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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

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

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

The general objective of the Directive 2011/24/EU¹ (hereafter 'the Directive') on patients' rights in cross-border healthcare is to facilitate the access to safe and high-quality healthcare in another Member State. To this end, patients are reimbursed for healthcare in accordance with the principles established by the European Court of Justice of the European Union and codified by the Directive. At the same time, Member States remain responsible for providing adequate healthcare in their territory. Moreover, the Directive promotes cross-border cooperation in healthcare between Member States for the benefit of EU citizens, regarding prescriptions, digital health (eHealth), rare diseases and health technology assessments (HTAs). The Directive applies to cross-border healthcare without prejudice to the framework provided by the social security coordination Regulations².

The Directive was due to be transposed by Member States by 25 October 2013.

Article 20(1) of the Directive requires the Commission to 'draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council' by 25 October 2015³, and every three years thereafter. The report is to include, in particular, information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and Article 8, and on the functioning of the European Reference Networks and National Contact Points (NCPs). This report also includes a chapter on the use of delegated powers pursuant to Article 17(1) of the Directive.

1. State of play of transposition

1.1. Completeness check

Before the transposition deadline (25 October 2013), the Commission's representatives visited all Member States to discuss the necessary transposition measures and to provide assistance, if requested. Additionally, transposition of the Directive was discussed with Member States within committees chaired by the Commission⁴.

After the transposition deadline, the Commission launched 26 infringement procedures for late or incomplete notification of transposition measures. Following this process, all Member States finally notified their complete transposition measures.

1.2. Compliance check

1.2.1. Systematic checks of Member States' transposition measures

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

² Regulations (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166, 30.4.2004, p. 1) and 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 (OJ L 284, 30.10.2009, p.1).

³ Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2015) 421 final, 04.09.2015.

⁴ The Committee under Article 16 of the Directive and the Cross-border Healthcare Expert Group.

The second phase of the compliance assessment started right after the national measure were notified. In this phase, the Commission has been assessing whether all national legal acts and other measures notified are in compliance with the Directive⁵. More than five hundred national measures transposing the Directive were notified to the Commission. The large number of national laws involved is partly due to the fact that the Directive regulated a number of issues which are under different regional/administrative levels and in separate pieces of legislation in Member States, such as reimbursement mechanisms⁶, information channels (National Contact Points, healthcare providers)⁷, patients' rights and entitlements⁸, professional liability⁹.

The Commission identified four priority areas for the compliance assessment which had the greatest potential to act as barriers to patients if left unaddressed: systems of reimbursement, use of prior authorisation, administrative requirements and charging of incoming patients. As a result of a systematic assessment of all notified measures, the Commission opened 11 own-initiative investigations gathering information for proper compliance assessment and others are in the pipeline.

a) Systems of reimbursement of costs for cross-border healthcare

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

Although the Commission has received no specific notifications under Article 7(9), certain transposition measures could be questioned as limiting the level of reimbursement for cross-border healthcare. This refers to Member States granting reimbursement of cross-border healthcare on the basis of lower levels of reimbursement, applicable to healthcare received from private or non-contracted healthcare providers within their own territory, compared to the level of reimbursement within the system of public healthcare or contracted healthcare providers. Three Member States, with varying conditions and extent, use the former lower reimbursement level as the reference point for reimbursement of the costs of cross-border healthcare under the Directive.

⁵ For the sake of continuity, in this report the term "*compliance check*" is used in line with the earlier Implementation Report of 2015, as meaning the compatibility of national transposition measures with the Directive's provisions. This is identical to "*conformity checks*" in the terminology used in the Commission Communication "*EU Law: Better results through better application*" C/2016/8600, OJ C 18, 19.1.2017 final, p. 10-20. Similarly, the term "*completeness check*" is equivalent to "*transposition check*" in the terminology used in the Communication.

⁶ Article 7(6) and Article 9.

⁷ Article 4(2) (a)-(b), 5(b), 6(3).

⁸ Article 4(2)(c), (e)-(f), 4(3), 4(4), 5(b)-(d), 7(1), 9(4)-(5).

⁹ Article 4(2)(d).

The Commission is considering the way forward in those cases, in particular in light of the case-law of the Court of Justice¹⁰.

b) Prior authorisation

The Directive (Article 8(2)) introduces the possibility for Member States to make reimbursement of costs for healthcare received in another Member State subject to prior authorisation. Such an option is by no means intended to be overused, as this would be regarded as restriction of the free movement of services¹¹.

