Presence of information on access to hospitals for patients with disabilities
Section 7: Prior authorisation			**Section 8: Quality and safety standards**		**Section 9: Entitlements for reimbursement of costs**		
• Presence of information on whether and which treatments require prior authorisation. Presence of information that prior authorisation is always necessary for planned	• Presence of list of treatments requiring prior authorisation. • Presence of information on procedures to obtain the reimbursement	• Providing forms for prior authorisation requests • Presence of information on time period for requests to be dealt with	• Presence of information on national laws, regulations, policies regarding patient safety. • Information on medical certifications and	• Presence of information on compliance checks and regulatory activity with respect to quality and safety standards (e.g. hospital inspection bodies, etc). • Information on quality measurements/indicators for healthcare providers	• Presence of information on which treatments are reimbursed • Presence of information on which treatments are not reimbursed	• Presence of requirements for the acceptance of invoices/clinical information • Presence of information on time period for reimbursement	• Presence of information regarding payment tools for reimbursement • Presence of information on type of tariffs to be applied • Presence of information

healthcare under the Regulation.	• Presence of information on procedures to obtain the prior authorisation under the Regulation and the Directive	qualifications required by the national healthcare system.		on the national quality strategy.

Annex 6: Cost-benefit assessment

Introduction

This annex compares the costs and benefits of the Directive using quantitative and qualitative data sources available to the evaluation. It contributes to evaluating efficiency of the intervention and informing considerations on effectiveness and EU added value. Another aim is to compare the most recent data available to the predictions of the 2008 Impact Assessment where a full Cost-Benefit Analysis (CBA) of policy options was carried out by the European Commission.

Methodology

The assessment was dependent on the cost-related data that was possible to collect as part of the desk research and field research activities. The types of costs attempted to assess include:

Table 4: Typology of costs assessed

Type of cost	Definition
Patients	
Non-reimbursable costs	Cost for the patients of accessing cross-border healthcare that are not reimbursed by the home Member States health system/ health insurer. These costs include both the part of cross-border healthcare treatment cost not covered by the home MS, as well as co-payments and travel and subsistence while getting treatment abroad.
Administrative burden for patients	Costs for patients to find information on cross-border healthcare rights, or incurred because of lack of awareness. Costs incurred due to lack of awareness of patient mobility rights (reimbursement not claimed, reimbursement claims rejected, delays in obtaining reimbursements, benefits-in-kind under EHIC refused by healthcare providers and up-front payment required, full reimbursement based on the Regulations on social security coordination regulation refused and only (a lower level) reimbursement under the Directive granted)
Member States	
Treatment costs	Costs arising from treatment being provided in another MS. Costs incurred due to the payment for the treatment being anticipated in time to the point of treatment abroad. Reimbursements to patients are not costs of the Directive as the cost of treatment is borne by the MS for treatment provided at home or abroad. However, treatment provided at home is subject to waiting lists. Therefore, in case of treatment provided abroad, MS need to anticipate the payment in time as patients access treatment abroad *before* they would have been able to do in the home MS. This creates an opportunity cost for MS quantified as the (theoretical) interest paid for anticipating the funds.
Compliance costs	Cost of implementing necessary systems to administer cross-border healthcare Compliance cost include the costs of estimating the cost of treatment provided domestically, making reimbursements, prior authorisations, and monitoring and continuity of care.
Administrative costs	Costs incurred in meeting legal obligations to provide information

Type of cost	Definition
	Administrative cost is the cost of setting up and running NCPs, including websites, brochures, information centres and human resources.
European Commission	
Funding cost and implementation costs for ERNs	Set-up cost and annual allocations, as well as funding for projects such as the ERN clinical practice guidelines and ERN professional mobility programme Cost of supporting implementation of the Directive These include costs of coordination, consultation, information exchange, monitoring, evaluation and enforcement
Centres of expertise and healthcare providers included in ERNs	
Compliance and administrative costs of ERNs	These include co-funding and indirect and hidden costs that centres of expertise and healthcare providers bear in their engagement with ERNs

The types of benefits the study team attempted to assess include:

- **Treatment benefits**: these are benefits from cross-border healthcare through treatments being provided more quickly, measuring health improvements based on the number of patients accessing healthcare treatment in another MS through the Directive and the type of the treatment (estimated based on the cost of the treatments reimbursed).

- **Patient benefits**: measured as improved experience, increased knowledge and awareness, simplification, support, quicker and cheaper access to care, speed of and satisfaction with reimbursement process and continuity of care.

- **Social benefits** in terms of different impacts for different social groups. Socio-economic inequalities in health care can arise through multiple channels, including unequal knowledge of own health needs and skills in understanding what treatment options and healthcare pathways are available. The 2008 Impact Assessment predicted that "by increasing legal clarity and availability of information concerning the possibilities of cross-border healthcare to a wider public, these inequalities would be reduced". In other words, the directive would be expected to have disproportionate benefits on disadvantaged socio-economic groups, leading to greater empowerment of patients.

- **Benefits for rare and complex diseases community**: improved diagnoses / consultations; reductions in time to diagnosis; benefits of knowledge creation, knowledge sharing and collaboration; staff training improved health outcomes; cost-savings due to virtual consultation; improved research and innovation due to pooling of knowledge and data on rare diseases patients.

- **Other benefits for Member States:** cooperation, lessons learning, shared good practices, more efficient use of health system capacity and resources in MS and across EU. The 2008 Impact Assessment identified multiple channels through which the Directive could overall improve or in fact worsen the functioning of health systems and overall quality of care across MS:

- Enhanced cooperation on healthcare.
- Lessons learning and sharing of good practices across MS through concrete comparisons and demonstration.
- Higher utilisation of resources in receiving countries and economies of scale for receiving health institutes. The possible downside for receiving countries is excessive pressure on already strained health systems affecting domestic provision; we will aim to assess the likely direction of this effect qualitatively, based on stakeholders' perceptions and any available literature.
- Choice for patients incentivising domestic health systems to adapt and improve capacity to meet demand (particularly if they risk losing patients and access to funding where patients decide to be treated abroad). The 2008 Impact Assessment envisioned this mechanism as one of the potential benefits of the Directive, but benefits were not estimated. We will collect any available qualitative evidence and literature for this mechanism, keeping in mind that it is unlikely that data will have been collected systematically.

In the assessment of costs and benefits, the following comparative analyses are provided:

- Administrative and financial costs compared to the baseline scenario costs for the preferred option estimated in the 2008 Impact Assessment to determine how the actual implementation costs compare to the expected costs.[2]
- Assessment of the identified costs in comparison to the benefits. The type of analysis is mainly qualitative due to the general unavailability of quantitative data. Reference costs have been provided when those have been identified to give an indication of their magnitude and allow for comparison.
- Factors that influence the costs and benefits.
- Costs and benefits by stakeholder group and qualitative analysis on degree of proportionality of costs and benefits by stakeholder group. The assessment, is mostly qualitative, paying particular attention to costs and benefits to patients, including:
  - improved awareness about ERNs, including access to care, usefulness of communication channels established by NCPs, and potential reach of HCPs and patients;
  - access to information, by different socio-economic groups and effectiveness of support to take up opportunities;
  - administrative waiting time and costs for patients to access the planned healthcare and receive the reimbursements.

[2] These were EUR 30.4 million per year in treatment costs, EUR 315 million per year in compliance cost, EUR 60 million per year in specific administrative burden

Efficiency indicators

In May 2021, the contractors carrying out the parallel study on enhancing the implementation of the Directive, organised a stakeholder workshop to present the Directive's intervention logic and, with the input from participants, select the most appropriate indicators to evaluate it considering their relevance and feasibility. According to the analytical report that followed the study, when considering indicators covering costs and benefits of the system, it is important to bear in mind that, while the various costs are usually paid upfront, benefits accrue over many years and often more challenging to monetise. Based on the workshop discussions, the following indicators were retained:

- **Qualitative indicators include the perception of:**
  - administrative burden on patients, HCPs and healthcare insurance bodies;
  - balance of costs and benefits of setting up the ERN system by stakeholder group;
  - level of resources provided by MS to national ERN members;
  - level of resources provided by the EC to Coordinators Group, ERN coordinators and Board of Member States;
  - balance of costs and benefits of setting up the ERN system (e.g. CPMS, website, translation costs);
  - benefits of earlier diagnosis and access to treatment in patients' quality of life;
  - benefits of wider expertise available from experts participating in virtual consultation;
  - costs and benefits ratio versus traditional model.

- **Quantitative indicators** include:
  - administrative waiting times to process (i.e. processing times) requests for (i) prior authorisation and (ii) reimbursements;
  - administrative costs for handling applications for prior authorisation and reimbursement (low feasibility);
  - number of patient complaints about administrative procedures (low feasibility).

All the above indicators have been considered in the assessment of efficiciency and in the present cost-benefit assessment (please refer to Annex I, EQM) but, as predicted, it was challenging for the study team to support the assessment with quantitative data.

An overview of the evidence available against all benefits and cost categories is shown in the Table 4 below.

Limitations

The methodology is largely qualitative due to several limitations with the quantitative data:

- There is a lack of systematic data on the Directive, particularly on the cost side. As a result of this it has not been possible to replicate the CBA calculations for a full comparison of (monetised) costs and benefits with the 2008 Impact Assessment. The main sources of quantitative data are the annual Member State data on cross-border patient healthcare reports compiled by the European Commission. These include important evidence such as the number of patients mobility cases using the Directive annually, however there are significant gaps, inconsistencies in definitions used, and discrepancies in reporting by Member States. Cost data from Member States that would allow to estimate their cost of compliance with the Directive and the administrative burden are not collected in a centralised and easy-to-compare way. This evaluation has used quantitative, non-monetary data available to interrogate assumptions in the CBA and make new transparent assumptions where useful to draw comparisons and insights.

- The literature reviewed offers limited insights into the quantification or estimation of Directive benefits and costs, particularly at an aggregate EU level.

- The 2008 Impact Assessment's CBA could not quantify or monetise all the recognised benefits and costs, for example any effects on healthcare inequality which do not lend themselves to quantification or monetisation. It also could not consider some cost and benefit categories, including the non-reimbursable costs and the administrative burden borne by patients and the cost of supporting implementation of the Directive or funding costs for ERNs by the members of the networks and Member States. This evaluation has filled these gaps with quantitative and qualitative evidence available.

- The evaluation did not aim to isolate the impact of the Directive from the multiple factors simultaneously affecting the observed outcomes and quantitatively estimate effects of the Directive. As such the quantitative data available cannot be deemed 'additional' to the Directive.

Takeaways of the Cost Benefit Assessment

The **total health benefits of the Directive for patients are likely to be minor** due to limited cross-border patients' flow. The study team estimates that around 330,000 EU citizens may be using the Directive annually to access healthcare abroad, a lower number than the 780,000 people predicted in the 2008 Impact Assessment.[33,34] It had been assumed that 10% of EU citizens on a waiting list for

[33] Wilson, P, Andoulsi, I, Wilson, C (2021) *Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.*

[34] While 250,000 mobility cases were officially reported by Member States for 2019, there are data gaps from several large EU countries including Germany, which might lead to an undercounting of cases. We adjust this figure by imputing missing data with the average rate the average rates of reimbursements and prior authorisations per 100,000 people from countries with available data. This is equivalent to assuming that countries with missing data have the same rate of cross-border patients per population as the average of the other countries. The resulting number is not adjusted for other factors such as age composition or regional border areas and is therefore not necessarily accurate. It is nonetheless useful to compare with the EU-wide estimates of the Impact Assessment.

a procedure in their home MS would access healthcare abroad through the Directive annually, however in reality only less than 1% did.[35] Other data sources including interviews and the literature reviewed concur that cross-border patients' flow have been more modest than anticipated (see EQ2). However, the number of cross-border patients is already higher annually than the 2008 Impact Assessment had expected in the scenario in which no Community action had been taken (195,000 people in the 'do-nothing' scenario).

Whilst there is no systematic data on the types of cross-border treatments, the available evidence points to **the Directive being mainly used for lower value treatments**. The use of the prior authorisation regimes introduced in 21 countries[36] has been low – only about 7,000 requests per year, against 280,000 requests for reimbursements post-treatment.[37] In addition, the average reimbursed amounts to patients including prior authorisations across all reported cases in 2019 was EUR 367. This low cost of procedures per case suggests the Directive might be used primarily to reimburse lower value treatments. Indeed, dental care and ophthalmologic care appear to be common treatments in at least two countries.[38] In contrast, the 2008 Impact Assessment had taken an implied average cost per case of EUR 3,900. Specifically, it had predicted that more expensive hospital care (EUR 7,000 cost per case), for example a hip replacement, would make up 50% of cases, with the other 50% due to less expensive non-hospital care (EUR 800 cost per case), for example an eye surgery. The health benefits per case are therefore likely to be lower than it had been anticipated.

The Directive has contributed to expanding and clarifying patients' rights to cross-border healthcare, however **significant knowledge and information gaps remain among EU citizens**. The recent Eurobarometer of July 2021 has showed that only 25% of EU citizens are "well informed" about healthcare rights in another EU country, 8 percentage points more than in 2014. Insufficient awareness of healthcare providers and treatment options as well as their prices, waiting times and quality in other EU countries is a persisting constraint facing patients (see EQ3 and EQ4). As such healthcare choice is still likely stifled by limited knowledge and the benefits of the Directive for patients have likely not been fully realised yet.

Due to the limited cross-border patients' flow, **stakeholders believe the impact of the Directive on domestic healthcare systems has been minor** (see EQ16). As such, the Directive might not yet have improved the efficiency of healthcare provision across the EU that was hoped for in the 2008 Impact Assessment. However, most data sources agree that the Directive has enhanced cross-border cooperation in healthcare between neighbouring countries and border regions, specifically through the support to studies and workshops (see EQ8 and EQ31). Stakeholders have suggested that patients living in EU border regions have particularly benefitted from the Directive (see EQ10).

[35] Calculated from the total number of annual patients using the Directive as share of EU citizens on a waiting list. Data on EU population and share of citizens on waiting list for healthcare procedures are from Eurostat.
[36] Ecorys, Technopolis (2021) *Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (unpublished)*
[37] Wilson, P, Andoulsi, I, Wilson, C (2021) *Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.*
[38] Denmark and Poland. See CBA table below for details.

There are several channels through which the Directive might have affected inequality in the access to healthcare. Several studies have pointed out that the need for the patients to pay for treatment upfront, prior to receiving it as set out in the Directive, puts citizens from poorer economic backgrounds at a disadvantage (EQ10). Further, the Directive's requirement that Members States should only reimburse the cost of the procedure in the Member State of affiliation puts at a disadvantage the citizens of countries with lower tariffs for medical treatment, such as Eastern European countries. These patients would have to pay for the difference in cost between the two Members State of affiliation and the receiving Member State. Finally, through the Directive, better-off patients are also better able to access treatments abroad that are not yet available in their home MS or that are provided after long waiting times (see EQ16). In contrast, the 2008 Impact Assessment had predicted that the legal certainty of reimbursement provided by the Directive would compensate, at least in part, for any adverse effect on inequality and be an improvement against the 'do-nothing' scenario. In reality, **because the patients' flows have been limited, the net effect of the Directive on inequality might have been negligible**.

In terms of the costs of the Directive, data are not sufficient to calculate or estimate aggregate costs across different cost categories. However, **from the perspective of Member States, the treatment costs, compliance costs and administrative burden have likely been minor**. Treatment costs for Member States, or the opportunity cost of anticipating the cost of treatment because of patients' use of healthcare options in another country, might have been only EUR 920,000 annually as compared to the EUR 30.4 million estimated by the 2008 Impact Assessment due to the low reimbursement amounts made. It had also been estimated that compliance with the Directive would cost EUR 315 million annually to Member States, a figure that was based the assumption that cross-border healthcare would represent 1% of total national government expenditure on healthcare. However, in reality the share of cross-border healthcare (under the Directive) on the total has been only a 0.01%.[39] As a result, compliance costs have been minor and as low as EUR 6 million annually. Interviews with Member States confirmed administrations have not faced significant financial or resource implications from the need to comply with the Directive, which results for example in cost of estimating cost of treatment provided domestically or managing reimbursements and prior authorisation regimes. Finally, the administrative burden—defined in an EU context as the cost incurred in meeting legal obligations to provide information—have also reportedly been marginal as the volume of information requests by citizens to NCPs have been minor across all countries. In most countries, NCPs employ one to three full-time staff, with one country reporting six staff are needed to cope with volume of requests.

In contrast, **the costs borne by citizens for using the Directive are likely to be substantial**. Specifically, patients have faced high cost of travelling and receiving treatment abroad. For example, a trip for one person from Sofia to Dublin could cost EUR 927 inclusive of return flight ticket and accommodation and subsistence for two days/nights. Patients have also been exposed to the risk that their Member State of affiliation or insurer might not reimburse them or might reimburse only in part. These 'non-reimbursable' costs represent a financial barrier for many citizens to access cross-border healthcare, which suggests they

[39] 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*.' Report for the European Commission.

are significant (see EQ2). In addition, patients have also incurred in an administrative burden. For example, mobility case processing times by Member States administrations are rather long (about 42 days on average for prior authorisation requests and 56 days for mobility reimbursements).[40] Also over 10% of all claims are refused, while complex prior authorisations procedures are also creating significant administrative difficulties (see EQ21). It must be noted that these costs for patients were not fully anticipated or quantified in the 2008 Impact Assessment.

The ERNs have started to generate benefits for patients with rare and complex diseases, particularly through the intermediate outcomes of better diagnosis and understanding of treatment options available by healthcare providers (see EQ11). Important strides have also been made with exchange of knowledge and best practice among ERN members and generation of knowledge through new research (pooling of expertise and pooling of patients) (see EQ12 and EQ13). The European Commission has contributed funding for EUR 31.8 million over 5 years to ERNs as well as grants totalling EUR 20.9 million.[41] The ERN coordinating centres have also committed 40% of the funding. For ERN members there have also been hidden, non-quantifiable costs arising from time spent by staff from time spent by ERN members managing and administering ERN activities (see EQ18 and EQ21). Assuming a hidden cost of EUR 130 for each of the 2,166 virtual panels delivered through ERNs, the total hidden cost of virtual panels is estimated at EUR 280,000.[42]

[40] Wilson, P, Andoulsi, I, Wilson, C (2021) *Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.* Retrieved from: 2019_msdata_en.pdf (europa.eu)
[41] European Court of Auditors (2019) *Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required*. Retrieved from: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=49945
[42] See details of the calculations in the CBA table below.