Presently, six Member States plus Norway¹² have no prior authorisation system¹³ in place at all, giving patients freedom to choose and reducing administrative burden.

As indicated in recital 44 to the Directive and according to the constant case-law of the Court of Justice, Member States may make reimbursement of the costs of cross-border healthcare subject to prior authorisation when it is both necessary and reasonable¹⁴; such a scheme must also be based on objective and non-discriminatory criteria¹⁵. This is reflected as well in Article 8(2)(a) of the Directive, which allows Member States to use a system of prior authorisation in particular for healthcare that is subject to planning requirements if it involves overnight hospital accommodation or if it requires use of highly specialised and cost-intensive medical infrastructure or medical equipment. In practice, prior authorisation systems are based almost entirely on the said Article 8(2)(a) on which this report will therefore focus¹⁶.

Any system of prior authorisation shall be restricted to what is necessary and proportionate to the objective to be achieved, and may not constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of patients¹⁷.

Article 8(7) of the Directive requires Member States to ‘make publicly available which healthcare is subject to prior authorisation’.

The concern of the Commission in this respect is that systems of prior authorisation should not suffer from the lack of legal certainty and transparency about which treatments are subject to and fit the criteria of prior authorisation. In order to provide more clarity, numerous structured dialogues with Member States were launched in relation to lists of healthcare subject to prior authorisation. Some lists were considered overly extensive; concerns were also raised in relation to

¹⁰ See, for example, case C-372/04 *Watts*, paragraph 100.

¹¹ Recital 38 of the Directive.

¹² Directive 2011/24/EU was due to be transposed by the EFTA countries Iceland, Liechtenstein and Norway no later than 1 August 2015.

¹³ Seven countries (Czech Republic, Estonia, Finland, Lithuania, The Netherlands, Sweden and Norway) did not choose to introduce a prior authorisation system.

¹⁴ See e.g. Case C-205/99 *Analir and Others* [2001] ECR I-1271, paragraph 38; case C-157/99 *Smits and Peerbooms*, paragraph 90.

¹⁵ See e.g. Case C-205/99 *Analir and Others* [2001] ECR I 1271, paragraphs 35-38; case C-157/99 *Smits and Peerbooms*, paragraphs 80- 90.

¹⁶ Articles 8(2)(b) and (c) also allow Member States to require prior authorisation when the healthcare involves treatments presenting a particular risk for the patient or the population, or when it is provided by a healthcare provider that could give rise to serious and specific concerns relating to the quality or safety of the care.

¹⁷ Article 8(1) of the Directive.

the requirement of prior authorisation for each type of healthcare abroad exceeding one consultation with a specialist per patient per year. The dialogues provided for a good proactive mechanism to trigger positive effects for patients.

If prior authorisation is considered necessary, a detailed and sufficiently defined shortlist of treatments should be publicly available.

c) Administrative procedures regarding cross-border healthcare

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

"There is still very little experience about cross-border healthcare among patient communities." ([European Patients' Forum](#) – October 2016)

Some Member States require patients to provide a certified translation of their medical documentation in order to obtain their reimbursement. Indeed, the sworn translation can represent a disproportionate obstacle to free movement of services, for example in several countries the cost of the translation could be higher than the reimbursement of the outpatient service.

One Member State introduced an excessive minimum threshold (of 15 Euros) for reimbursement that roughly equalled average reimbursement tariffs for outpatient healthcare in that Member State.

Another Member State required a certificate from the foreign National Contact Point attesting that the healthcare to be provided within its territory would be compliant with the necessary safety and quality standards in place. In addition, a written confirmation is required from the healthcare provider on its availability to grant the requested healthcare in the period indicated by the applicant for prior authorisation.

Following discussions with the Member States on the proportionality and necessity of all the requirements referred to above, these were lifted in the interest of patients.

Certain Member States introduced systems of prior notification whereby the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate, as provided for under Article 9(5) of the Directive. Even if a Member State does not apply such mechanism of prior notification, Article 9(5) requires Member States to reimburse patients without undue delay. The prior notification option is a mechanism worth upscaling, supporting Member States to comply with their obligation.

d) Fees for patients from other Member States

Article 4(3) requires Member States to observe the principle of non-discrimination with regard to patients from other Member States. It also notes that Member States may, under certain circumstances, adopt measures regarding access to treatment; however, such measures must be justified, proportionate and necessary; they must also be announced publicly in advance.