Table 5: Overview of the Costs and Benefits of the Directive

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
Patients			
Treatment benefits Health benefits for patients accessing cross-border healthcare treatments through the Directive. The total benefits depend on the number of patients using the Directive, the types of treatment received, the relative speed of treatment and quality of care in the receiving MS against the home MS.	*Directive scenario:* 780,000 patients (of which 390,000 hospital care and 390,000 non-hospital care) 3 months earlier treatment received on average in receiving MS against home MS EUR 7,000 average cost of treatment abroad for hospital care EUR 800 average cost of treatment abroad for non-hospital care EUR 585 million in total benefits 10% of citizens on a waiting list will access cross-border healthcare through the Directive 1.6% of EU citizens are on a waiting list *Do-nothing scenario:* 195,000 patients	329,589 authorised or reimbursed patient mobility cases estimated across 30 countries (250,869 (5,637 subject to PA + 245,232 not subject to PA) official cases reported with data gaps for 14 countries; missing data has been imputed using the average rates of reimbursements and prior authorisations per 100,000 people from countries with available data; population data has been retrieved from Eurostat) EUR 367 average reimbursement per mobility case calculated as total reimbursement divided by number of approved mobility cases (proxy of treatment type). According to the literature reviewed common treatments are: • Dental care (e.g. Denmark reported that dental care made up 84% of reimbursements in 2019). • Ophthalmologic care (e.g. between November 2014 and March 2015 the Polish NHF received 777 applications for reimbursement of medical expenses abroad amounting to approximately EUR 950 000, of which 81% were for cataract surgery.) Upward trend in number of patients from 2015 to 2018	Moderate contribution to removing obstacles to healthcare in another MS, but limitations remain for patients e.g., upfront payment of treatment cost and lack of information on patients' rights (see EQ2) Disproportionate benefits for patients living in border regions (see EQ31)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
	EUR 98 million in total benefits	Less than 1% of citizens on a waiting list accesses cross-border healthcare through the Directive annually 0.9% of citizens are on a waiting list annually No systematic data available on procedures waiting times across MS Source: elaboration from 2019 Member State Data on cross-border patient healthcare and Eurostat (European Union Statistics on Income and Living Conditions)	
Patient benefits Extent to which the implementation of the Directive address patients' needs to access healthcare. The benefits include knowledge and awareness of patients' rights, greater choice of healthcare options, quality and extent of support received from NCPs, speed and ease of accessing care, speed and ease of	Not estimated/quantified	25% of people in the EU 'well informed' about healthcare rights in another EU country (+8 percentage points against 2014) 72% of people in the EU 'not well informed' about healthcare rights in another EU country (-6 percentage points against 2014) Source: European Commission, Eurobarometer 95, 2021	Moderate contribution to improving patients' knowledge of patients' rights, but significant information gaps remain e.g., on healthcare providers and treatment options in another EU country and their costs/prices, waiting times and quality. Also limited knowledge of NCPs among citizens/patients (see EQ3 and EQ4). Administrative issues pertaining to reimbursement, procedures to access care, prior authorisation also perceived as impediments (see EQ3)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
getting reimbursements, extent of continuity of care, and overall satisfaction with cross-border healthcare.			Patients are overall satisfied with the quality of care received abroad (see EQ4) Most NCPs developed an independent website to cater to the needs of citizens seeking information on cross-border healthcare. Accesibility of the website was scored high (70% across all NCPs). Content and completeness; usability; and information on healthcare providers received average scores of above 80%. However, NCPs' websites scored low in terms provision of information on: patients' rights (45%)' prior authoristaion (65%), quality and safety standards (53%), and reimbursement (37%) Source: Web analysis – Annex 5) In several Member States the Directive has acted as a driver for the development of patients' rights, greater domestic transparency, introduction or adaptation of mandatory professional liability insurance, and implementation of quality indicators and standards (EQ 16)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
Social benefits Extent to which the Directive reduces inequalities in access to healthcare.	Not quantifiable. Predicted to be positive on balance. The Impact Assessment anticipated that people in higher socio-economic groups would enjoy greater ability to take advantage of free movement principles given cost of treatment needs to be anticipated by patients; however, the legal certainty of reimbursement was expected to compensate at least in part for this inequality. Specifically, legal certainty should improve equity of cross-border healthcare against the do-nothing scenario.	[No available data]	Overall the social impacts of the Directive have likely been mixed (some positive and some negative) Limited evidence on healthcare inequality (see EQ10) Some studies pointed to patients from countries with lower tariffs for medical treatment such as Eastern European countries to be at a disadvantage vis-à-vis patients from the other countries due to cost difference to be paid. Less mobile patients such as people with disabilities are also at a relative disadvantage. Patients can access treatments abroad that are available in their home MS but are provided after long waiting times(see EQ16). Interviews pointed to disproportionate benefits for patients' sub-groups including patients with rare diseases, patients living in border regions, patients with some specific conditions e.g., patients with urgent needs to get treatment that could not use the Social

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
			Security coordination regulations (EQ10)
Benefits of ERNs Health and other benefits for patients from the ERNs. These include improved and quicker diagnoses and consultations through ERNs as well as knowledge generation and sharing.	Not implemented at the time of the impact assessment	**Contribution to clinical care** 1.67 million patients being treated by ERN members (potential beneficiaries) 2,100 cases assessed in virtual consultations in the CPMS Source: European Commission 2021, Minutes of Board of Member States meeting on ERNs **Research and knowledge generation in 2020** 732 clinical trials within the ERN (compared to 389 in 2018); 162 new clinical practice guidelines written by the ERN (compared to 2 in 2018); and 143 Clinical Decision Making Tool (compared to 30 in 2018) 405 observational prospective studies within the ERN (compared to 113 in 2018; and 1243 accepted peer-reviewed publications in scientific journals regarding diseases within the scope of the ERN and which acknowledge the ERN reviewed publications	Early evidence of health benefits for patients with rare and complex diseases; likely to be relatively more effective in countries with insufficient number of patients or lacking technology or expertise (see EQ11) Recognised contribution of ERNs to healthcare providers, particularly in terms of better diagnosis and understanding of treatment options (see EQ11) Significant progress achieved with exchange of knowledge and best practice among ERN members and generation of knowledge through new research (pooling of expertise and pooling of patients) (see EQ12 and EQ13)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
		Knowledge sharing in 2020 1183 congresses/ conferences/ meetings at which the ERN activities and results were presented (compared to 948 in 2018) 1,044,949 individual ERN website hits (compared to 413,232 in 2018) Source: ERNs monitoring data Increse in the number of ERN members (to almost 1,500 ERN units by January 2022) extending the possibility for patients with rare and low prevalence as well as complex diseases and conditions to access highly specialised healthcare. Source: DG SANTE, Europa	
Non-reimbursable costs Cost for the patients of accessing cross-border healthcare that are not reimbursed by the home Member States health system/ healthinsurer.[43]	Not considered	Benchmarks for the unit cost of travelling to access cross-border healthcare (unit considered: 1 return flights, 2 days of accommodation and subsistence in the country of treatment): EUR 631 for a trip from France to Spain (Paris to Madrid) EUR 927 for a trip from Bulgaria to Ireland (Sofia to Dublin)	High costs of travelling and receiving treatment abroad, as well as cost of paying upfront for treatment with ensuing risks of non-reimbursement (see EQ2, EQ17) Most patients in countries with lower tariffs for medical services (cannot afford treatment abroadwhere tariffs are higher as

[43] Some Member States, such as Portugal, do include other expenses in the patients' entitlement for reimbursement

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
These costs include both the part of cross-border healthcare treatment cost not covered by the home MS, as well as co-payments and travel and subsistence while getting treatment abroad.		Calculations using unit costs of return flights, accommodation and subsistence from the EC guidance on fees reimbursable for travels of staff and consultants; available at: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/unit-cost-decision-travel_en.pdf	they are reimbursed their home tariffs and have to cover the difference
Administrative burden for patients Costs for patients to find information on cross-border healthcare rights, or incurred because of lack of awareness. Costs incurred due to lack of awareness of patient mobility rights (reimbursement not claimed, reimbursement claims rejected, delays in obtaining reimbursements,	Not considered	Cross-border reimbursements (without prior authorisation) average processing time: 56 days Prior authorisation average processing time: 42 days (9 countries have not introduced prior authorisation) There are substantial variations both across MS and between patients depending on the nature and circumstances of the case 16% of prior authorisation requests refused (1,131) 11% of reimbursement requests refused (33,367) Source: 2019 Member State Data on cross-border patient healthcare	Significant administrative difficulties identified such as complex administrative procedures for prior authorisation, uncertainty about reimbursable amounts (see EQ21) Time and cost implications of significant information gaps for example lack of understanding of what medical treatments are included in their home MS basket of care, lack of information on cost/prices abroad (see EQ2)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
benefits-in-kind under EHIC refused by healthcare providers and up-front payment required, full reimbursement based on the Regulations on social security coordination regulation refused and only (a lower level) reimbursement under the Directive granted)			
Public authorities of the MS (including public insurers)			
Treatment costs Costs arising from treatment being provided in another MS. Costs incurred due to the payment for the treatment being anticipated in time to the point of treatment abroad. Reimbursements to patients are not costs of the	*Directive scenario:* EUR 30.4 million calculated as the opportunity cost of anticipating the cost of treatment provided in another MS *Do-nothing scenario:* EUR 1.6 million	EUR 920,000 calculated as 1% of EUR 92 million total reimbursements reported by MS (4% annual interest rate * 0.25 years payment anticipated) Source: elaboration from 2019 Member State Data on cross-border patient healthcare	Marginal impact on MS national health budgets (see EQ17)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
Directive as the cost of treatment is borne by the MS for treatment provided at home or abroad. However, treatment provided at hom is subject to waiting lists. Therefore, in case of treatment provided abroad, MS need to anticipate the payment in time as patients access treatment abroad *before* they would have been able to do in the home MS. This creates an opportunity cost for MS quantified as the (theoretical) interest paid for anticipating the funds.			
Compliance costs Cost of implementing necessary systems to administer cross-border healthcare Compliance cost include the costs of	*Directive scenario:* EUR 315 million calculated as a reduction of cost of compliance against do-nothing scenario (from 5% to 3% of total healthcare costs) + EUR 15m due to higher	EUR 6 million estimated as a fixed rate (5%) of total reimbursements made by MS through the Directive, using the estimated number of annual cases (329,589) and the average amount reimbursed per case (EUR 367) Source: elaboration from 2019 Member State Data on cross-border patient healthcare	Compliance costs are considered minor by MS (see EQ20)

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
estimating the cost of treatment provided domestically, making reimbursements, prior authorisations, and monitoring and continuity of care.	cost of hospital care *Do-nothing scenario:* EUR 500 million Cross-border healthcare was assumed to be responsible for 1% of total national government expenditure on healthcare across the EU	Cross-border healthcare accessed through the Directive is estimated to be responsible for 0.01% of total national government expenditure Source: 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.' Report for the European Commission.	
Administrative cost Cost incurred in meeting legal obligations to provide information Administrative cost is the cost of setting up and running NCPs, including websites, brochures, information centres and human resources.	*Directive scenario:* EUR 60 million calculated as a reduction of administrative burden against do-nothing scenario *Do-nothing scenario:* EUR 100 million	[No available data]	Estimated to be minor by MS; most NCPs have between one and three full-time equivalent staff [1], while one MS reported to have six staff running an NCP to cope with the volume of information requests and processing of claim Source: [1] Ecorys, KU Leuven and GfK Belgium (2018) Study on cross-border health services: enhancing information provision to patients. [2] Interviews.
Indirect benefits and costs for MS health systems Indirect benefits and	Not quantifiable	[No available data]	Cross-border cooperation in healthcare enhanced between neighbouring countries and border regions through Community

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
costs of the Directive for MS health systems These include enhanced cooperation on healthcare, lessons learning and sharing of good practices across MS, efficiencies in healthcare provision across MS such as economies of scale, reduced pressure on health systems from cross-border flow of patients		Money saved from avoiding misdiagnosis of rare disease patients thanks to ERNs? E.g. 2 million EUR for kidney disease	action such as support to studies and workshops (see EQ8 and EQ31) Efficiency gains deriving from cross-border healthcare are minor; in the same vein, cross-border healthcare has not increased pressure on domestic healthcare provision of receiving MS (see EQ16)
European Commission			
Funding cost and implementation costs for ERNs Set-up cost and annual allocations, as well as funding for projects such as the ERN clinical practice guidelines and ERN professional mobility programme	Not estimated as ERNs had not been established at the time of the IA	EUR 52.68 million in funding between 2017 and 2020	Considerable amounts invested mainly on the development of ERN tools, especially the CPMS

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
Cost of supporting implementation of the Directive These include costs of coordination, consultation, information exchange, monitoring, evaluation and enforcement			
Benefits of cross-border healthcare Longer term benefits of cross-border healthcare in the EU	Not quantifiable The Impact Assessment predicted that the Directive, and Community action on cross-border healthcare, would contribute to the growth, competitiveness and cohesion of the Union as a whole.	Not quantifiable	No data available
Centres of expertise and healthcare providers included in ERNs			
Compliance and administrative costs of ERNs These include co-funding and indirect and hidden costs	Not considered	Estimate cost of at least EUR 19.9 million in co-funding between 2017 and 2020 Estimate hidden cost of virtual panels falling on ERN members of EUR 280,000, assuming that 4 highly specialised professionals meet for 30 minutes for each of the 2,166 consultations	40% co-funding contributed by the coordinating centres Considerable hidden costs arising from time spent by ERN members' staff managing and administering

Cost-benefit category	Impact Assessment 2008 *(forecasts per annum)*	Quantitative/monetary data *(annual, latest year available)*	Qualitative data *(based on public consultation data, interviews, and literature reviews)*
that centres of expertise and healthcare providers bear in their engagement with ERNs		provided by ERNs until November 2021 (cost per panel EUR 130). Based on the assumption that a highly specialised professional works 200 days per year for 8 hours a day at an annual salary of EUR 104,000. The assumed annual salary draws from OECD data on remuneration of health professionals: https://stats.oecd.org/index.aspx?queryid=30025	ERN activities (see EQ18 and EQ21) Until the announced grant changes come into effect (with 100% funding from the EC), there were concerns on the financial sustainability of ERNs
Benefits for ERN member organisations	Not considered	**Research and knowledge sharing** See activities outlined in the patients' section **Education and training in 2020** 583 educational activities aimed at healthcare professionals organised by the ERN (compared to 138 in 2018) 1,446 educational activities aimed at healthcare professionals delivered by the ERN coordination team or HCP members of the ERN (compared to 77 in 2018) Source: ERNs moniroing data Increase in the number of ERN members (to almost 1500 ERN units by January 2022) extending the geographical scope and reach of the ERNs. Source: DG SANTE, Europa	Initial progress towards an increase in the speed and scale with which innovations in medical science and health technologies in the field of RD are developed. Pooling of expertise through the exchange of knowledge and best practices in rare diseases, which, together with the pooling of patients' data through the patient registries provides a platform for ERN members to conduct and share research in the field of rare diseases (EQ 12 and 13) The ERN members reinforce, and are simultaneously further reinforced, by other EC funded initiatives in rare diseases such as the Joint programme on rare diseases or the ERICA project.

Annex 7: Workshop discussion paper

Virtual workshop to present the preliminary results of the evaluation of Directive 2011/24/EU

Discussion paper

Agenda

Time	Discussion topic
13.30	Welcome words
13.45	Introduction to the study and presentation of preliminary findings
14.30 - 16.15	Discussion on patients' rights provisions
	Coffee break
	Discussion on cooperation in rare diseases and ERNs
16.15 - 16.30	Concluding remarks

Introduction

The Directive 2011/24/EU on patients' rights in cross-border healthcare was adopted on 24 April 2011. Under this Directive, EU nationals have the right to seek planned healthcare in another EU country and claim reimbursement of treatment costs from their national health system or health insurance provider. Moreover, the Directive promotes cooperation in healthcare between Member States in several areas, especially in rare and complex diseases, European Reference Networks (ERNs), border regions, recognition of prescriptions, and data collection

The European Commission is currently evaluating how well the rules are working in particular regarding patients' access to safe and high-quality healthcare in another EU country and cooperation between Member States, especially on rare diseases. The current discussion paper is based on the preliminary findings of a study conducted by Tetra Tech, empirica and Asterisk to support the Commission's evaluation of the Directive. This included the following data collection activities:

- review of relevant literature;
- analysis of National Contact Points (NCPs) websites;
- public consultation (193 responses)[44];
- interviews and questionnaires engaging 285 stakeholders at EU and national level[45].

The findings presented in this paper cover the following topics:

I. Provisions on **patients' rights** to cross-border healthcare;

II. Cooperation in **rare diseases** and the **ERNs.**

[44] A factual summary of the public consultation is available from the Have Your Say website.

[45] These included Commission officials; national authorities; EU-level organisations representing healthcare providers, professionals and insurers, and consumers; national healthcare providers, insurers, pharmacist and patients' ombudsmen; representatives of ERNs; patients and patient representatives.

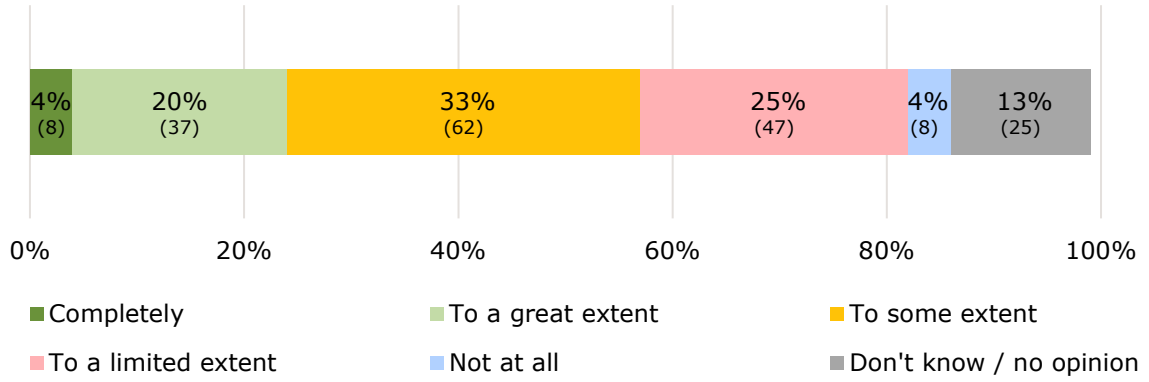
I. PATIENTS' RIGHTS TO CROSS-BORDER HEALTHCARE

The Directive aims to provide a legal framework for cross-border healthcare in the EU. It sets out the rights and entitlements of patients seeking healthcare abroad. It also establishes the responsibilities of the Member States of affiliation and treatment in relation to provision of information to patients, prior authorisation, reimbursement, follow-up treatment, etc. This paper presents the preliminary findings of the study on how well the Directive has worked to date in terms of facilitating access to cross-border healthcare and free movement of services.

A. What is working well?

Despite important gaps and persisting issues in the data provided by Member States, a small upward trend in the number of patients accessing cross-border healthcare under the Directive was observed until 2018. In 2019, the number of requests (and requests granted) for cross-border healthcare slightly decreased. Although numbers are still low overall, they show that **patients are making use of the Directive**, indicating it is in some way **facilitating cross-border healthcare** and **aiding the free movement of health services**. However, there is limited evidence to date to show that the Directive has had a major impact in enabling patients to access better quality or cheaper services abroad, with lower waiting times. As depicted in Figure 19, the majority (57%) of public consultation respondents felt that the two EU schemes that apply to cross-border healthcare (the Directive and the Social Security Coordination Regulations) have met patient needs to access cross-border healthcare at least some extent, with only 4% indicating they had not met them at all.

Figure 19: In your experience, do the EU schemes meet patients' needs on accessing healthcare in another EU country? (n=187)



***Source**: Public Consultation*

Overall, based on evidence collected, the Directive has contributed to removing obstacles to cross-border healthcare and to free movement of healthcare services mainly by:

- **bringing additional legal clarity** in relation to patients' rights to cross-border healthcare and establishing a framework that enables them to exercise these rights;
- **creating NCPs** and establishing clear obligations for Member States and healthcare providers in relation to the provision of information to patients, which has resulted in a gradual improvement of patients' awareness of their rights;

- **enhancing freedom of patients' choice of the healthcare services** in the EU by enabling access to healthcare abroad, for the most part, without prior approval[46], including private care.

- **regulating the recognition of medical prescriptions across the EU,** although there are some persisting issues in relation to the verification of prescriptions from other countries, including language barriers or pharmacists not being able to verify whether the prescription was issued by a doctor legally entitled to do this.

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

B. What are the remaining issues?

There are still some **information gaps** hindering access to cross-border healthcare and free movement of health services. For instance, patients yet not feel sufficiently informed about their rights and entitlements, indicating that many are not able to make an informed choice about cross-border healthcare. Awareness of the NCPs is low and NCP websites are not always effective in providing information to patients. For instance, although the websites' content has improved over the years, there are persisting gaps across NCPs in relation to the availability, completeness, clarity and accessibility of information. The most significant gaps relate to information related to patients' rights[47], information on entitlement for reimbursement of costs, quality and safety standards, differences between the Directive and the Social Security Coordination Regulations, availability of information in English and/or minority languages, and coverage of the needs of specific groups (e.g. people with disabilities).

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

- administrative procedures at national level that appear to be disproportionate to the objective of administering prior authorisation and reimbursement procedures[48];

- gaps in relation to awareness of healthcare providers of their obligations under the Directive, especially in relation to prior authorisation and prices;

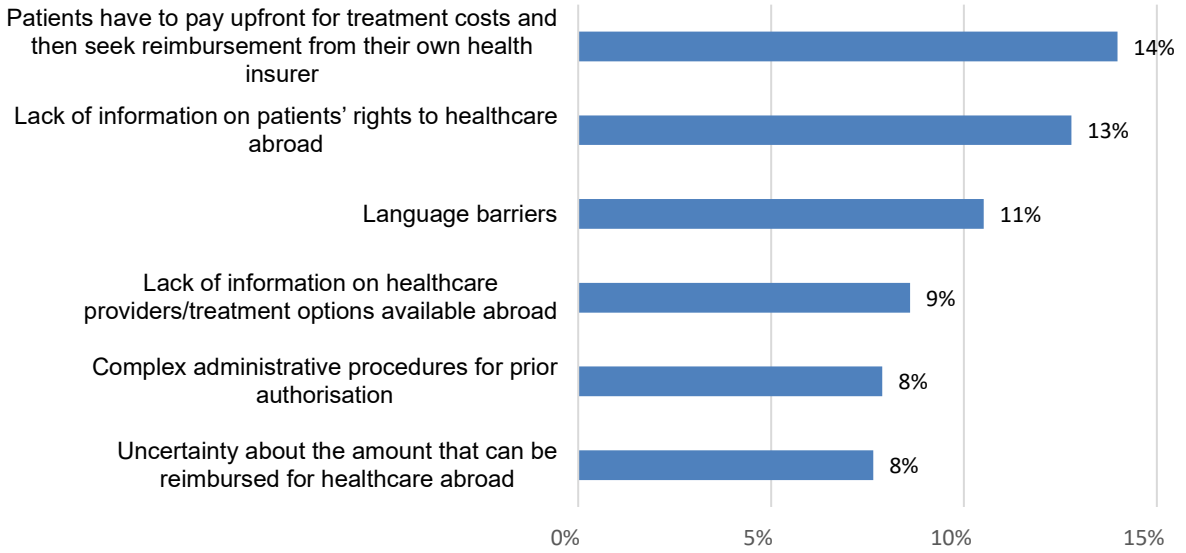
- lack of clear integrated information and user-friendly procedures on cross-border healthcare treatment pathways under the two mechanisms (Directive and Social Security Regulations).

Moreover, according to stakeholders, there are some **needs that the Directive currently does not address**. These are mainly financial[49], mobility[50] and language[51] needs. Adding to this, prior-authorisation for patients with rare diseases may be more difficult to obtain due to

[46] In 2019, the number of requests for PA received (excluding France and Greece) was 4,649, with requests authorised amounting to 3,953 in 2019. Excluding France, the number of requests for reimbursement received without PA amounts to 112,847, and the requests granted to 90,674.
[47] The assessment of information on patients' rights included the following issues: information on the definition of waiting time; information on rights in case of undue delay and in the event of harm; information on access to hospitals for disabled patients, on how to access electronic medical records, on mechanisms to settle disputes (e.g. reimbursement issues); information on rare diseases and the ERNs; information on complaint procedures in case of follow-up treatment issues.
[48] For example, requests for official/certified ('sworn') translation of documents, the costs of which may be higher than the reimbursement of the services themselves.
[49] This relates to paying upfront for treatment, limits to reimbursement based on the Member State of affiliation's levels and the travel costs (e.g., trip and accommodation).
[50] The Directive contains no specific provisions addressing the needs of those less able to travel (e.g., elderly people or people with disabilities).
[51] The Directive does not mandate language support for cross-border patients i.e., it does not explicitly mention the right of patients to access information in a language they understand or cross-linguistically (e.g., via translation and/or interpreting)

the clinical evaluation required. These needs prevent some patients from traveling, ultimately challenging equal access to cross-border healthcare. As depicted in Figure 20, financial problems (i.e., having to pay upfront) were perceived by public consultation respondents to be one of the biggest barriers to accessing cross-border healthcare, as well as information gaps, language barriers and complex administrative procedures.

Figure 20: In your experience, what are the biggest barriers to cross-border healthcare? Please select a maximum of 5 main barriers (n=169, 837 selections)[52]



***Source**: Public Consultation*

In relation to reimbursement, the system of **voluntary prior notification** is believed to be a useful way of reducing the financial risk for patients as it provides them with an estimation of the amount to be reimbursed after being treated abroad. However, it is only applied in eight countries.

C. What are the future patient needs?

In relation to future needs for access to healthcare, one of the main developments is possibly the digitalisation of healthcare and the **increasing use of telemedicine**. The use of telemedicine has accelerated during the COVID-19 pandemic and several models for its reimbursement are emerging at national level. The Directive is relevant to address this emerging trend as it enables cross-border telemedicine. However, the lack of a clear, EU-level approach towards the reimbursement of cross-border telemedicine services could result in a fragmented and/or restrictive application of the Directive by Member States, which could ultimately hinder the use of this form of healthcare provision. Therefore, it is important that the Commission continues to examine the extent and the ways in which telemedicine is reimbursed at the national level and assesses the need for further (legal or non-legal) initiatives in this respect.

II. COOPERATION IN RARE DISEASES AND THE ERNs

The ERNs were established in 2017 as cross-Europe virtual healthcare provider networks to facilitate collaboration on rare or low prevalence complex diseases that require highly specialised knowledge or treatment. The Directive envisages them as a

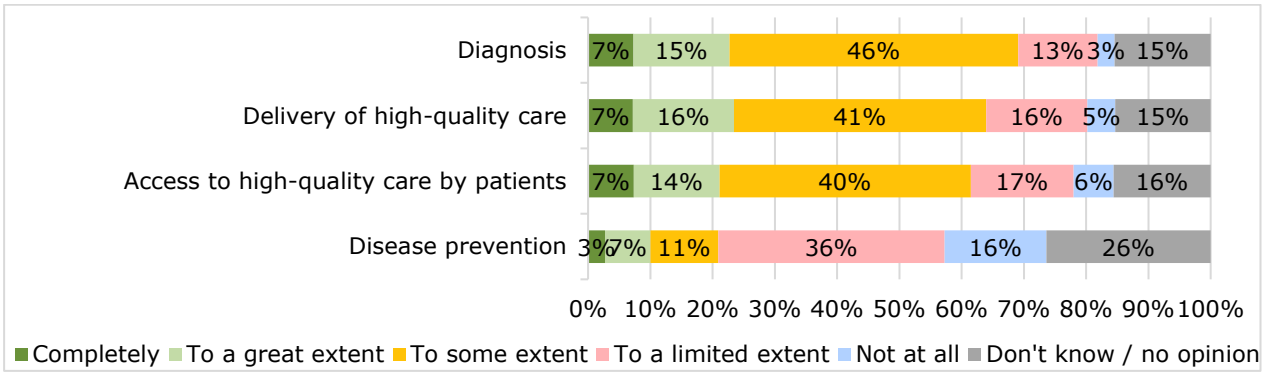
[52] In this question, respondents were asked to select the 5 main barriers from a pre-defined list of 21 barriers. In Figure 2, we present the top-six barriers.

means of sharing knowledge and expertise, concentrating resources and patients, and thereby improving diagnosis and treatment for those with rare conditions.[53] ERNs are expected to benefit patients in two main ways: by pooling of expertise for the diagnosis and treatment of patients and by generating and increasing the knowledge and expertise of the medical community in treating these diseases. The latter is to be achieved by increasing the number of known cases and thus enabling, among others, the development of registries and research collaboration.[54]

A. What is working well?

The study's preliminary findings show that the Directive is overall effective in: **supporting the diagnosis and care of patients with rare or complex diseases** (Figure 21), promoting knowledge sharing, and contributing to research. This is in line with the European Court of Auditors' report on the Cross-border Healthcare Directive, which stressed the possibility that ERNs give to patients and doctors across the EU to access the best expertise and timely exchange of life-saving knowledge, without having to travel to another country[55].

Figure 21: To what extent have ERNs helped achieve the objectives in the following areas?



***Source**: Public Consultation*

Through training, development and dissemination of guidelines and other materials, operational activities, and scientific and clinical cooperation, ERNs have provided healthcare professionals with access to a cross-border pool of expertise and knowledge. ERNs are also creating a **critical mass of patients' data** through the patient registries, which are expected to provide a platform for research and lead to the collection and coordination of experience in treating patients with rare conditions requiring complex treatments. ERNs have already facilitated large clinical studies to improve understanding of diseases and develop new drugs by gathering a large pool of patient data.

The establishment of the virtual consultation panels through the **Clinical Patient Management System (CPMS)**, a dedicated IT platform and telemedicine tool developed by the Commission to allow healthcare providers from all over the EU to work together virtually to diagnose and treat patients, was generally assessed positively by stakeholders. It was highlighted as being increasingly used for the diagnosis and treatment of patients with rare diseases. Currently, more than 1.6 million patients are being treated by the ERN members.[56]

B. What could be improved?

[53] European Commission (2015) *Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.* Available at : https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf
[54] European Commission (2018) *Rare diseases 2008-2016.* Retrieved from: https://op.europa.eu/en/publication-detail/-/publication/fd1f05fc-6def-11e8-9483-01aa75ed71a1
[55] European Court of Auditors (2019) *Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.* Available at: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=49945
[56] Meeting minutes ERN Board of Member States: : https://ec.europa.eu/health/ern/latest_updates_en

Stakeholders surveyed and interviewed for the study agreed that the Directive has been generally effective in supporting the diagnosis and treatment of patients with rare and complex diseases, especially considering that it has been less than five years since the ERNs have been established. However, there are some **practical barriers to accessing the expertise of ERNs for both healthcare providers** and **patients**. For the former, barriers are: non-interoperable IT facilities; administrative burdens; insufficient integration of ERNs in the national health systems; and lack of awareness or knowledge on how to access the ERNs, especially for healthcare professionals outside the field of rare diseases. For patients, the main barriers are: lack of awareness and information; language issues; and reimbursement issues.

Interviewees also reported issues relating to the **resources required to set up and maintain the ERN infrastructure**, noting that the networks have spent already a lot of time in the development of tools and technologies to support the work of ERNs. This is an on-going issue which is impacting on the effectiveness of the ERNs as a lot of resources are spent in coordinating and developing the networks instead treating patients. They also noted that, at this early stage of development, the ERNs have been more successful in contributing to the diagnosis of patients with rare or complex diseases (rather than treating them) given the focus on knowledge sharing activities of these first five years. The CPMS has also presented some problems and shortcomings as the **system has been found complicated for some tasks and not always fit for purpose**. This has resulted in virtual consultation being underused.

Finally, a key issue affecting the effectiveness of ERNs is related to the funding system. To support the ERNs' operations, the Commission has provided funding from different spending programmes (Health Programme, Connecting Europe Facility (CEF)) and through different mechanisms (grants and tenders). Administrative burdens have resulted in healthcare professionals' time being sometimes used on administrative tasks (identifying and applying for funding) instead of patient-related work. Whilst the funding provided at the EU level enabled the operations of the ERNs to take place over the first four years of their existence, the European Court of Auditors highlighted that, with the current funding system, "the ERNs face significant challenges to ensure they are financially sustainable and are able to operate effectively within and across national healthcare systems."[57] However, with **support from Member States and changes to the funding system introduced with the new EU4Health Programme, some of these problems could potentially be solved** Article 13(6) of Regulation 2021/522 establishing the EU4Health Programme, sets out that, under the Programme, direct grants shall be awarded without a call for proposals to ERNs[58].

C. What are the future needs?

In terms of future needs, stakeholders noted that under the current model hospitals are often not reimbursed by other Member States for the **time spent by their experts in virtual consultations discussing the cases of foreign patients** . Suggestions on how to address this issue included providing virtual consultations as part of the hospitals' services; providing financial reimbursement based on national rates or pre-defined indicators; or adding a specific budget line for this in ERNs budget.

Furthermore, both the literature and the majority of consulted stakeholders noted the importance of **integrating ERNs into the national healthcare systems**. To address this issue, a Working Group on Integration was set up and a statement was adopted by the ERN Board of Member States in 2019 encouraging Member States to facilitate the integration of ERNs to their healthcare systems.

[57] European Court of Auditors (2019) *Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required*. Available at: https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=49945
[58] See: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0522&from=EN

Questions for the workshop

The information presented above are emerging findings based on evidence collected to date by the contractors. At this workshop, we would like to invite you to complement these findings with your views and/or additional information.

Questions for the workshop
• **To what extent do you agree with these emerging findings? Is anything missing / underplayed / overplayed?**
• **Has the Directive had any other effects, either positive or negative, that are not reflected in the emerging findings presented in the workshop? Do you know of (or can you provide) additional data to complement these findings?**
• **In your view, what are the priority areas where implementation of the Directive could be improved? What actions could be taken? At what level could these be taken (EU / national / provider or insurer-level)?**
• **As healthcare needs evolve, especially since the COVID-19 pandemic, are there any needs that the Directive is or is not well placed to address in the future?**
• **Do you have any other suggestions as to how to enhance access to cross-border healthcare (including access to ERNs expertise) and free movement of services?**

Annex 8: Consultation synopsis report

1. 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 2);
- Consultation results (Section 3).

2. 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 in section 1.2.

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 6 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.

Table 6: 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, questionnaires or information requests	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); 4 (DE); 1 (DK)	High in PL and FR; Medium in NL; Low in DE and DK

Consultation activity	Stakeholder group	Nr of stakeholders targeted	Nr of stakeholders responding	Level of engagement
	ERNs	N/A	64	Medium[59]
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 (see Table 6), 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.

- **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

[59] 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.

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.

3. CONSULTATION RESULTS

The results of the various stakeholder consultation activities are presented below per overarching question (as presented in section **Error! Reference source not found.**).

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[60]) 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

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

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 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[61] 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.

[61] 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.

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 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[62] 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.

[62] Denmark, Estonia, Greece, Ireland, Italy, Poland, Sweden and Norway.

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.

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 very 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 apropriate 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, 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 paediatric 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 care, 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 upfront, 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 9: Prescription case study report

SUMMARY

- This annex contains the report of a case study analysis based on an online survey targeted at active pharmacists in five EU Member States (Denmark, Germany, France, Netherlands and Poland) as part of an ex-post evaluation support study of the Directive 2011/24/EU to ensure EU patients' rights in cross-border healthcare (CBHC Directive).

- The CBHC Directive, as one pillar of the legal framework for cross-border patient mobility, was adopted and came into force on 9 March 2011. It facilitates access to safe and high-quality cross-border healthcare in the Union, embodies the right to patient mobility and promotes cooperation on healthcare between Member States.

- However, a 2012 study on the recognition of prescriptions across borders showed that citizens who presented their prescriptions abroad were likely to not receive their prescribed product. The study associated problems related to non-dispensation mostly to verification and authenticity of prescriptions and language barriers. As patient mobility has been increasing until 2020, the number of foreign prescriptions sought to be dispensed in other EU Member States was assumed to increase, too.

- The present case study was aimed to renew the 2012 study, updating the baseline data and replicating its methodology. 158 pharmacists across five study countries responded to an online survey and rated the probability that several issues caused dispensing problems when being presented a foreign prescription. Suitable drugs were selected for a sample of five pathologies (Asthma, COPD, Hypertension, Ischaemic Heart Disease and Osteoarthritis/Rheumatoid Arthritis) and country-specific prescription mock-ups filled with fictive, yet authentic patient information. The survey took place between August and October 2021.

- In the context of cross-border patient mobility and the mututal recognition of prescriptions, the analysis provides indicative evidence for an estimated increase of foreign prescriptions presented in pharamacies in the EU of around 400% (from 1.46 foreign prescriptions per pharmacy per month in 2012 to 5.86 in 2021) and a reduction of non-dispensation probability of nine percentage points (from 55% in 2012 to 46% in 2021).

    - The data shows that an estimated 7.7 million foreign prescriptions are sought to be dispensed in another EU Member State each year (estimated minimum: 5 million; estimated maximum: 12.5 million).

    - Based on the analysis of the probability of non-dispensing derived from the survey data, 46% of all foreign prescriptions (3.6 million in total) are likely to not being dispensed.

    - The key problem drivers to non-dispensation are verification of prescriptions and prescribing physician, while presenting

prescriptions in a different language can pose a high barrier for pharmacists in some EU Member States. This means that the average pharmacist is missing some important information on foreign prescriptions or experiences issues in identifying certain information when dispensing foreign prescriptions.

- Overall, the robustness of these findings is limited, as the analysis is based on a total of 158 submitted questionnaires and 948 prescription observations (compared to 996 questionnaires and 11,952 prescription observations in 2012). Nevertheless, the analysis yields indicative data on existing problems associated with the mutual recognition of prescriptions across the EU.
- The study closely followed the 2012 methodology to ensure comparability of results and improved this approach in two aspects: reduced survey length and more precise depiction of estimated foreign prescriptions per pharmacy in the EU and by geograohical location. This approach is fit to be replicated in larger scenarios with an updated research on available drugs and devices. Methodological approach and prescription mockups can be used in future studies which could include additional study countries to compare or validate the results of the present report. The prescription mockups can be further adapted to test the recognition of printed ePrescriptions in the future.

1. INTRODUCTION

This report contains a case study analysis based on an online survey targeted at active pharmacists which was conducted in the context of the evaluation support study of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare.

1.1. Context and case study objective

The case study was conducted as part of the ex-post evaluation support study of the CBHC Directive, specifically on the recognition of prescriptions issued in other Member States. It seek to answer Evaluation Question 9 of the ex-post evaluation study: "How effective were the Directive and the Implementing Directive 2012/52/EU to regulate the recognition of prescriptions across EU borders?".

158 Pharmacists in five countries were presented with mock-up prescriptions containing authentic patient information and asked to rate a list of six factors based on the probability that these would cause dispense problems.

The case study was designed to produce data that is comparable to the 2012 study "Health Reports for Mutual Recognition of Medical Prescriptions: State of Play"[63] carried out by Matrix. Therefore, this case study reviewed, revised and replicated the existing methodology to ensure data comparability. By updating the state-of-play across a selection of Member States and pathologies, this case study extents the evidence base in this area.

1.2. Structure of the report

The structure of the report is as follows:

- **Section 2** presents a summary of the policy context and background of the case study;
- **Section 3** details the applied methods and flags deviations from the 2012 methodology as blue boxes;
- **Section 4** provides the results of the analysis of the case study data and key findings;
- **Section 5** presents concluding remarks.
- **Appendix 1** includes example prescription mockups and the survey questionnaire is available in Annex 10.

[63] Matrix (2012). 'Health Reports for Mutual Recognition of Medical Prescriptions: State of Play'.

2. POLICY CONTEXT AND BACKGROUND TO THE CASE STUDY

EU Public Health responsibilities are specifically addressed in Article 168 of the Treaty on the Functioning of the European Union, which sets an objective of 'a high level of human health protection'. Article 168 also reinforces the concept of cross-border healthcare and encourages cooperation between the Member States to improve the complementarity of their health services in cross-border areas. The CBHC Directive, as one pillar of the legal framework for cross-border patient mobility, was adopted and came into force on 9 March 2011, whereas its transposition was not fully completed by Member States until late 2015. The Directive facilitates access to safe and high-quality cross-border healthcare in the Union, embodies the right to patient mobility and promotes cooperation on healthcare between Member States.

Article 11 of the of the CBHC Directive gives effect to the principle of mutual recognition of medical prescriptions and empowers the Commission to adopt practical measures to assist such recognition. These measures aim 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.[64]

As the Directive's Impact Assessment[65] acknowledges, there are situations where citizens may decide that their healthcare needs are best addressed in another Member State. Situations with relevance to the context of the case study include:

(1) **citizens living in border regions**, where the nearest appropriate healthcare provider may be across the border in another Member State, and where efficient provision of care may be best achieved through providers serving populations across borders throughout their local region;

(2) **lack of capacity**, where local services are unable to provide the appropriate healthcare and there is capacity available in another Member State;

(3) **personal preference** of the individual receiving care, who may, for example, reside in another Member State but wish to receive care in his or her country of origin, or who may be seeking a cheaper treatment in another Member State.

Before the disruptions caused by the Covid-19 pandemic, patient flows and requests for information about cross-border healthcare have increased until 2020[66]. Viewed in the context of the total patient flow within Member States, however, cross-border patient mobility and financial dimensions remain relatively low. In 2012, EU citizens were estimated to request the dispensation of an

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[64] SWD(2012) 450 final, Commission implementing directive laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

[65] Full impact assessment of the Directive on patients' rights in cross-border healthcare, 2 July 2008. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52008SC2163

[66] 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.* Report for the European Commission. Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjqid-zqOD0AhXQh_0HHb0aDIUQFnoECAcQAQ&url=https%3A%2F%2Fec.europa.eu%2Fsocial%2FBlobServlet%3FdocId%3D22295%26langId%3Den&usg=AOvVaw3jundLSNC-XvpKZGcst_te

estimated 2.33 million prescriptions in another Member State, while the total number of estimated prescriptions across the EU amounted to 6.5 to 10 billion[67]. Based on the above, it can be assumed that an uptake of cross-border prescriptions is line with the increasing trend in patient mobility.