Member States may define the fees for the delivery of healthcare in their territory. However, Article 4(4) requires Member States to ensure that healthcare providers apply the same scale of fees to patients from other Member States as they do for domestic patients in a comparable medical situation. If there is no comparable price for domestic patients, Article 4(4) places an obligation on providers to charge a price calculated according to objective, non-discriminatory criteria. Once defined, fees and tariffs must be applied equally to both nationals and non-nationals. Outside the public schemes, the Commission has not identified any issues of implementation and Member States did not choose to introduce measures regarding access for incoming patients.

During the transposition period, there were some arguments raised by Member States that existing public tariffs do not represent a comparable price because important elements, for example from general taxation (e.g. capital investment costs), are not represented in the public tariff which is not fully cost-recovering. Member States therefore can build a comparable cost-based price for the actual cost of the health service, which should be based on objective and non-discriminatory methodology that does not financially discriminate between "domestic" covered under local public schemes and "cross-border" patients for a given intervention. However, it should be kept in mind that the establishment of a cost-based pricing system might well have implications for reimbursement obligations¹⁸ of Member States to outgoing patients.

1.3. Other issues

Interestingly, the requirement for professional liability insurance¹⁹ came up during the completeness checks as a problematic issue in several Member States. Even if healthcare providers *de facto* have liability insurance, in practice, there was often a lack of legislation requiring such systems to be in place. Moreover, it was also difficult for some Member States to implement the principle which extends patients' choice to healthcare providers located in another Member State, irrespective of whether or not they are contracted by the statutory health system in that Member State.

The Commission is continuing its intensive dialogues with the Member States to achieve the best possible transposition of the Directive. It has been confirmed that structured bilateral meetings with Member States give the possibility to explain remaining concerns and find acceptable solutions for the benefit of EU citizens. A great majority of the issues of compliance

¹⁸ Article 7(4) of the Directive.

¹⁹ Article 4(2)(d) of the Directive requires the existence of a system of professional liability insurance or an equivalent or essentially comparable guarantee or similar arrangement.

examined with Member States at issue have led to a common agreement.

The good results of this resource-intensive work have led to fewer administrative burdens on citizens accessing cross-border healthcare, more compressed prior-authorisation systems and lighter procedures for exercising the basic patient rights enshrined in the Directive.

As of 1 June 2018, the completeness check phase is finalised as all the infringement proceedings related to that phase have been closed, the compliance checks and structured dialogues are ongoing and one infringement case is open.

2. Data on patient mobility

In accordance with Article 20 of the Directive, Member States report on an annual basis on their patient mobility under Directive 2011/24/EU. These reports cover healthcare with or without prior authorisation, requests for information about healthcare, healthcare provided, reimbursements made and reasons for which healthcare was reimbursed, or not.

The present report gives a high-level overview of the data received in 2015, 2016 and 2017. It should be noted that the data discussed below may also include some cases of healthcare reimbursed under the social security coordination Regulations²⁰. This is because not all Member States are able to maintain a strict separation between the data on reimbursements for healthcare under the Directive 2011/24/EU and the Regulation (EC) No 883/2004 (EC) or under bilateral cross-border agreements.

The data presented below covers reports on mobility for three years (2015-17) but the number of countries in each year is not equal. Data was received in 2015 from 23 Member States and Norway; in 2016, from all 28 Member States plus Norway and Iceland; and in 2017 from 26 Member States. It should be noted that, since not all Member States were able to supply information on each issue in each year, the baseline numbers of reports are therefore not identical for each issue.