3. METHOD AND SCOPE OF THE CASE STUDY

As outlined in section 2, the nucleus of this case study is related to issues with foreign[68] prescriptions sought to be dispensed in other EU Member States for a specific drug or device in relation to a particular pathology. The following paragraphs present the overall approach to the case study, the selection of surveyed Member States, pathologies and drugs/devices, as well as the limitations of the chosen approach.

3.1. Process and overall approach

In accordance with the 2012 methodology, an online survey specifically targeted at active pharmacists in Europe was carried out to evaluate potential barriers in verifying and dispensing foreign prescriptions in the EU.

In this new iteration of the survey, respondents were presented with a total of six foreign prescriptions from three of the five study countries and asked to rate the probability that several issues caused dispensing problems. In the early stage of the study, the team engaged in conversations with the Pharmaceutical Group of the European Union (PGEU) to ensure their guidance and support. In addition, a familiarisation interview was conducted with the project manager of the 2012 study to validate the approach and discuss methodological challenges (which resulted in modifications detailed at the end of this section and section 3.6.). The online survey was carried out between August and October 2021, with several e-mail reminders sent out. Channelled through PGEU, the online survey link was distributed to national pharmacists' associations in each of the five study countries via e-mail who, in turn, disseminated the link to their members[69]. This is in line with the approach taken in the 2012 study.The survey was implemented using EUSurvey, as it generates several benefits: (1) organisational and technical measures ensure Data Protection and GDPR compliance; (2) the online survey can be transferred to the Commissions Services in order to be adapted or repeated any time; and (3) the integrated translation function facilitates swift translation into local language in future surveys if more or all EU countries were to be included[70].

The prescriptions presented in the online survey were manually designed by the study team based on real prescription templates commonly used in each of the study countries. These mock-ups were then filled with fictive, yet authentic patient

[67] Matrix (2012). 'Health Reports for Mutual Recognition of Medical Prescriptions: State of Play'

[68] Note that "foreign" refers to "from another EU Member State" thorugout this report.

[69] The study team assumes that the potential outreach to pharmacists did not change significantly compared to 2012. Although it was not possible to check which national organisations were contacted in 2012, one difference to be expected is the number of operating pharmacies in each country. We do assume that the organisations contacted in 2012 are still members of PGEU in 2021 and that potential outreach is indeed comparable.

[70] The study team opted for translation by native speakers for this survey.

information (e.g., name, address, insurance ID, prescribing physician and relevant drug/device information).

The survey questionnaire included one general question on the respondents profession and their place of work, as well as one question on the estimated number of received foreign prescriptions per month. The main part of the questionnaire presented a total of six questions per prescription asking pharmacists to what extent they would expect a variety of factors to cause dispensation problems, namely:

- Verifying the authenticity of the prescription;
- Verifying the prescribing physician;
- Language in which the prescription is written;
- Insufficient information on the prescription;
- Access to the correct drug/device;
- Access to alternative drug or device if the one on the prescription is unavailable.

Respondents were asked to rate the probability of these items to cause dispensing issues according to four categories: "definitely not", "unlikely", "likely" and "definitely".

The survey was translated into the official language of each of the five Member States to make it more accessible to local pharmacists who may not speak English.

Survey lenght

One main point of criticism of the 2012 study concerned the length of the survey questionnaire which encompassed 56 questions. To keep the length of the survey manageable for individual respondents, the overall questionnaire length was reduced to 38 questions (six prescriptions with six questions each plus two general questions). In order to encourage more responses, not all pharmacists were given questions on all selected pathologies. Each individual pharmacist was given six foreign prescriptions from three countries. See section 3.3. for further details.

Estimated number of foreign prescriptions

A minor improvement to the 2012 methodology concerns the answer options for the question on experience with foreign prescriptions. The 2012 study surveyed this item with four intervals starting with "below 5" to "above 20". In order to allow for more analytical detail, a fifth option was added to this question allowing respondents to select "0" estimated foreign prescriptions received per month. The results of the analysis of average foreign prescriptions received per month turned out to be different compared to the 2012 results, as the number of pharmacists per answer

3.2. Selection of Member States

The 2012 study surveyed seven EU Member States with a varying degree of response rates. Given the shorter timeframe for the implementation of this case study, the study team limited the scope to those countries with the highest response rates in the 2012 study: **Denmark, Germany, France, Netherlands**

and Poland[71].

3.3. Selection of pathologies

A thorough selection process on which pathologies to include in the survey was conducted in the context of the 2012 study. The methodology followed as part of the present study is in line with the sound reasoning of that process. The selected conditions are common and likely to affect people when they are abroad. They are typically treated with medication that has been associated with harm when it is not available, given in a different formulation or dose, administered via a different device, or mistaken for an alternative drug. However, the study team hypothesis was that people suffering from diabetes, epilepsy, depression and bipolar disorder are relatively less likely to travel abroad without adequate medical care, if at all. Secondly, these pathologies had the lowest response rates in the 2012 study. Although the study team does not necessarily presume that these observations are causally linked, they justify exclusion from the present study given the reduced study scope. The pathologies surveyed in the present study are **Asthma, COPD, Hypertension, Ischaemic Heart Disease and Osteoarthritis/Rheumatoid Arthritis**.

Allocation of pathologies and countries was agnostic to any kind of assumptions and performed starting with the first prescriber-dispenser combination (DE and DK) for Asthma. The remaining pathologies were then allocated by prescribing country, where every third prescriber-dispenser combination was skipped to reduce the overall survey length for individual pharmacists.

Table 7: Pathology/country distribution for the online survey

		Prescriber				
		DE	DK	FR	NL	PL
Dispenser	DE		IHD		Arthiritis	Hypertension
	DK	Asthma		COPD	Asthma	
	FR	COPD			COPD	IHD
	NL		Arthitis	Hypertension		Arthritis
	PL	Hypertension	Asthma	IHD		

3.4. Selection of drugs & devices

The table below illustrates the complete list of drugs/devices and dosages included in the case study survey. The identification of drugs and devices included a two-step validation process.

[71] The thorough selection process for study coutries in 2012 involved a two-tiered approach: 1) ranking of all EU Member States according to key criteria, of which the top countries were chosen (tourism, intra-EU migration, health tourism, prescribing/dispensing problems), and 2) country selection was qualitatively tested and triangulated (e.g., Italy and Ireland were replaced by Poland and Greece to include a country with overall low drug availability and one with a different alphabet). As hand-written prescriptions are expected to be less relevant today compared to 2012, such considerations were not adopted for the present study.

1. For the selected pathologies, drugs and devices included in the 2012 study were presented to the national pharmacist associations, which were asked to validate the market availability in the respective countries. Drugs and devices which are still available were used in the present study.

2. In case a certain drug or device was no longer available on the national market, the associations were then asked to provide information on proven, alternative drugs and devices, including brand/substance name and recommended dosage. In case the national associations did not provide such information, the study team engaged in desk research and expert consultation with physicians in the concerned Member States to identify suitable alternatives. The alternative drugs and devices identified were validated by pharmacists in the respective countries.

In accordance with the 2012 methodology, two sets of drugs and devices were conceived to test wether drug availability is a likely cause for non-dispensation:

- drug A (unlikely to cause dispensing problems): commonly available in all five Member States;
- drug B (more likely to cause dispensing problems): less frequently prescribed for the respective pathology.

Table 8: Drugs and devices included in the survey: drug A (commonly available in all MS)

		Prescriber				
		DE	DK	FR	NL	PL
Dispenser	DE		Simvastatin 20 mg; take one tablet once daily at night orally; 100 stk. (blister) filmovertrukne		Naproxen 250 PCH, tabletten 250 mg; 250 mg om de 8 tot 12 uur; 56 tabletten	Ramiprilum tabletki 1,25 mg; take two tablets orally once daily; 30 tabl.
	DK	Fluticason 250 µg pro Einzeldosis Pulver- Inhalator; take two puffs twice daily; 120 Einzeldosen Pulver-Inhalatoren		Tiotropium 18µg pdre p inhal en gél: l'inhalation du contenu d'une gélule une fois par jour à heure fixedans la journée à l'aide du dispositif Handihaler; Plq/30+Handihaler	Fluticasonpropionaat Volumatic CFK vrij, aerosol 250 microgram/dosis; 250 microgram tweemaal daags; 1 inhalator	
	FR	Tiotropium 18 Mikrogramm Kapsel mit Inhalationspulver; take one capsule once daily; Hartkapseln m. Pulver z. Inhal			Tiotropium 18 microgram, inhalatiepoeder in harde capsules; éénmaal per dag de inhoud van één capsule(18 microgram tiotropium) te Inhaleren; 1 HandiHaler en 30 capsules (3 blister strips).	Simvastatinum tabletki powlekane 20 mg; take one tablet once daily at night orally; 28 tabl. (2 x 14)

		Prescriber				
		DE	DK	FR	NL	PL
	NL		Naproxen 250 mg 100 stk. Tabletter; take one tabletorally twice daily; 56 tablets	Ramipril 2,5 mg; 2,5 mg par jour; B/30 comprimés		Naproxenum natricum tabletki powlekane 220 mg; takeone tablet orally twice daily; 40 tabl.
	PL	Ramipril 2.5 mg; take one capsule orally once daily; Tabletten 50 ST	Flixotide (Fluticasonpropionat) Inhalationspulver e i Diskos® 250 mg/dosis	Simvastatine 20mg cp pellic séc; 20 mg/jour administrés par voie orale en une prise unique le soir: B/28 comprimés		

Table 9: Drugs and devices included in the survey: drug B (less frequently prescribed in all MS)

		Prescriber				
		DE	DK	FR	NL	PL
Dispenser	DE		Trandate 100mg labetalol, 1 tabl. 2-3 gange dagl., 50 stk.		Ony normal tablets without slow/sustained release is available, Surgam®, TIAPROFEENZUUR TABLET 300MG, GENZYME EUROPE BV	Chlortalidonum tabletki 50 mg; take one tablet each day in the morning; 20 tabl.
	DK	Budesonid/Formoterol Combination preparation Symbicort Turbohaler and inhalation powder, 2 x 160 µg/4,5 µg per day.		Bamifylline 300mg cp enr: 2 comprimés par jour; Le comprimé sera avalé sans être croqué, avec un verre d'eau, de préférence en dehors des repas; Plq/40	Theolair®, THEOFYLLINE TABLET MGA 175MG, MYLAN B.V.	
	FR	2,5 µg Tiotropium (Tiotropiumbromid ×1 H2O) and 2,5 µg Olodaterol (Olodaterolhydrochlorid), Spiloto Respimat			Ciclesonide 80 Inhalator, aërosol, oplossing 80 microgram/dosis; 160 microgram eenmaal daags; 1 inhalator met 60 nauwkeurig afgemeten pufjes.	Torasemidum tabletki 2,5 mg; take two tablets once a day; 60 tabl.
	NL		Sulfasalazin enterotabletter 500mg, 2 gange dgl., 100 stk.	Tertatolol 5mg; Un comprimé par jour en une prise		Nimesulidum tabletki 100 mg; take one tablet

		Prescriber				
		DE	DK	FR	NL	PL
				matinale; B/30 comprimés		twice a day; 60 tabl
	PL	Amlodipin, 5mg 1x daily, tablets	Bambec tabletter 10mg, 10-20 mg (1-2 tabletter) dagligt ved sengetid. Tabletglas med 100 stk.	Zofénopril 30mg cp pellic: 30 mg par jour; B/28 comprimés		

3.5. Calculating non-dispensing probability

This chapter briefly introduces the statistical approach to calculating non-dispensing probability and extrapolating the estimated number of foreign prescriptions per pharmacy in the the study countries. The analysis does include the data from countries with a response rate >1. As the study country Denmark does not meet this criterion, it was excluded from further analysis.

The online survey was designed to voluntarily involve pharmacists in the five study countries as experts, whose task was to assess whether a total of six[72] factors would "definitely not", "unlikely", "likely" or "definitely" cause a problem in dispensing a particular drug.

The obtained responses were coded as follows:

Equation 1: Probability response coding

$$(Definitely\ not = 0; Unlikely = 1; Likely = 2; Definitely = 3)$$

Based on these coded responses, a weighted average was calculated for each individual prescription observation using the formula below. Pharmacists were allowed to not rate individual factors for a given prescription. Nevertheless, a response with only one rated factor was given an equal weight as one where all six factors were scored.

Equation 2: Weighted average prescription code

$$Weighted\ average\ (Prescription) = \frac{W_{F1}(y) + W_{F2}(y) + \cdots + W_x(y)}{\Sigma y}$$

The final probability for not dispensing a prescription was calucalted as follows:

[72] These factors are: (1) verifying the authenticity of the prescription, (2) verifying the prescribing physician, (3) language in which the prescription is written, (4) not all the information you need is written on the prescription, (5) access to the correct drug/device and (6) access to alternative drug or device if the one on the prescription is unavailable.

Equation 3: Non-dispensing probability

$$P(Not\ dispensed) = \frac{Weighted\ average\ (Prescription)}{3}$$

3.6. Limitations and comparison to the 2012 study

The case study was aimed to replicate the analysis undertaken in the 2012 study on problems associated with the recognition of prescriptions in the EU, which back then further included an impact analysis on financial costs and patient harm. The authors of the present case study report sought to adopt the 2012 methodolgy as far as possible, as there was no significant criticism following the publication in 2012 and after a thorough review by the study team together with the 2012 project manager. As a result of this review, only some minor changes were applied to motivate more responses through reduced complexity and to allow a more detailed analysis of estimated foreign prescriptions received:

- number of studied countries reduced from seven to five;
- number of included pathologies reduced from eight to five;
- survey length per respondent reduced from 54 to 38 questions;
- response category for estimated foreign prescriptions per month "below 5" split into two categories "0" and "1-5", adding a fifth response category;
- added a section on the geographical distribution of respondents and estimated prescriptions.

Where possible, up-to-date data was collected via desk research (e.g., on total prescriptions dispensed across the EU and number of pharmacies) but this was not successful in all cases[73]. Therefore, the data on total prescriptions dispensed across the EU presents a mix of old and new data that most likely almost, but not quite, reflect reality.

Adding a fifth response category to the question on experience with foreign prescription significantly impacted the results. Although this presented an added-value to the predecessor study, it complicated a direct comparison of results. The present analysis is more accurate in depicting the estimated number of foreign prescriptions received **per each response category**, especially towards the first two categories ("0" and "1-5").

In order to ensure a high robustness of this analysis, i.e., a high response rate, several measures have been implemented:

- Only countries with a high response rate in the 2012 study were selected as study countries for this survey.
- Due to expected complications and delays during the summer period, the survey was open for 12 weeks (August – October) and therefore longer than the original survey in 2012 (July – August), which yielded particular low response rates, too, e.g., for Greece.
- During the survey phase, a total of three follow-ups via e-mail were distributed via the Pharmaceutical Group of the European Union (PGEU),

[73] The year for each data source is indicated in table 8.

who in turn distributed these to their national member associations. The study team had not direct influence on the survey distribution, which was the same approach taken in the 2012 study. In contrast to the 2012 study, the authors also did not had the chance to engage in a dedicated stakeholder buy-in during a physical or digital event to promote and highlight the importance of this undertaking to national pharmacy associations or individual pharmacists. The presentation of the study at the PGEU General Assembly in Berlin on 21 June 2011 was highlighted as an important mechanism to boost survey responses by the authors of the 2012 study, both in the study report and during the famiiarisation interview with the study's project manager.

- One main driver for a low response rate or high rate of unsuitable responses in the 2012 study was the lengthy questionnaires. Thus, the study team decided to significantly reduce the complexity by reducing the overall amount of questionnaire items (pathologies and countries).
- Prescription mock-ups were designed and implemented into the survey to make the questionnaire more appealing and to enhance the realism behind this approach.
- All surveys were translated by native speakers into national language of each study countries to remove any language barrier which might cause respondents not to submit an answer.

The study team did employ several key measures to ensure adequate survey conditions. However, these had mostly indirect effects and demonstrate that the low response rate were outside of the study team's control.

Overall, the robustness of the findings is limited, as the analysis is based on a total of 158 submitted questionnaires and 948 prescription observations (compared to 996 questionnaires and 11,952 prescription observations in 2012). Following the exclusion of Denmark from the analysis[74], 157 valid questionnaires and 912 eligible prescription observations were analysed[75]. Although no direct feedback was provided by the national pharmacy associations, the study team reflected potential reasons for the low response rate with PGEU. It can be assumed that pharmacists were not able to respond or did not want to respond to this survey, as this effort came on top of already high workloads, particularly due to COVID-19-related testing and distribution of Digital COVID Certificates. The reasons for Danish and German pharmacists to be particularly unresponsive could not be examined further.

Nevertheless, the analysis yields indicative evidence on persisting problems associated with the mutual recognition of prescriptions across the EU. Also, this study closely followed the 2012 methodology to ensure comparability of results and improved this approach in two aspects: reduced survey length and more precise depiction of estimated foreign prescriptions per pharmacy in the EU and by geographical location. This approach is fit to be replicated in larger scenarios with an updated research on available drugs and devices. The methodological approach and prescription mock-ups can be used in future studies which could include additional study countries to compare or validate the results of the present

[74] Only one questionnaire was submitted for Denmark.
[75] A prescription observation was deemed suitable when at least one question was answered.

report. The prescription mock-ups can be further adapted to test the recognition of printed ePrescriptions in the future.

4. SURVEY RESULTS

This section presents the key findings from the online survey in a mix of descriptive and analytical statistics operations. Each submitted questionnaire corresponds to six possible prescription responses. A total of **158 respondents** submitted the online questionnaire with varying degrees of response rates and completeness across the five countries. **This amounts to 948 prescription observations**.

Table 10: Pharmacists responding: corresponding prescription numbers; prescriptions by drug type and pathology

Dispensing country	Respondents	Prescriptions	Common drug (A)	Uncommon drug (B)	Arthritis	Asthma	COPD	Hypertension	IHD
DE	4	24	12	12	8			8	8
DK[76]	1	6	3	3		4	2		
FR	55	330	165	165			220		110
NL	26	156	78	78	104			52	
PL	72	432	216	216		144		144	144
Total	158	948	474	474	112	148	222	204	262

To keep the length of the survey manageable for individual respondents and to encourage more responses, not all pharmacists were presented questions on all five pathologies. This resulted in variations in the number of prescription responsesper country and per pathology, with the fewest prescription responses obtained on Arthritis (112), and the most prescription responses obtained for IHD (262).

All respondents answered the questions related to profession (and described themselves as pharmacists), place of work and experience with foreign prescriptions, while some chose to answer only some of the questions on a certain prescription. A prescription response was only included into the analysis if one or more dispensing questions were answered on that drug. **Of 948 prescription responses, 36 (3.8%) were not suitable**, because all six questions were left blank for that drug. The sample size for the evaluation of whether drugs are dispensed or not therefore consists of **912 suitable responses**. The study team did not identify any specific reasons why some pharmacists left all six questions blank. The distribution of unsuitable prescription responses across drug type and pathology was not striking (15 A-type and 21 B-type; 13 on COPD, 11 on IHD and 4 each on Asthma, Hypertension and Arthritis, respectively). The majority of blank responses is attributed to French pharmacists (19), followed by Polish pharmacists

[76] Note that Denmark is excluded from further analysis, since only one questionnaire was submitted.

(11) and Dutch respondents (6). It could be argued that COPD and IHD medicines prescribed in other countries are less well-known to pharmacists, especially in France, due to various reasons, including, but not limited to, less frequent dispensation of medications for said pathologies to domestic patients or different use of drugs prescribed for the same pathology in other countries. However, the authors did not find reliable evidence to support this assumption. Despite the availability of a commentary function, none of the pharmacists who submitted unsuitable responses chose to provide further information on why these questions were left blank.

The proportion of suitable responses did vary by pathology, but not by A/B drug type. The overall amount of responses not suitable for analysis was quite low. The data sample and the amount of excluded prescription responses was too small to draw any conclusions on the effect of a downwards biased non-dispensing probability which the authors in the 2012 study hypothesised[77]. There is no information available on the amount of potentially or actually contacted pharmacists by the national pharmacist associations.