2.1. Patient mobility with prior authorisation

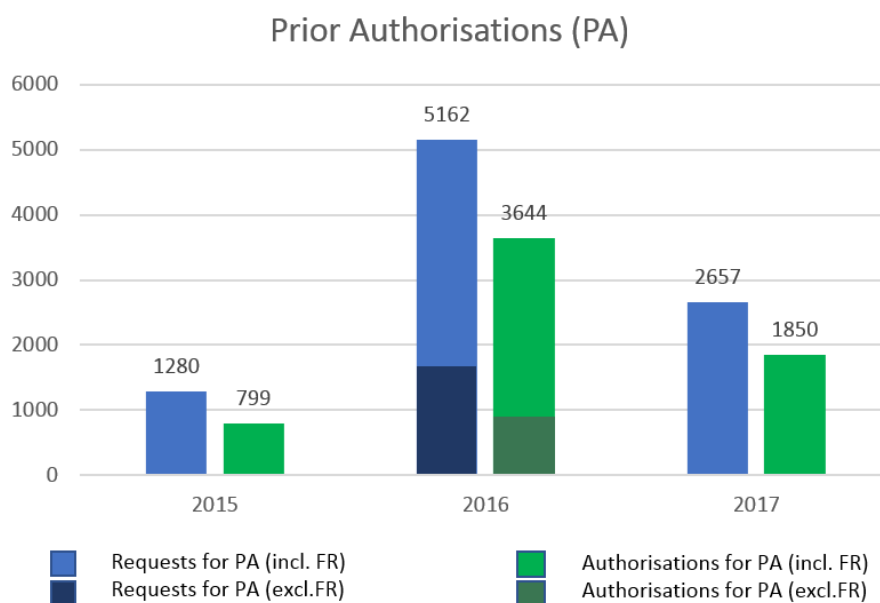
As stated before (see Chapter 1.2.1.b), the Directive allows on certain conditions the Member States to set up a system of prior authorisation (PA). The aggregated data reported by Member States on the number of requests for PA in 2015, 2016 and 2017 show that such requests remain generally low. Nevertheless, a steady increase has occurred since 2015, with more than twice as many requests for PA being made and authorised in 2017 as in 2015 across the Member States.²¹

²⁰ See footnote 2.

²¹ It should be noted that France was able to report data on healthcare subject to PA only in 2016. Accordingly, Figure 2 should be interpreted knowing that in 2016 France accounted for 3510 of the 5162 requests for PA and 2579 of the 3644 authorisations for PA. The data excluding France are represented in darker shade in the lower part of the column.

Based on the reported data for planned cross-border care under the Regulations, in 2015, Member States issued around 55,000 authorisations²² for planned treatment abroad. If this number is compared to the reported number of PA for cross-border care under the Directive in 2016 (the latter being the most comparable year), it may be estimated that cross-border with PA under the Directive amounts to approximately 6% of the authorised treatments in another Member State. However, this estimate should be interpreted with some caution because, as noted above, not all Member States are able to fully separate those claims made under the Directive and those made under the Regulations.

Figure 1: Prior Authorisation Requests and Authorisations



2.2. Patient mobility not subject to prior authorisation

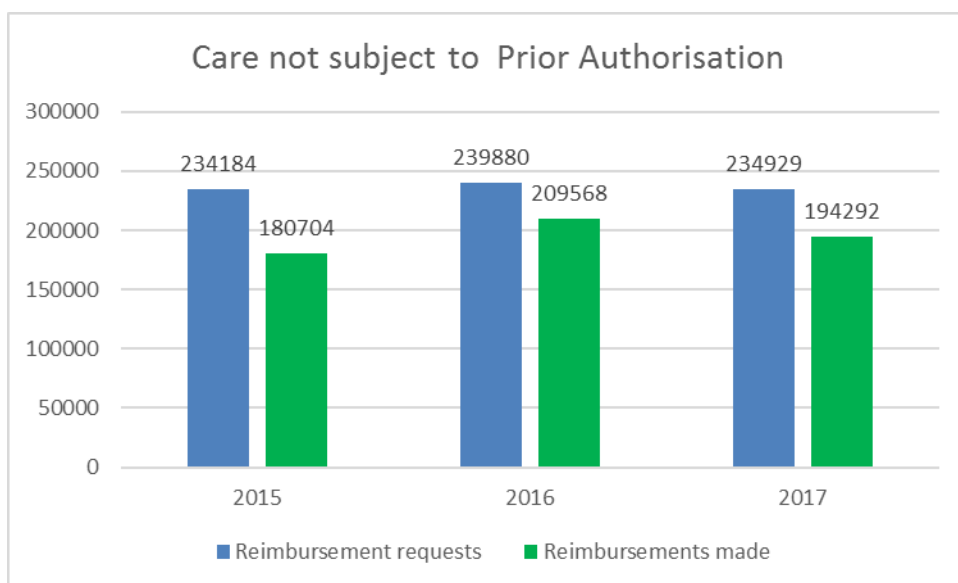
The total number of such requests for reimbursements was relatively low in all three years as a share of total patient care, but has remained very steady. In 2015 the total number of requests granted was 180,704 across 19 Member States plus Norway; in 2016 the number of requests granted over 22 Member States amounted to 209,568; and in 2017 the total number of requests granted was 194,292 across 20 Member States. Adjusting for the number of countries reporting data, this shows that EU citizens’ use of the rights granted under the Directive had no significant growth or reduction over the three years of the reporting period.