Table 11: Percentage of responses suitable, by drug type and pathology

Dispensing country	Total	Common drug (A)	Uncommon drug (B)	Arthritis	Asthma	COPD	Hypertension	IHD
% of responses suitable	96.20 %	96.20 %	96.20 %	96.43 %	97.30 %	94.14 %	98.04 %	95.80 %
Total	912	456	456	108	144	209	200	251

4.1. Frequency of foreign prescriptions presented

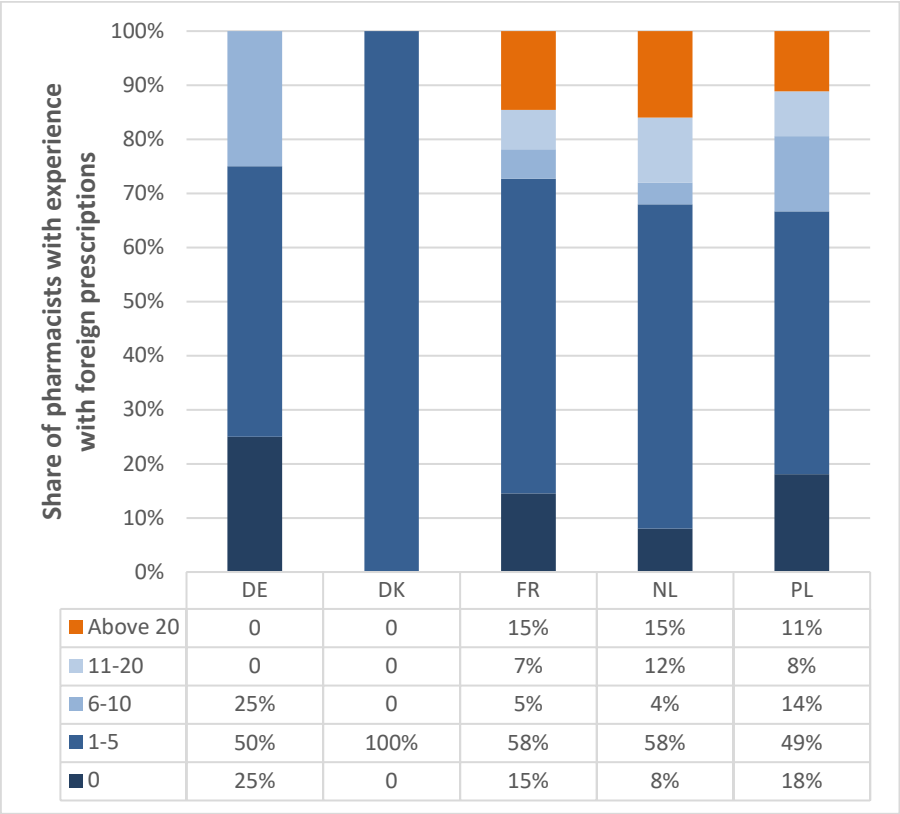
There was a generally low level of experience in dealing with foreign prescriptions amongst the survey participants. Of all respondents, 54% received five or less foreign prescriptions each month, and 15% did not receive foreign prescriptions at all. Therefore, **69% of all respondents had little or no experience with foreign prescriptions**. On average, 10% dealt with six to ten of these per month, 8% with eleven to twenty and 13% with more than 20 prescriptions per month.

Experience varied between Member States, although not considerable. **15% of French and Dutch respondents received more than 20 foreign prescriptions per month, compared to 11% in Poland and 0% in Germany**[78]. The below figure summarises country-specific experiences.

[77] The authors of the 2012 study hypothesised that, because 38% of all observations were not suitable for analysis, those who did not respond were probably more likely to not dispense a drug prescribed by a foreign prescription.

[78] Note that the German sample consists of only four questionnaires, which does not allow for a meaningful comparison in this regard.

Figure 22: Experience with prescriptions from other EU Member States (per month)



	DE	DK	FR	NL	PL
Above 20	0	0	15%	15%	11%
11-20	0	0	7%	12%	8%
6-10	25%	0	5%	4%	14%
1-5	50%	100%	58%	58%	49%
0	25%	0	15%	8%	18%

4.1.1. Number of foreign prescriptions

Based on the survey results, it is possible to estimate the range of foreign prescriptions presented for dispensing across the four Member States per month[79]. As per the table below, each month, an estimated 209,287 to 523,823 prescriptions are sought to be dispensed across these countries.

Table 12: Range estimates of absolute number of prescriptions (per month)

Dispensing country	Lower Bound	Upper Bound	Number of Pharmacies	Absolute Lower Bound	Absolute Upper bound
Germany	2.00	5.00	18,753[80]	37,506	93,765
France	4.76	12.18	20,736[81]	99,932	255,550

[79] Denmark has been exlcuded from this part of the analysis, as only one questionnaire was submitted.

[80] ABDA.de (2021): Zahl der Apotheken sinkt auf 18.753. [online] Bundesvereinigung Deutscher Apothekerverbände. Available at: https://www.abda.de/aktuelles-und-presse/pressemitteilungen/detail/zahl-der-apotheken-sinkt-auf-18753/

[81] Statista.com (2020): Number of pharmacies in France from 2009 to 2019 [online] Available at: https://www.statista.com/statistics/1227694/pharmacies-number-france/

Dispensing country	Lower Bound	Upper Bound	Number of Pharmacies	Absolute Lower Bound	Absolute Upper bound
Netherlands	5.31	13.27	2,000[82]	10,642	26,605
Poland	4.57	11.04	13,300[83]	61,208	147,903
Total			**54,789**	**209,287**	**523,823**

Note: shaded cells indicate approximations based on 'more than 20' meaning 'between 21 and 50'

Based on the 2012 methodology, lower and upper bounds were calculated by taking the average of the minimum and maximum values across the individual response categories (i.e. 0, 1-5, 6-10, 11-20, above 20) and applying the below equations, where W = percentage of overall responses per category, and min/max = respective minimum and maximum value per category.

Equation 4: Number of foreign prescriptons (across four Member States, per month

$$Lower\ Bound_{MS} = W_0(min1) + W_{1-5}(min2) + W_{6-10}(min3) + W_{11-20}(min4) + W_{21-50}(min5)$$

$$Upper\ Bound_{MS} = W_0(max1) + W_{1-5}(max2) + W_{6-10}(max3) + W_{11-20}(max4) + W_{21-50}(max5)$$

The theoretically unlimited scope of the "above 20" foreign prescriptions option posed a problem in calculating the absolute number of foreign prescriptions received per month. The authors of the 2012 study therefore assumed that "above 20" means between 21 and 50 and the study team follows this assumption for the present analysis.

The above presented estimated range of foreign prescriptions received per month is not suitable for deriving any conclusions on non-dispensing probability, for which a point estimate is preferred. Although respondents seem to have relatively more experience with foreign prescriptions now compared to 2012 (8% of Dutch and 1% of French and Polish pharmacists indicated to receive more than 20 foreign prescriptions per month in 2012 compared to 15% of Dutch and French pharmacists and 11% of Polish pharmacists in 2021), the majority of respondents had little or no experience with foreign prescriptions, meaning that the data is positively skewed. A simple arithmetic mean would not be representative and overstate the experience pharmacists have with foreign prescriptions. As the authors of the 2012 study proposed, a different approach was taken to produce a weighted point estimate based on the response rates and total number of pharmacies in the four analysed countries.

In a **first step**, the questionnaire responses were standardised. The varying response rates per each response category across the four countres were multiplied by the relative share of pharmacists in each study country.

Table 13: Weighted distribution of foreign prescriptions (per month)

	Percentage distribution
0	19%

[82] Statist.com (2021): Number of public pharmacies in the Netherlands from 2017 to 2021, by type [online] Available at: https://www.statista.com/statistics/708786/number-of-public-pharmacies-in-the-netherlands-by-type/

[83] Statista.com (2021): Number of pharmacies in Poland from 2018 to 2021 [online] Available at: https://www.statista.com/statistics/1100052/poland-number-of-pharmacies/

	Percentage distribution
Between 1-5	53%
Between 6-10	14%
Between 11-20	5%
Above 20	9%

Since the data is positively skewed, it was assumed that this was also reflected within each response category. In a **second step**, each interval was divided into five equally sized sections to which the overall distribution weights were assigned[84].

Thirdly, the arithmetic averages of the four sections for each of the four intervals were multiplied by the respective weights to obtain a point estimate of the "average experience" within each interval.

In the fourth step, the resulting range-specifc point estimates were multiplied by the weights again and then summed-up to obtain an overall point estimate of the average prescription per pharmacist.

Based on the collected data, the average pharmacy across the four Member States deals with 5.86 foreign prescriptions per month. When multiplied with the number of pharmacies in the four countries (55,131), the total number of prescriptions received per month in the four Member States is 320,908 (3,850,892 foreign prescriptions per year). Extrapolated to the EU, and assuming that the four Member States represent 49.747% of all prescriptions dispensed in the EU[85], this results in **645,073 prescriptions being presented for dispensation each month (7,740,876 foreign prescriptions presented for dispensation per year)**.

4.1.2. Number of total prescriptions

For additional context, the number of foreign prescriptions dispensed in the EU can be seen compared to the number of total prescriptions dispensed within one year. The study team engaged in desk research to update the 2012 data on the estimated number of dispensed prescriptions per country. In case no information was available, the 2012 data was relied upon. Based on the information presented in the below table, a **total of 6.67 billion prescriptions are dispensed across the EU each year**. Consequently, the number of foreign prescriptions dispensed across the EU annually equals 0.0012% of all prescriptions dispensed.

Table 14: Estimated number of dispensed prescriptions (annually)

Country	Estimated number of prescriptions per year	Year
Austria	113,800,000	2017
Belgium	336,150,000	2009

[84] The first interval „0" was omitted. This divides the 1-5 interval into sections of 1-1,8, 1,8-2,6, 2,6-3,4, 3,4-4,2 and 4,2-5 which are assumed to be distributed with the following weights respectively: 19%, 53%, 14%, 5% and 9%.

[85] Table 8 indicates that 3,318,292,000 prescriptions are dispensed in the four Member States annually. This equals 0.49747% of the total 6,670,270,449 prescriptions dispensed across the EU.

Country	Estimated number of prescriptions per year	Year
Bulgaria	N/A	N/A
Cyprus	4,536,000	2008
Czech	70,000,000	2019
Germany	445,000,000	2020
Denmark	67,203,000	2008
Estonia	8,600,000	2018
Greece	265,599,000	2009
Spain	999,000,000	2010
Finland	65,668,000	2019
France	1,979,046,000	2010
Hungary	173,924,449	2019
Ireland	123,309,000	2010
Italy	541,000,000	2020
Lithuania	10,300,000	2018
Latvia	6,800,000	2018
Luxembourg	9,504,000	2009
Malta	8,127,000	2010
Netherlands	240,000,000	2016
Poland	654,246,000	2009
Portugal	44,579,000	2020
Romania	321,138,000	2009
Sweden	86,000,000	2020
Slovakia	67,959,000	2007
Slovenia	28,782,000	2009
Croatia	N/A	N/A
EU4	**3,318,292,000**	
Total	**6,670,270,449**	

4.1.3. Foreign prescription extrapolation

The survey targeted five EU Member States and yielded suitable data from four countries (Poland, France, Netherlands, and Germany). Therefore, the study team **extrapolated for the entire EU based** on data obtained on pharmacists' experience with foreign prescriptions per month and calculated the **number of annually received foreign prescriptions**.

The below table provides a step-by-step overview of the quantification of pharmacists' experience with foreign prescriptions:

- a **point estimate** of 5.86 foreign prescriptions per pharmacy per month; and
- a **range estimate** of between 207,674 and 519,760 monthly foreign prescriptions presented across the four targeted countries.

Table 15: Overview of calculation of EU annual foreign prescriptions

Point estimate, surveyed countries			
	Monthly foreign prescrptions per pharmacy	**EU4 monthly foreign prescriptions**	**EU4 annual foreign prescriptions**

Transformation	*from earlier analysis*	*multiply by 54,789 (number of pharmacies[86])*	*multiply by 12*
Result	**5.86**	**320,908**	**3,850,892**
Point estimate, EU			
	EU4 monthly foreign prescriptions	**EU27 monthly foreign prescriptions**	**EU27 annual foreign prescriptions**
Transformation	*multiply by 54,789 (number of pharmacies)*	*divide by 49.747, multiply by 100 (49.747% of all prescriptions in EU27)*	*multiply by 12*
Result	**320,908**	**645,080**	**7,740,876**
Range estimate, surveyed countries			
		EU4 monthly foreign prescriptions	**EU4 annual foreign prescriptions**
Transformation		*from earlier analysis*	*multiply by 12*
Lower Bound		**207,674**	**2,492,088**
Upper Bound		**519,760**	**6,237,120**
Range estimate, EU			
	EU6 monthly foreign prescriptions	**EU27 monthly foreign prescriptions**	**EU27 annual foreign prescriptions**
Transformation	*from earlier analysis*	*divide by 49.747, multiply by 100 (49.747% of all prescriptions in EU27)*	*multiply by 12*
Lower Bound	**207,674**	**417,460**	**5,009,520**
Upper Bound	**519,760**	**1,044,806**	**12,537,672**

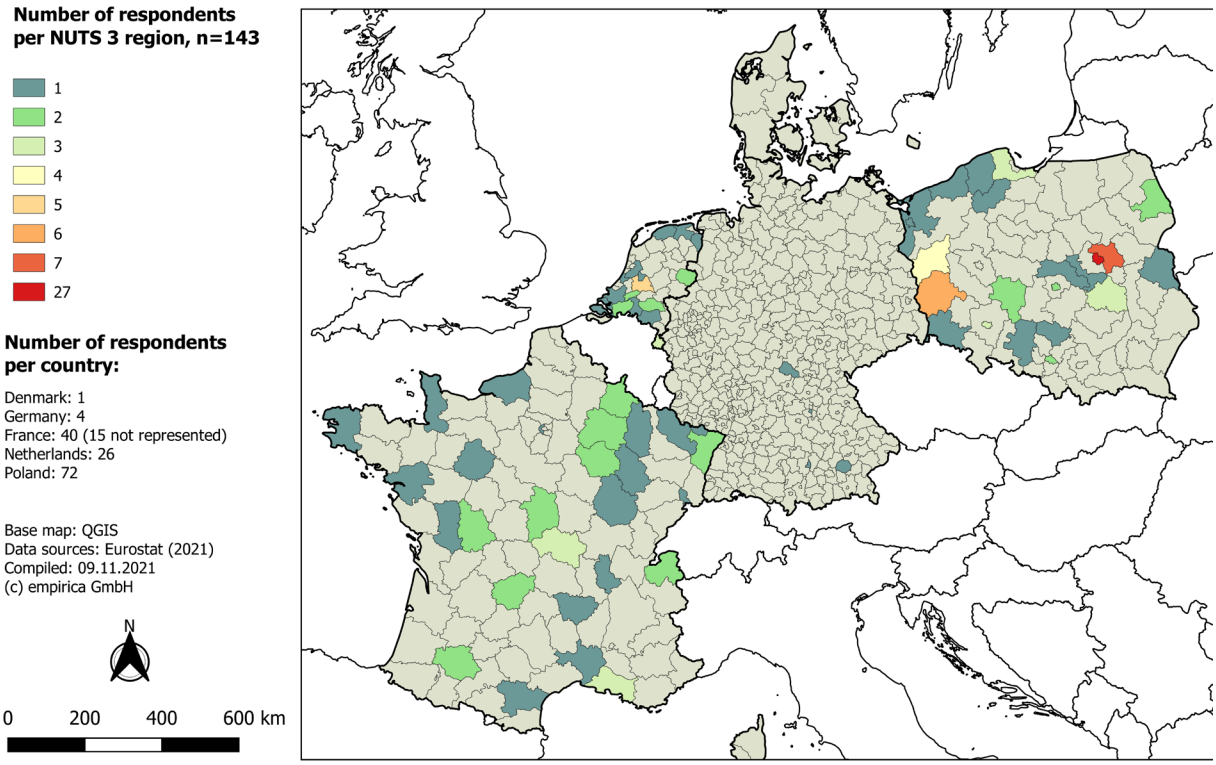
4.1.4. Geographical distribution of respondents' place of work

As per the below map, some responses were submitted from pharmacists working in border regions, however, the majority of respondents indicated to work in non-border regions. The study team assumed that, provided the survey invitation reached a significant amount of pharmacists in each country, those working in border reagions would be more likely to respond to the survey as the topic of foreign prescriptions is more likely to apply to them compared to pharmacists living in areas with a low density of foreign EU citizens or cross-border commuters. The majority of respondents indicated their place of work based on the local administrative unit, which were mapped to the EU NUTS 3[87]. 15 respondents from France, however, did not choose to indicate their place of work and are not represented in the below figure.

[86] See distribution of pharmacies per country in table 6 on page 23.

[87] The NUTS classification or "Nomenclature of territorial units for statistics" is a EU-wide standardised system for hierachially dividing the economic territory of the EU. Its purposes are harmonisation of regional statistics, socio-economic analyses of the regions and the framing of EU regional policies. Read more at: https://ec.europa.eu/eurostat/web/nuts/background

Figure 23: Geographical distribution of respondents place of work according to EU NUTS 3 units, n=143



The largest share of Polish respondents (34) work in or in the vicinitiy of Warsaw and another 13 work somewhat close to the Polish-German border region. Also counting three respondents from the Poland's east, 22% of Polish responsents work in border regions. Dutch respondents mostly worked in the region of Rotterdam and south to south-west of Utrecht (15), close to the Belgian border (five), while another five respondents work in the Dutch-German broder region. The picture for France is mixed: nine respondents indicated to work in the French-German, French-Belgian and French-Swiss border region, which leaves around 80% of the respondents (31[88]) not working in border regions. A fraction of these do reside in touristic areas, such as the French Mediterranean coast, Normandy and the Bretagne, where contact with foreign prescriptions of tourists would be likely.

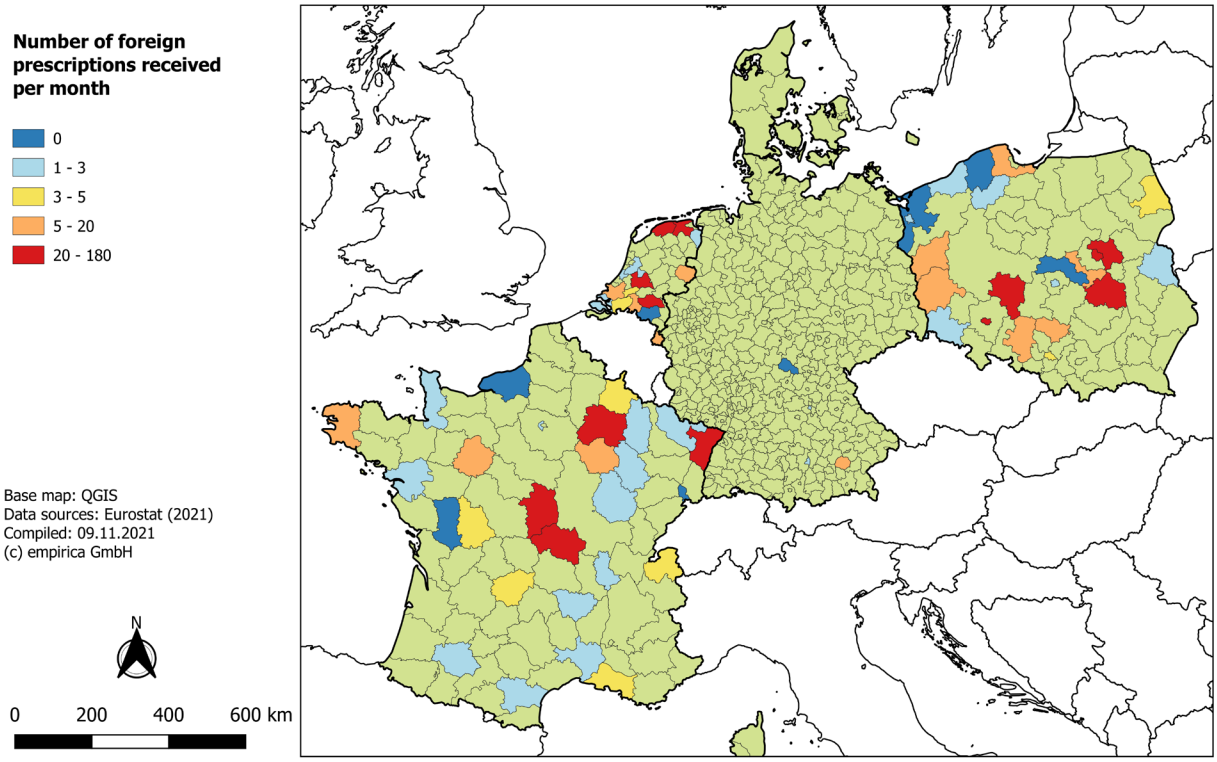
In addition to looking at the individual location of each respondents, the number of foreign prescriptions received by the respondents in each regions can yield insights into how intense the contact with foreign prescriptions in each region could be estimated. The values per region were calculated with the weighted averages of prescriptions per response category described in section 4.1.1.

Responding pharmacists working in the French-German and, to some extent, in the French-Belgian border region are estimated to receive a relatively high number of foreign prescriptions per month. The northern parts of the Netherlands, which are a popular tourist destination, also show a high amount of estimated foreign

[88] This does not include the 15 respondents, who did not indicate their place of work. These included, around 70% of respondents do not work in border regions.

prescriptions per month. Experience with foreign prescriptions in the Polish-German border region, in contrast, is limited as the data shows. Polish regions marked in red are densely populated metropolitan areas with a high response rate, hence the large total amount of prescriptions received.

Figure 24: Geographical distribution of estimated foreign prescriptions received per EU NUTS 3 unit, n=143

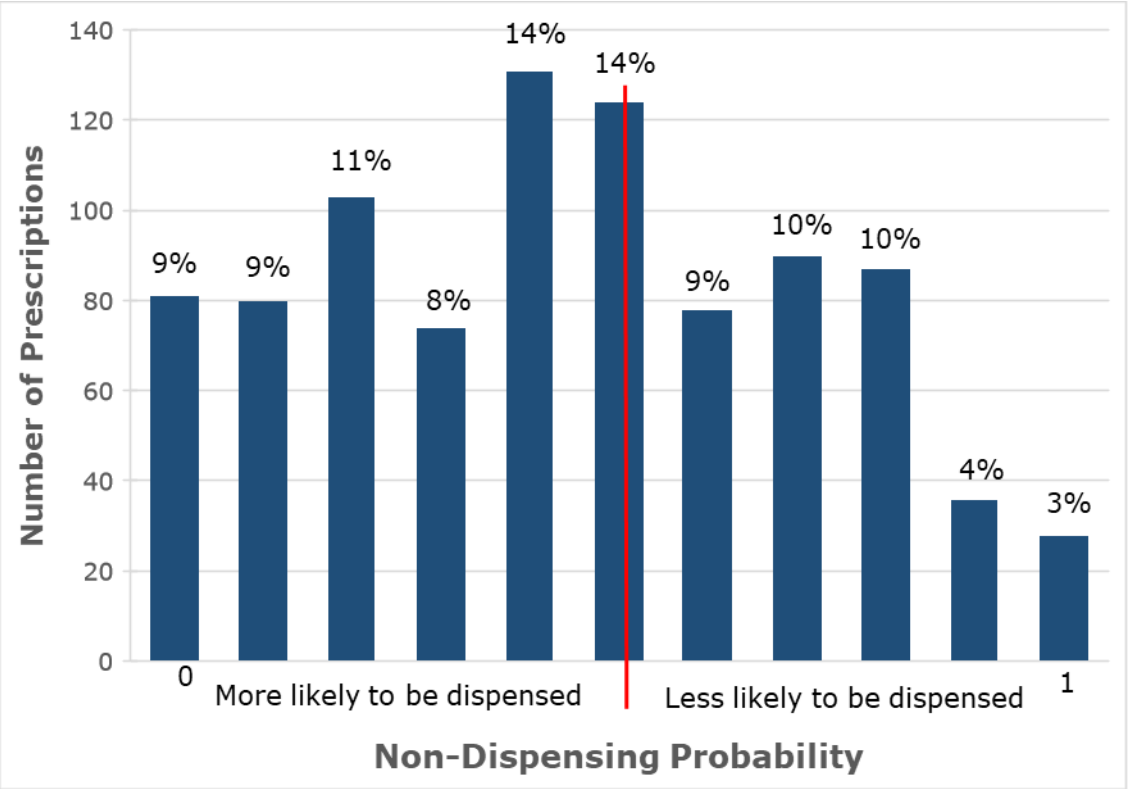


4.2. Non-dispensing probabilities for foreign prescriptions

The below histogram of the distribution of probabilities shows, that, across all suitable prescription responses (912 out of 948 responses), **it is more likely that a drug is dispensed rather than not dispensed**. Overall, the probability of not dispensing a drug when using a foreign prescription is 46%, i.e. **the probability of being able to obtain a drug is 54%**. Compared to the results of the 2012 study, in which the probability of not obtaining a drug when using a foreign prescription was 55% and, thus, the probability of being able to obtain a drug was 45%, the data presents an improvement of dispensing probability of nine percentage points[89].

[89] The mean non-dispensing probability in 2012 across all eight pathologies was 55.5%. Excluding diabetes, depression and epilepsy, the mean non-dispensing probability would have been 55.4% in 2012. Although some pathologies were associated with higher non-dispensing probability, the exclusion of some pathologies is likely to not have impacted the overall non-dispensing probability.

Figure 25: Distributional histogram of non-dispensing probabilities



The histogram presents discrete probability categories between 0 and 1 against the absolute number of observations within each category, i.e. the relative frequency on the whole sample. 9% of all observations show a non-dispensing probability nearest to 0 (compared to 3% in 2012), while 3% of all observations have a non-dispensing probability nearest to 1 (compared to 7% in 2012)[90]. This translates to a total of 81 prescriptions which would be expected to definitely be dispensed, whereas 28 prescriptions would be expected to definitely not be dispensed.

Despite the increase in overall dispensing probabilities, there remain problems in dispensing 46% of all foreign prescriptions. Thus, different categories of information are analysed in the subsequent sections: non-dispensing probability by pathologies, drug type, prescribing and dispensing country.

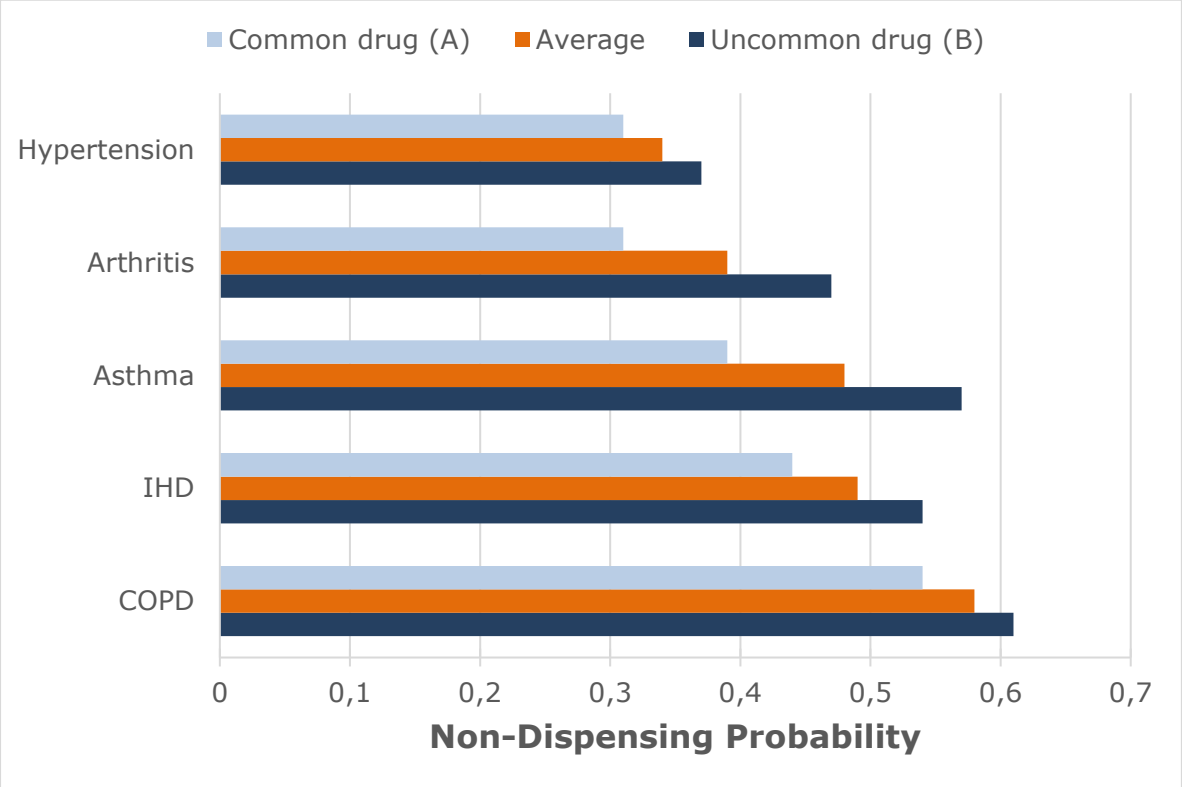
4.2.1. Pathologies and drug type

Non-dispensing probabilities vary by pathologies and drug type. **Medication prescribed on foreign prescriptions for COPD are most likely not to be dispensed** (58% of all cases), based on the survey data. On the contrary, **drugs and medicinal products for hypertensive patients are not dispensed in only 34% of all cases**. The data confirms that dispensing problems occur less frequently with drug A medication (which show a non-dispensing probability of 40% on average), compared to drug B medication (with a non-dispensing

[90] The mean non-dispensing probability in 2012 across all 8 pathologies was 55.5%. Excluding the Diabetes, Depression and Epilepsy, the non-dispensing probability would have been 55.4% in 2012. Although some pathologies were associated with higher non-dispensing probability, the exclusion of some pathologies in the current case study is likely to not have impacted the overall non-dispensing probability.

probability of 51%).

Figure 26: Non-dispensing proabilities by pathology



A more detailed depiction of non-dispensing probabilities by pathology and drug type as well as statistical key figures are presented in the below table[91]. While **the use of different drugs (A and B type) for hypertension and COPD appears to have only a small effect on non-dispensation** (6% and 7% respectively), the **difference in non-dispensing probability between drug type for Arthirits and Asthma are overall higher** (16% and 18% respectively), suggesting that the prescribed drug type has a higher impact on the non-dispensing probability for these conditions. Note that the overall response count for these two pathologies is significantly lower than for the remaining ones, which might have contributed to a larger range of non-dispensing probability.

Table 16: Mean non-dispensing probabilities, standard deviations and standard errors of the mean estimates

Pathology	Drug type	Non-dispensing probability	Difference A-B	Sample standard deviation	Standard error for the mean
Arthritis	Overall	0.39		0.68	0.06
Arthritis	A	0.31	0.16	0.62	0.08
Arthritis	B	0.47		0.67	0.09
Asthma	Overall	0.48		0.73	0.06

[91] Note that average pathology results are simply the arithmetic mean of the drug A and drug B probabilities. Because there was no significant difference in the number of responses to 'A' and 'B' prescriptions, this is a legitimate way in which to estimate the pathology-specific probabilities.

Pathology	Drug type	Non-dispensing probability	Difference A-B	Sample standard deviation	Standard error for the mean
Asthma	A	0.39	0.18	0.73	0.08
Asthma	B	0.57		0.71	0.08
COPD	Overall	0.58		0.78	0.05
COPD	A	0.54	0.07	0.75	0.07
COPD	B	0.61		0.77	0.07
Hypertension	Overall	0.34		0.74	0.05
Hypertension	A	0.31	0.06	0.85	0.08
Hypertension	B	0.37		0.82	0.08
IHD	Overall	0.49		0.81	0.05
IHD	A	0.44	0.10	0.75	0.07
IHD	B	0.54		0.78	0.07

Overall, the non-dispensing probability ranges from 31% (Arthirits/A, Hypertension/A) to 61% (COPD/B). Compared to 2012, the decrease in non-dispensing probability per pathology ranges from 19% (Arthirits and Hypertension) to 11% (Asthma, COPD, IHD). Due to the overall small sample size of the analysis[92], the observed standard deviations[93] and the standard errors[94] are rather high. This reduces the reliability of our findings and any conclusions should hence be regarded as indicative. It should be noted that the true non-dispensing probabilities are, in reality, likely to range by one standard error below and above the estimated non-dispensing probabilities (e.g. Arthritis/A: 0.23 - 0.39 with a standard error of 0.08).

4.2.2. Prescribing and dispensing countries

Issues related to the non-dispensation of foreign prescriptions exist both in terms of the country of origin of the prescription as well as the country in which the drug is sought to be dispensed. German[95], Dutch and Polish pharmacists are more likely to dispense foreign prescriptions, with German pharmacists showing the lowest non-dispensing probability (28%). Prescriptions originating from Germany also have the lowest non-dispensing probability (40%), while Dutch prescriptions are most likely to not be dispensed abroad (61%). Foreign prescriptions are less likely to be dispensed in France with a non-dispening probability of 59%.

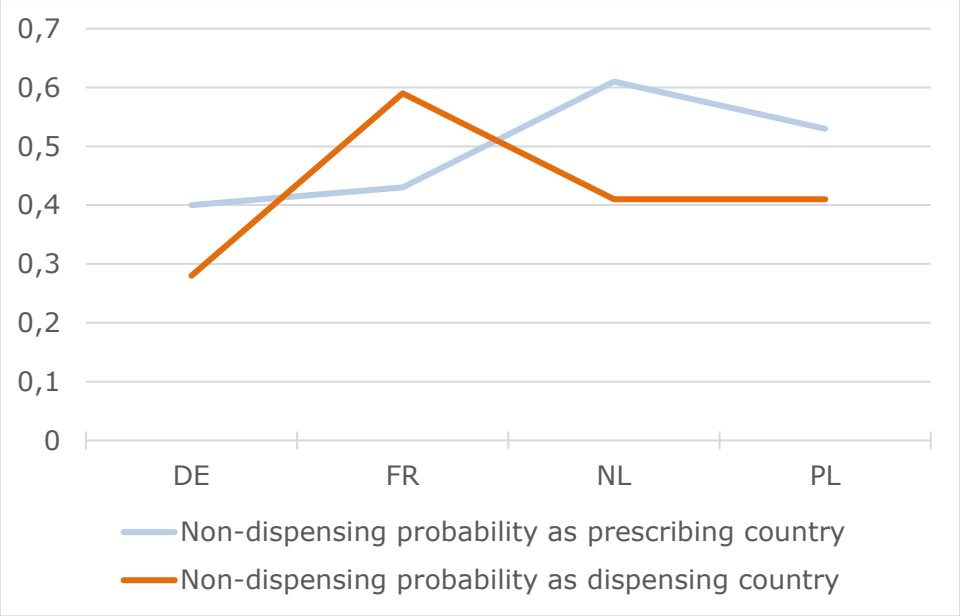
[92] In total, the survey yielded 948 suitable prescription observations. For comparison, the 2012 survey analysed 7440 suitable prescriptions observations.

[93] The sample standard deviation denotes the square root of the sample variance, i.e., how far the individual data points differ from the mean value.

[94] The mean standard error denotes an estimate of how far the actual probability is likely to vary from our estimate of the probability.

[95] It must ne noted that the result for Germany is not reliable, as only four pharmacists responded to the survey.

Figure 27: Probabilities by prescribing and dispensing country



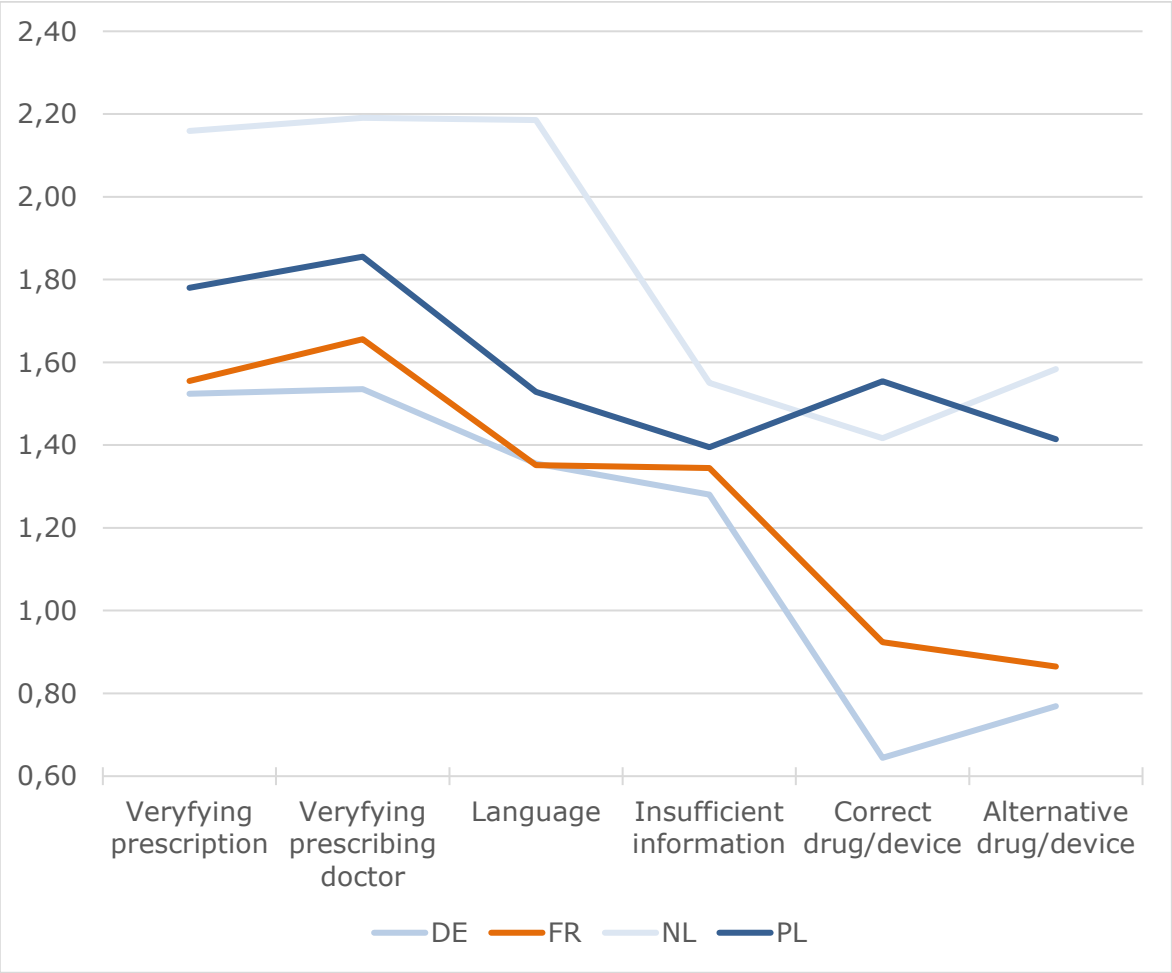
4.3. Underlying problem drivers for non-dispensing

This section analyses the underlying problem drivers for non-dispensation: veryfying prescription, veryfying prescribing doctor, language, insufficient information, correct drug/device and alternative drug/device. The problems are viewed from the perspective of both the prescribing and the dispensing countries.

4.3.1. Prescribing countries

The figure below illustrates the key problem drivers which contribute to problems in dispensing foreign prescriptions. It graphs the seven problem drivers against their average code score, by prescribing country. The measure used here is the 0-3 scale that was used to code pharmacists' responses to questions – a higher code score denotes more problems.

Figure 28: Key problem drivers (prescribing country)



As had been concluded in the 2012 study, **the two greatest problem drivers for non-dispensation are related to verification and authenticity problems** (see figure above). The average codes for the questions on "verifying the authenticity of the prescription" and "verifying the prescribing physician" are 1.75 and 1.81, respectively. In addition, and as a new result compared to the 2012 study, **language seems to be associated with a higher non-dispensation probability** (with an average code of 1.61), **especially in relation to prescription originating from the Netherlands** (2.19). These are also strongly related to an average code for "verifying the authenticity of the prescription" and "verifying the prescribing physician", which could explain the high non-dispensation rate of Dutch prescriptions mentioned earlier.

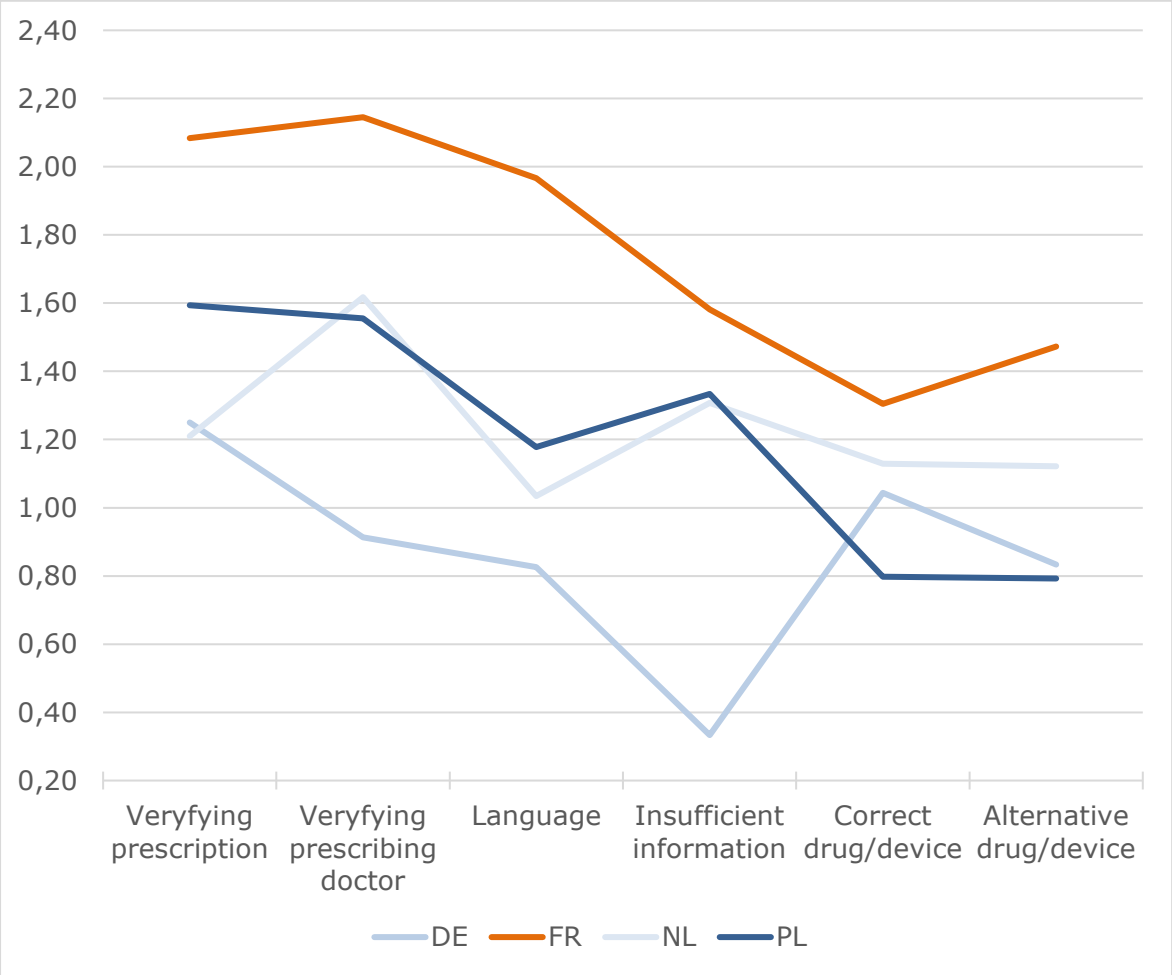
Due to the limited number of countries analysed, no reliable conclusion can be drawn on country-by-country variance. However, the availability of the prescribed drugs or their substitutes poses the least likely problem for non-dispensation, as these items show the overall lowest average codes (1.13 and 1.16, respectively). Availability of drugs prescribed on Dutch or Polish prescriptions are three times more likely to cause issues abroad, than those on German or French prescriptions. Pharmacists in all countries rate the completeness of information presented on foreign prescriptions quite similar (with a range of only 0.27), indicating that the average pharmacist might be missing some important information on foreign

prescriptions or might experience moderate issues in identifying certain information when dispensing foreign prescriptions across all countries.

4.3.2. Dispensing countries

As before, the next figure illustrates the key problem drivers which contribute to problems in dispensing foreign prescriptions – but from the perspective of dispensing countries. This analysis investigates whether pharmacists in particular countries require stricter verification processes as those in other countries or whether drug availability is a problem in some countries. As mentioned before, Germany[96] is the country most likely to dispense foreign prescriptions, while France is least likely to do so.

Figure 29: Key problem drivers (dispensing country)



Similar to the results in the previous section, **access and availability to drugs are less severe problems compared to other categories**. Poland and Germany show the lowest scores in both categories. The Netherlands score relatively low as well, which confirms the results from the 2012 study that these

[96] It must ne noted that the result for Germany is not reliable, as only four pharmacists responded to the survey.

countries are likely to be more experienced with foreign prescriptions and thus store a wider range of drugs. From all countries, drug availability is a more severe problem in France.

Pharmacists from Germany have the least problems with the information presented on foreign prescriptions (0.33), whilst pharmacists from the other three countries generally indicate that important information is missing on prescriptions from all countries, which poses an intermediate risk to the dispensing probability. The **language** in which the prescription is written seems to be more problematic in the Netherlands and Poland than in Germany.

While **verification and authenticity** issues are less of a problem for German (1.25) and Dutch (1.21) pharmacists, **France scores highest in both categories (2.08 and 2.15)**. Also, **language seems to be a severe problem for dispensing foreign prescriptions in France** (1.97), while prescriptions originating from France show the lowest average score. This indicates a general low level of familiarity with cross-border prescriptions amongst French pharmacists and language barriers. **Generally, these categories present the largest barrier to dispensing foreign prescriptions across all counties**, providing indicative evidence that there still remain EU-wide verification and authenticity problems associated with foreign prescriptions. It can be expected that the reported barriers to dispensation can partially be reduced with increased interoperability of national eHealth infrastructures and wider uptake of ePrescriptions. Also, language barriers could be reduced due to automatic translation functions when transferring an ePrescription into another country (see answer to EQ11 in the final report on the study supporting the evaluation of the CBHC Directive).

The correlation matrix below indicates that there are relatively strong correlations between verifying the prescription and the prescribing doctor as well as between access to the correct drug/device and availability of alternative drugs/devices. This confirms the 2012 results (0.8 compared to 0.85 and 0.77 compared to 0.79, respectively), although it has to be kept in mind that the overall sample size of this analysis reduces the reliability of these results.

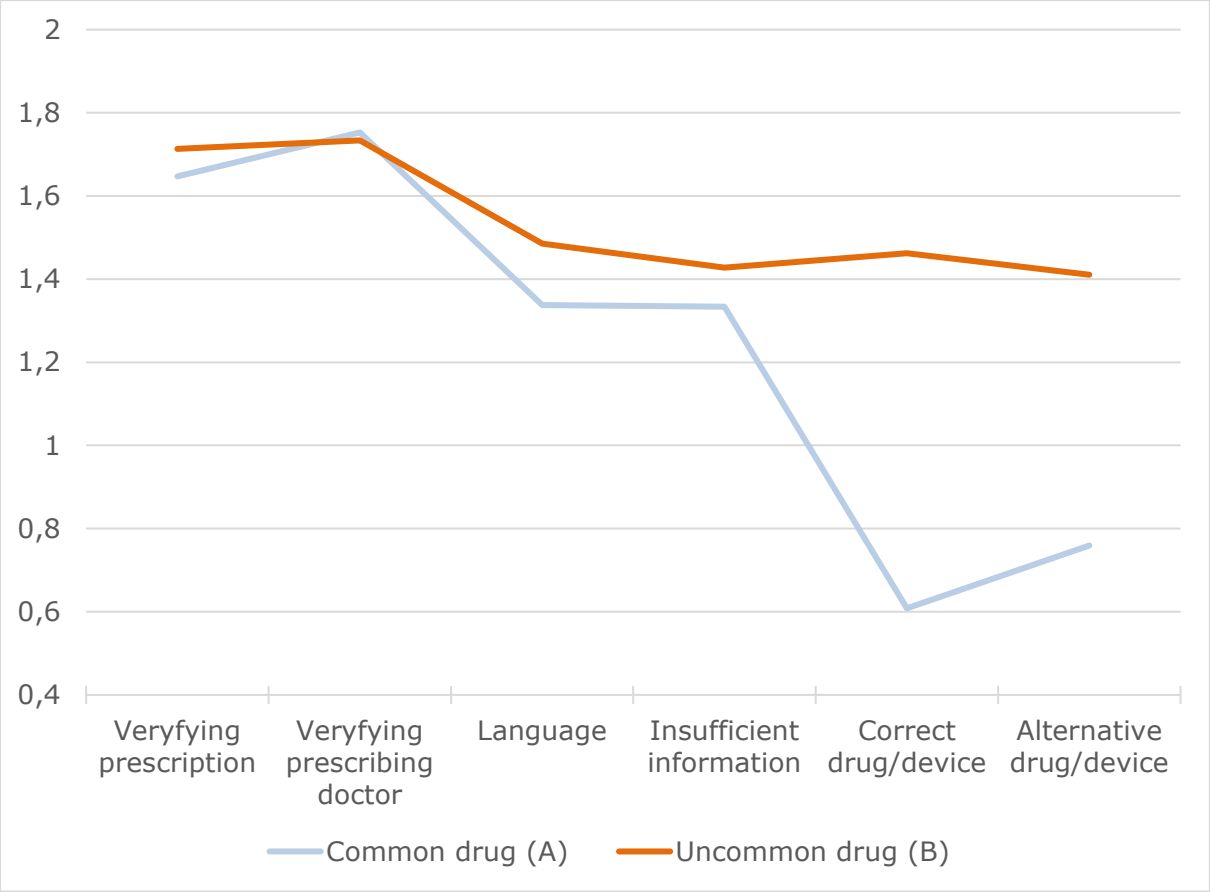
Table 17: Dispensing problems correlation matrix

	Veryfying prescript-ion	Veryfying prescrib-ing doctor	Lang-uage	Insuffi-cient informa-tion	Correct drug/ device	Alternative drug/ device
Veryfying prescription		0.80	0.51	0.48	0.22	0.31
Veryfying prescribing doctor	0.80		0.49	0.50	0.25	0.34
Language	0.51	0.49		0.49	0.34	0.41
Insufficient information	0.48	0.50	0.49		0.29	0.36
Correct drug/device	0.22	0.25	0.34	0.29		0.77
Alternative drug/device	0.31	0.34	0.41	0.36	0.77	

4.3.3. Drug type

Compared to the 2012 data, both drug A and B type cause fewer dispensing issues and drug A type prescriptions generally cause less severe problems compared to drug B type prescriptions. Inter-drug type differences remain minor, with the exception of access and availability questions. This is in line with the 2012 findings and supports the hypothesis that type B drugs which are less commonly available or prescribed pose greater challenges for dispensing foreign prescriptions.

Figure 30: Key problem drivers (by drug type A and B)



5. CONCLUSIONS

This case study was carried out in the context of the evaluation of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 to ensure patients' rights in the EU in cross-border healthcare (CBHC Directive). As of specific interest, Article 11 of the of the CBHC Directive gives effect to the principle of mutual recognition of medical prescriptions across borders and empowers the Commission to adopt practical measures to assist such recognition. These measures aim 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. The case study effectively updates the baseline data obtained in a previous study from 2012.

The study team updated the baseline data with data obtained from an **online survey targeted at active pharmacists in five EU Member States** (Denmark, Germany, France, Netherlands and Poland), from which a total of 158 pharmacists

submitted their contribution. The field experts provided their estimation and view on dealing with foreign prescriptions from other EU Member States on five pathologies (Asthma, COPD, Hypertension, Ischaemic Heart Disease, Osteoarthritis/Rheumatoid Arthritis).

Main results

The analysis provided indicative evidence of an estimated increase of foreign prescriptions presented to pharmacies in the EU of 400% (from 1.46 foreign prescriptions per pharmacy per month in 2012 to 5.86 in 2021) and a reduction of non-dispensation probability of nine percentage points (from 55% in 2012 to 46% in 2021).

The data show that **an estimated 7.7 million EU prescriptions are sought to be dispensed in other EU Member States each year** (estimated minimum: 5 million; estimated maximum: 12.5 million). Compared to the total volume of prescriptions dispensed each year across the EU, the amount of foreign prescriptions equals 0.0012%. The average EU pharmacy receives 5.87 foreign prescriptions each month. On average, 16.5% of pharmacies do not deal with foreign prescriptions at all[97].

Based on the analysis of the probability of non-dispensing derived from the survey data, **46% of all foreign prescriptions (3.6 million in total) are likely not to be dispensed** due to a range of six factors (veryfying prescription, veryfying prescribing doctor, language, insufficient information, correct drug/device and alternative drug/device). In total, 9% (81) of foreign prescriptions would definitely be dispensed, whilst 3% (28) would definitely not be dispensed.

Further analyses confirmed that **more commonly available medicines (drug A type) cause less severe dispensing problems** and that, generally, access to and availability of less frequently prescribed drugs may still be an issue in some EU countries. The **key problem drivers to non-dispensation are verification of prescriptions and prescribing physician**, while presenting prescriptions in a **different language can pose a high barrier** for pharmacists in some EU Member States.

[97] Note that this value presents the artithmetic average of responses in this category for four countries and that the value for Germany represents only one respondent.

Appendix 1: Country-specific prescription mockups

Figure 31: Danish prescription mockup presented in the online survey to German, Dutch and Polish pharmacists

Figure 32: German prescription mockup presented in the online survey to Danish, French and Polish pharmacists

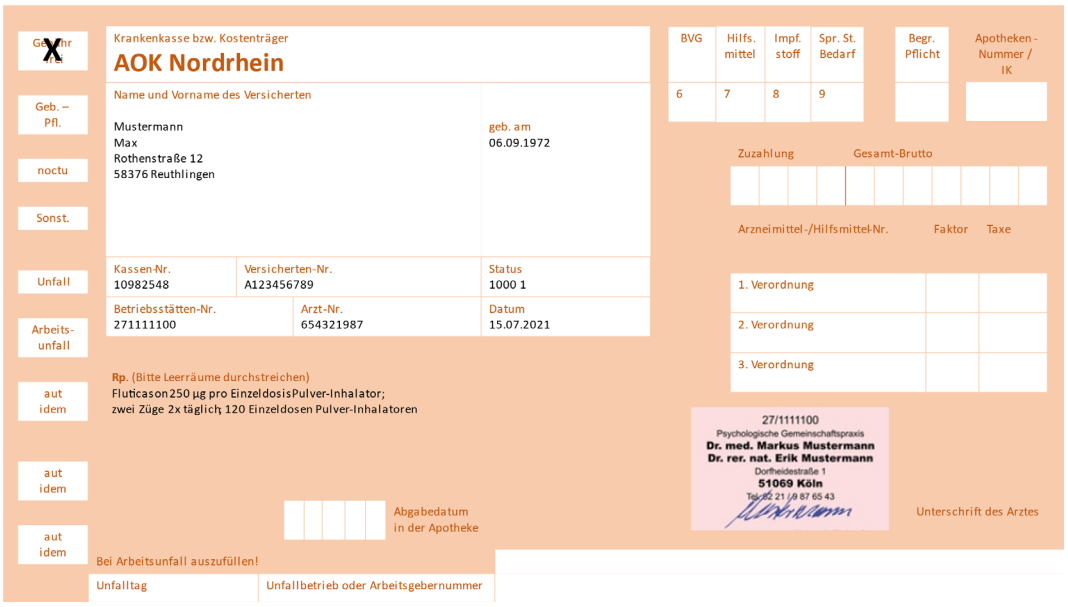


Figure 33: French prescription mockup presented in the online survey to Danish, Dutch and Polish pharmacists

Figure 34: Dutch prescription mockup presented in the online survey to Danish, German and French pharmacists

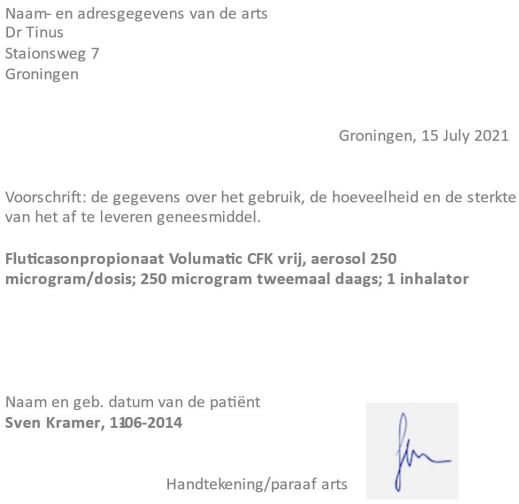


Figure 35: Polish prescription mockup presented in the online survey to German, French and Dutch pharmacists

Annex 10: Data collection tools for targeted stakeholder consultation activities

Topic guide for exploratory interviews

Questions for Commission services

1. From your perspective what do you see as the main objectives of this evaluation? What do you think it needs to achieve (or what would you hope it achieves)?
2. Is there any topic or issue of particular interest that the evaluation should explore?
3. We are at the early stages of our research and are refining our tools and methodology. What challenges do you think we may face and do you have any advice on how we can overcome these challenges?

Patients' rights

4. What was the Directive intended to achieve in terms of patients' rights when it was adopted? What was the situation like in terms of patients' rights then?
5. Were the objectives of the Directive broadly appropriate when they were established?
6. Since the Directive was adopted/ transposed, what are in your view the key events and wider context changes that may have affected the provision of cross-border healthcare?
7. Have objectives been broadly achieved? What is in your view a good outcome of the Directive in terms of patients' rights?
8. What has worked less well? Or which are the main gaps or areas for improvement?
9. How do you see the interaction of the Directive with the social security regulations?
10. Are patients sufficiently aware of the differences between the two ways of obtaining cross-border healthcare?
11. What about the national competent authorities? What are the challenges for them?

Rare diseases

12. What was the Directive intended to achieve in terms of EU collaboration in rare diseases when it was adopted? What was the situation like in terms of EU collaboration in rare diseases?
13. Were objectives broadly appropriate when they were established?
14. Have objectives been broadly achieved? What is in your view a good outcome of the Directive in terms of EU collaboration in rare diseases and the establishment of the European Reference Networks?
15. What has worked well?
16. What has worked less well? What are the main areas for improvement?

(Consult about planned engagement activities with the ERNs to make sure that our data collection does not affect ongoing and future technical evaluation work.)

Additional information and wrap-up:

17. Do you have documents or data sources that may be of use for the evaluation?
18. Do you have any additional suggestions or comments that you consider could be useful in the framework of the current study?

Questions for representatives of the insurance sector

1. What is your perspective of the Directive 2001/24/EC on the application of patients' rights in cross-border healthcare in terms of the role that it plays in the activities of your member organisations?
    - Interaction with Social Security Coordination Regulations, partnerships among neighbouring countries (e.g. ZOAST)

2. Do you consider that the Directive brings improvements to patients' rights? How? What is still missing?
3. Are your members clear of what the obligations of health mutuals and health insurance bodies are under the Directive? Is there a guidance available?

4. Are there any issues and challenges that member organisations have brought to your attention in relation to the implementation of the Directive?

    - E.g. reimbursement of cross border healthcare or prior authorisation

5. Are you aware of what has worked well under the Directive?

6. What are in your view the main areas for improvement? E.g.
    - Your organisation Position paper for the evaluation roadmap mentions a recommendation to simplify the legal framework for patients and for professionals, ***do you want to expand on this?***
    - What do you recommend in terms of further guidance for patients/ professionals/ insurers?

7. Are you aware on whether your member organisations are compiling data that could be relevant for the study? E.g.
    - Reimbursement costs/other costs related to the implementation of the Directive
    - Administrative burden of implementing the Directive
    - Number of consultation with patients who want to access cross-border healthcare (under the Directive)
    - Types of treatment that patients have received abroad (under the Directive)
    - Treatment/diagnosis on rare diseases

8. We would like to carry out a limited targeted survey among health mutuals and health insurance bodies. Could your organisation support us in the dissemination among their EU/EEA members?

9. Do you know of any documents or data sources that may be of use for the evaluation?

10. Do you have any additional suggestions or comments that you consider could be useful in the framework of the current study?

Questions for organisations representing pharmacists at EU level

1. From your perspective what do you think that the evaluation should try to achieve?
2. What was the Directive intended to achieve in terms of mutual recognition of prescriptions when it was adopted? What was the situation like in terms of mutual recognition of prescriptions?
3. Have objectives been broadly achieved? What is in your view a good outcome of the Directive in terms of mutual recognition of prescriptions?
4. What has worked less well? What are the main challenges and areas for improvement?
    - In your statement to the evaluation roadmap, you said:
        - "Community pharmacists observe that today, significant barriers remain in place which prevent patients to take full advantage of the CBHC directive. For community pharmacists this is especially noticeable in the area of recognition of prescriptions across borders." – *can you please expand on this?*
        - "EU rules on recognition of prescriptions have not yet been duly implemented into national legislation" – *do you know which ones?*
5. What has worked well?

CASE STUDIES

- Explain about the case studies: the Netherlands, Poland, France, Denmark and Germany
- Ask about collaboration in engaging with national representatives in study countries. Can they send an introductory email to them? [offer to draft the email and attach a letter from DG SANTE/or the evaluation information sheet]

Additional information and wrap-up:

6. Do you have documents or data sources that may be of use for the evaluation?

Interview guides – Field research

General interview guides for in-depth interviews with external stakeholders on patient rights in cross-border healthcare

RELEVANCE

1 To what extent do the Directive's objectives correspond to the current and future needs of EU citizens for cross-border healthcare?
    a) Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?

2 To what extent do the Directive's objectives correspond to the current and future needs of EU citizens for cross-border healthcare?
    a) Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?

3 To what extent do the Directive's objectives correspond to the current and future needs of EU citizens for cross-border healthcare?
    a) Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?

4 To what extent do the Directive's objectives correspond to the current and future needs of EU citizens for cross-border healthcare?
   a) Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?
   b) In which ways do you consider that the Directive is relevant to the current and future needs of EU citizens for cross-border healthcare? What about future needs?

5 Which provisions are less adequate to meet the needs of cross-border patients and why?

6 Are there new developments (technological, policy, etc.) since the Directive's entry into force, which have implications on patients' rights to cross-border healthcare?
   a) How do they impact on the relevance of the Directive?

7 Are the National Contact Points still relevant for meeting patient information needs? Please explain why.
   a) What could be improved as regards to NCPs?

8 Has the Directive had any effects beyond its scope?
   a) Has the Directive triggered any unexpected or unintended effects?
   b) In your opinion, how does this affect health inequalities in the EU?

EFFECTIVENESS

9 To what extent has the Directive contributed to removing obstacles to accessing healthcare in another Member State and the free movement of health services more generally in practice?
   a) Since the Directive entered into force, what factors have helped or hindered this access and movement?

10 To what extent has the Directive contributed to removing obstacles to accessing healthcare in another Member State and the free movement of health services more generally in practice?
   a) Since the Directive entered into force, what factors have helped or hindered this access and movement?

11 How effective has the Directive been in ensuring that clear information from healthcare providers and the National Contact Points is available and accessible to patients?
   a) To what extent are citizens aware of their rights and entitlements to be able to make an informed choice?

12 To what extent has the Directive contributed to increase transparency and comparability of healthcare (with regard to safety, quality, costs, waiting times etc.) across the EU?
   a. To what extent have Member States made the standards for quality and safety of care, applicable standards for health professionals transparent for citizens?
   b. To what extent were EU citizens provided with the necessary information on waiting times for cross-border healthcare requests (linked to patient information)
   c. What factors hinder the provision of clear and transparent information to patients?

13 To what extent have the administrative procedures for cross border healthcare and reimbursement mechanisms been effective?
   d. What are the main challenges with regards to administrative procedures and reimbursement mechanisms?
   e. What could improve?
   f. What has been the effect of the Directive on the cross-border provision and reimbursement of digital health services and products, including telemedicine?

14 To what extent does the Directive ensure continuity of care between Member States after cross-border treatment, including through facilitating and reimbursement of cross-border digital health services (including telemedicine)?

15 To what extent has the Commission encouraged cooperation in cross-border healthcare between neighbouring countries and border regions as provided by the Directive?

16 Has the Directive contributed to increased cross-border cooperation in healthcare and if yes, how?

17 Are you familiar with National Contact Points consultation arrangements with patient organisations, healthcare providers and healthcare insurers?
   a. how effective have these been?

If relevant, what is your opinion (and your experience) on the application of the system of voluntary prior notification?

18 How effective were the Directive and the Implementing Directive 2012/52/EU in regulating the recognition of prescriptions across EU borders?
   b. What factors, if any, continue to prevent the recognition of prescriptions in another Member State?

19 In your opinion, what are the drivers of patients' choice to seek cross border healthcare?
   c. Are there specific patient groups that are particularly benefiting from the patients' rights in cross-border healthcare as set out in the Directive? Please explain why.

EFFICIENCY

20 What have been the costs and administrative burdens to you/ your organisation/ your member organisations [choose as applicable] in relation to the application of the Directive?
   a. Were these costs and burdens justified and proportionate given the effects observed/ objectives achieved/ benefits obtained?
   b. Which factors influenced the cost side and to what extent?
   c. Which factors influenced the benefit side and to what extent?

21 Has the Directive led to a reduction in administrative burdens on patients in relation to cross-border healthcare and reimbursement of costs?
   a. What administrative burdens still exist for patients?
   b. How can procedures be further simplified?

COHERENCE

22 To what extent have the objectives of the Directive translated unambiguously into legal provisions to apply patients' rights in cross-border healthcare?
   a. Where do you think more clarity is necessary?

b. To what extent has the application of the legal framework by Member States been coherent with regard to costs for healthcare?

23 How does the dual system for accessing cross-border healthcare (this is, the Directive and the Social Security Regulations) have worked/are working in practice?
   c. To what extent is there overlap between the Directive and the Social Security Coordination Regulations?
   d. Has the Directive sufficiently clarified its relationship with the existing framework on the coordination of social security systems?
   e. How do you think this overlap has influenced the patients' choice for reimbursement of healthcare costs and the response by the Member State of affiliation?

24 How does the dual system for accessing cross-border healthcare (this is, the Directive and the Social Security Regulations) have worked/are working in practice?
   f. To what extent is there overlap between the Directive and the Social Security Coordination Regulations?
   g. Has the Directive sufficiently clarified its relationship with the existing framework on the coordination of social security systems?
   h. How do you think this overlap has influenced the patients' choice for reimbursement of healthcare costs and the response by the Member State of affiliation?

25 To what extent is the cross-border healthcare Directive aligned with other EU legislation?
   i. To what extent is the Directive coherent with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector?
   j. 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. For example, have there been any difficulties related to determining which rules apply or how to access the professional's liability insurance?

To what extent does the Directive enhance and complement other existing European structures such as the European Civil Protection Mechanism in line with its objectives?

EU ADDED VALUE

26 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?

27 What would be the most likely consequences of repealing the Directive's provisions on patients' rights in cross-border healthcare?

General interview guides for in-depth interviews with external stakeholders about European Reference Networks (ERNs)

RELEVANCE

1. How well do the Directive's specific objectives still correspond to the current and future needs of patients with rare and complex diseases and carers for cross-border healthcare?
    a. Has the Directive allowed citizens/patients enlarged the choice for treatment across MS?
2. Are the ERNs relevant for meeting the current and future needs of patients with rare and complex diseases? Why?
    a. Can you provide examples on how future needs of patients are/are not addressed by the ERNs?
3. Are there new developments (technological, policy, etc.) since the Directive's entry into force, which have implications on the rights of patients with rare and complex diseases to cross-border healthcare?
    a. How do they impact on the Directive's relevance?
4. Are the National Contact Points relevant for meeting rare and complex diseases patient/carer information needs?
    a. Have they been *effective* in providing this information?

EFFECTIVENESS

5. To what extent has the Directive contributed to removing obstacles to access to healthcare in another Member State for patients with rare and complex diseases?
    a. Since the Directive entered into force, what factors help or hinder such access?
6. How effective has the Directive been in supporting the diagnosis and treatment of patients with rare and complex diseases, including through virtual consultation panels?
7. To what extent has the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and the care for these patients?
    a. How can the situation be improved?
    b. What kind of reimbursement mechanism would be adequate for similar situations?
8. How have ERNs impacted research and knowledge sharing on rare and complex diseases among EU healthcare professionals?
9. To what extent is the use of ERNs and knowledge sharing effective to allow patients with rare diseases to receive the diagnosis and treatment they need, including potentially healthcare in another EU Member State?
10. How effectively has the Commission supported Member States in cooperating in the development of diagnosis and treatment of rare diseases?
    a. By making health professionals aware of tools available to them at Union level (in particular the Orphanet database and the ERNs)?

b. By making health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?

11. To what extent has the Directive triggered any unexpected or unintended effects in relation to cooperation in rare diseases and the establishment of ERNs?

EFFICIENCY

12. To what extent is the model of ERNs more or less cost-effective as compared to patients being physically transported to another MS and receiving healthcare there?

13. How significant are the costs and administrative burden caused by the Directive for you/ your organisation/ your members?

    a. How does this compare to the situation before it came into force?

14. To what extent are the costs of ERNs system and their tools justified and proportionate given the objectives achieved and benefits obtained?

COHERENCE

15. To what extent did the Directive contribute to activities on rare diseases at EU level?

    a. How do ERNs complement or contradict other activities?

EU ADDED VALUE

16. In what ways has 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?

Questionnaire for health insurance providers

1. To what extent patients contact you for information about cross-border healthcare? If so, do you provide information about the Directive 24/2011, the Regulation 883/2004 (the social security coordination Regulation) or both?
    a. What are the reasons for patients seeking care abroad under the Directive?
    b. What are the advantages/disadvantages of accessing cross-border healthcare under the Directive or the Regulations?

2. Based on your experience, are patients seeking to access healthcare in another EU country informed of their rights? To what extent are they able to make informed choices? For example, are they informed about:
    a. Treatments to which they are entitled under their benefit basket (i.e., treatments to be reimbursed)?
    b. Treatments which are subject to prior authorisation under the EU Directive 24/2011?
    c. Safety and quality of the care they will receive abroad?

3. Do you reimburse digital health services (incl. telemedicine) and products?
    a. Check if they can provide the number of claims and/or amount claimed annually

4. What are for your organisation the estimated costs associated to the application of Directive 2011/24/EU (e.g. FTEs[98] allocated to processing claims for reimbursement)?
    a. Check if there have been changes in cost burden since 2018 when they had been estimated under another study

5. What are the main challenges with regards to administrative procedures and reimbursement mechanisms that stem from the application of Directive 2011/24/EU? What could be improved? How?

6. Have you received complaints from patients in relation to procedures related to the application of Directive 2011/24/EU (e.g., reimbursement, prior authorisation, administrative burden, etc.)? If available, please provide the number and nature of complaints received annually.

7. Do you know to what extent continuity of care between Member States is ensured after cross-border treatment, including through reimbursement of cross-border digital health services (including telemedicine)?

8. What are for you the main advantages and disadvantages for cross-border patients to receive healthcare under the Directive 2011/24/EU?

9. And for health insurance bodies?

10. Do you consider that the Directive 2011/24/EU triggered any unexpected or unintended effects? If yes, what are the consequences of these effects?

11. What would be the most likely consequences of repealing the Directive's provisions on patients' rights in cross-border healthcare?

12. Is there anything you would like to comment in relation to your experience of patients accessing healthcare abroad and in particular to the EU Directive 2011/24/EU that has not been covered in this interview?

[98] Full Time Equivalent (FTE) – is a unit of measure that denotes the work of one full-time staff member over the course of a year. For example, 1 FTE means all of a staff member's time during a year, while 0.5 FTE means half of a staff member's time during a year, or all of a staff member's time over a six-month period.

Questionnaire for patients

1. Have you ever travelled to another country (EU MS, Norway, Iceland or Liechtenstein) to receive medical treatment?
2. Did you access your healthcare under the Cross-border healthcare Directive (2011/24/EU) or the Social Security Regulation (you use your EHIC card pr S2 form)?
3. Did you receive cross-border healthcare from a public or private healthcare provider?
4. Why did you choose to travel to another country to receive medical treatment?
5. How did you obtain information on your right to cross border healthcare?
6. Did you feel well-informed before, during and after your medical treatment around issues such as Prior authorisation, Reimbursement, Quality and safety, Healthcare providers abroad, Accessibility of hospitals for people with disabilities, Complaint and redress procedures, Transfer of medical records, Waiting times?
7. Were you aware of the existence of National Contact Points for Cross-border Healthcare? If so, did you make contact with them and what was your experience?
8. How satisfied were you with your Cross-border healthcare experience?
    a. Did you experience any difficulties in exercising your right to cross-border healthcare? For example, in relation to obtaining or understanding information, barriers to accessing healthcare, prior authorisation, reimbursement, continuity of care or anything else. If so could you please describe your experience?
9. What was your experience regarding the reimbursement for your medical treatment? Did you:
    a. received medical treatment free of charge at point of use?
    b. had to pay directly a small portion of the total amount of the medical treatment abroad myself?
    c. paid the medical treatment upfront and received reimbursement from the healthcare insurer in the MS of treatment?
    d. paid the medical treatment upfront and received reimbursement afterwards from my own healthcare insurer?
    e. received partial reimbursement for the cross-border treatment?
    f. received full reimbursement for the cross-border treatment?
    g. Experienced something that is not described above?

Targeted questionnaires – Field research

Questionnaire for healthcare providers (survey/interview)

A. Information about the respondent(s)

- Country
- Name of healthcare provider organisation
- Please indicate whether you operate in the public or private healthcare sector

B. Questionnaire

1. Have you/your members treated patients from other EU countries seeking care under the Directive 2011/24/EU?

2. Are you/your members aware of the rights to reimbursement of the medical costs for foreign patients? And if yes, specifically on the patients' rights set out under the cross-border healthcare Directive (EU Directive 2011/24/EU)?

3. Have you/your members recommended treatment in another country to your patients? In which particular cases?

4. Do you/your members give information on the following information to help individual patients from other Member States seeking to access cross-border healthcare?

    - Treatment options and availability
    - Services provided
    - Quality and safety standards
    - Prices
    - Prior authorisation required for treatment
    - Your registration status (proof of your license to practice medicine)
    - Insurance liability cover or other means of protection with regard to professional liability

5. Do you/your members require additional information/documentation from cross-border patients who make an appointment for a treatment compared to domestic patients?
6. Do cross-border patients require additional information/documentation before/after the treatment? (e.g. copy of medical records, details on invoices)
7. Do you/your members provide any information to patients regarding procedures to follow in case of harm?
8. Do you/your members know that there is a National Contact Point established in your country assigned to provide information on all aspects of cross-border healthcare?

9. Which medical fees do you apply for the treatment of cross border patients?

    - Are the medical fees charged equal to the ones related to patients accessing public healthcare?
    - Are the medical fees charged based on agreed tariffs between health insurers and providers if applicable in your country?
    - Are the fees charged equal to the ones related to patients accessing healthcare as private individuals?
    - Are there other tariffs being used?

N/A= not applicable

10. Which payment tools are available to cross-border patients in order to pay for the treatment?
11. Do you/your members provide follow up treatments to domestic patients who were treated abroad? If yes, how do you ensure continuity of care of cross-border patients?
12. Is there anything you would like to comment in relation to your experience of foreign patients and in particular to the EU Directive 2011/24/EU that has not been covered in the questionnaire?

Questionnaire for ERN coordinators

A. Information about the respondent(s)

- ERN
- Name
- Position

B. Objectives of the Directive

1. To what extent do the Directive 2011/24/EU objectives correspond to the current needs of patients with rare and complex diseases and carers for cross-border healthcare?

- To create ERNs that are fully operational including their organisational structure, to carry out their clinical, knowledge sharing, research, and other activities
- To give healthcare providers across the EU access to the best expertise and timely exchange of life-saving knowledge by combining skills of healthcare professionals involved and resources used
- To ensure that EU patients have better access to high quality healthcare services for rare or low prevalence complex disease

Indicate: To a great extent, To some extent, To a small extent, Not at all, Don't know, Please add any comments you may have

2. Are these objectives also relevant for the future needs of patients with rare and complex diseases?

- Yes
- No
- Why/why not?

3. Are there new developments (technological, policy, etc.) since the Directive's entry into force, which have implications on the rights of patients with rare and complex diseases to cross-border healthcare?

4. Please indicate to what extent do you agree with the following statements

- The Directive has effectively enlarged the choice of patients with rare diseases to access treatment across Member States

- The Directive has effectively contributed to removing obstacles to access to healthcare for patients with rare and complex diseases

- The Directive has been effective in supporting the diagnosis and treatment of patients with rare and complex diseases, including through virtual consultation panels

- ERNs have effectively impacted research and knowledge sharing on rare and complex diseases among EU healthcare professionals

- ERNs have effectively contributed to the exchange of knowledge and best

- Practices in rare diseases

- ERNs effectively complement other activities on rare diseases at EU level

- The Directive and the ERNs have effectively provided an added value for patients with rare and complex diseases compared to the national situation alone

Indicate: Strongly agree, Agree, Disagree, Strongly disagree, Don't know, Please add any comments you may have

5. Has the Directive triggered any unexpected or unintended effects, positive or negative, in relation to cooperation in rare diseases and the establishment of ERNs? If yes, what are the consequences of these effects?

C. Costs and administrative burdens

1. Based on your experience, to what extent do you agree with the following statements regarding costs and benefits of the ERN model?

- The model of ERNs is more cost-effective when compared to patients being physically transported to another MS to receive healthcare

- The costs of the ERNs system and their IT tools are justified and proportionate given the objectives achieved and benefits obtained

2. To what extent has the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and the care for these patients?

- To a great extent
- To some extent
- To a small extent
- Not at all
- How can the situation be improved?

3. To what extent has the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and the care for these patients?

- To a great extent
- To some extent
- To a small extent
- Not at all
- How can the situation be improved?
- What kind of reimbursement mechanism would be adequate?

4. How significant are the costs and administrative burden caused by the Directive for your ERN members?

- Very significant
- Somewhat significant
- Slightly significant
- Not at all
- How can the situation be improved?

D. Data availability

1. Please indicate whether you collect data on the following aspects answering yes, no and if available, please indicate a link here or send the document together with this questionnaire send the document together with this questionnaire, also add any comments you may have)

- Number of patients treated by your ERN and affiliated partners
- Number of virtual consultation panels held
- Number of research collaborations established
- Number of clinical trials / studies conducted by your ERN
- Number of clinical trials / studies conducted by your ERN
- Number of publications by your ERNs

E. Support to ERNs

1. To what extent are the National Contact Points relevant for meeting the information needs of patients with rare and complex diseases and their carers?

- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

2. To what extent has the Commission made health professionals aware of tools available to them at Union level (in particular the Orphanet database and the ERNs)?

- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

3. To what extent has the Commission made health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?[99]

- To a great extent
- To some extent
- To a small extent
- Not at all

[99] Regulation (EC) No 883/2004 on the coordination of social security systems https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0883

- Don't know
- Please explain what is working well and/or what can be improved

4. To what extent are the National Contact Points relevant for meeting the information needs of patients with rare and complex diseases and their carers?
- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

5. To what extent has the Commission made health professionals aware of tools available to them at Union level (in particular the Orphanet database and the ERNs)?
- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

6. To what extent has the Commission made health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?
- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

7. To what extent has the Commission made health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?
- To a great extent
- To some extent
- To a small extent
- Not at all
- Don't know
- Please explain what is working well and/or what can be improved

8. What would be the most likely consequences of repealing the Directive's provisions on rare and complex diseases and the ERNs?

Questionnaire for pharmacists (case studies)

The aim of the survey is to evaluate potential barriers in verifying and dispensing foreign prescriptions in the EU. To this end, you will be presented with a total of six prescriptions from three of the five study countries and asked to rate the probability that several issues cause dispensing problems. Dispensing problems are problems which put you in a position where you may decide to not dispense the drug. However, you may find that some or all of these issues do not cause dispensing problems

The questionnaire was made accessible on EUSurvey and has been translated to the national languages (DE, DK, FR, NL, PL).

1. About you

- Profession
- Locality

2. How many foreign prescriptions do you estimate you receive per month?

- 0
- 1-5
- 6-10
- 11-20
- Above 20

PER COUNTRY: Mock up prescription per condition (6 for each country: 3 for drug A and 3 for drug B)

3. Looking at the above prescription from [country], would the following issues definitely not / unlikely / likely/ definitely cause dispensing problems?

- Verifying the authenticity of the prescription
- Verifying the prescribing physician
- Language in which the prescription is written
- Not all the information you need is written on the prescription
- Please indicate what information needed for the dispensation of the requested prescription is missing
- Access to the correct drug/device
- Access to alternative drug or device if the one on the prescription is unavailable

For each issue, indicate: Definitely not, Unlikely, Likely, Definitely, You can elaborate on your response below

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