In the case of the Regulation (EC) No 883/2004, unplanned cross-border healthcare is mostly reimbursed between Member States on receipt of a request from the Member State of treatment. In 2015, some 2 million such requests were issued by Member States, while reimbursements for cross-border treatments under the Directive not requiring PA amounted to just over 180,000 in 2015. It would seem therefore that the opportunities offered by the Regulation (EC) No 883/2004 under the European Health Insurance Card are more widely used than those under the Directive.

²² <http://ec.europa.eu/social/main.jsp?catId=1154&langId=en>

This is understandable since in many cases the level of reimbursement under the Regulations will be higher²³ than under the Directive and Member States are required to ensure that citizens are advised on the most suitable route for a claim.

Figure 2: Requests for Reimbursement without prior authorisation



2.3. Financial Implications of Patient Mobility

In terms of the financial dimensions of patient mobility, the year 2016 (for which the most complete data exist), may be taken as an example of the level of reimbursements made for care under the Directive. Based on responses provided by Member States approximately €65,000,000 was spent across all EU countries collectively on care with and without PA in 2016. Noting that the OECD [Health at a Glance](#)²⁴ report for 2017 estimates that in EU countries the average spent on healthcare is 10% of GDP; and that [Eurostat](#)²⁵ reported EU GDP in 2017 at €15.3 trillion; the expenditure across the EU on cross-border healthcare incurred under the Directive may therefore be estimated at 0.004% of the EU-wide annual healthcare budget. These are of course highly schematic figures, but when read in conjunction with the figures of the cost of cross-border healthcare under the Regulations (which amount to approximately 0.1%), it is clear that the vast majority of healthcare budgets is spent domestically. As the figures have been moderate and stable over the years, impact on national health budgets arising from patients wishing to access cross-

²³ Under the Directive reimbursement is usually at the rate that would have been made in the country of insurance, while under the Regulations it is at the rate of cost in the country of treatment.

²⁴ https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017/health-expenditure-in-relation-to-gdp_health_glance-2017-45-en

²⁵ <http://ec.europa.eu/eurostat/tgm/refreshTableAction.do;jsessionid=9ea7d07e30dd3bf0a52b9a8a474c872db039e243c026.e34OaN8Pc3mMc40Lc3aMaNyTa3eQe0?tab=table&plugin=1&pcode=tec00001&language=en>

border healthcare appears marginal. This is true for all countries, no matter whether they introduced prior authorisation or not.

2.4. Direction of Patient Mobility

Looking at flows of patients travelling for healthcare after receiving prior authorisation, the greatest flow was from France to Spain. Where authorisation was not required, the greatest flow was from France to Germany. These patterns previously identified have not changed significantly from 2015 to 2017.

Flow Map 1 in Annex B represents the aggregated flows across 2015, 2016 and 2017 for treatment requiring prior authorisation²⁶. The flow maps, as well as the raw data, show clearly that most patients travel from France to other countries, with patient mobility from France to Spain and France to Germany being the most prevalent. For the years 2015 and 2017, when France was not able to provide data on patient mobility with PA, Luxembourg to Germany and Ireland to UK were amongst the most common cases of patient mobility.

Flow Map 2 in Annex B represents the aggregated flows across 2015, 2016 and 2017 for treatment without prior authorisation. Again, a clear pattern emerges showing that France has the greatest number of travelling patients, with the three most common countries for healthcare provision being Spain, Portugal and Belgium in all three years. After patients travelling from France, the next most frequent cases of patient mobility were patients travelling from Denmark to Germany; followed by Poland to Czech Republic and Norway to Spain. It is interesting to note that the additional data from Denmark indicates that the bulk of this patient mobility is for dental care.

Two significant trends emerge from the data on the direction of patient flows, whether it is mobility with or without PA. The first is that over the last three years the majority of patient mobility has been between neighbouring countries. This would suggest that, on the whole, patients prefer to receive healthcare near their home if possible, and that if they do elect to travel, they prefer to travel to a neighbouring country. The second trend is seen in the overall pattern of the flow maps in the annex. While about half the patient mobility is accounted for by movements from France to its neighbouring countries, the other half of the flow is made up by small numbers of patients travelling throughout the EU to receive care – both to neighbouring countries and to countries further away. This would suggest that while 50% of patient mobility may be driven by issues of proximity, and possibly also collaborations between clinicians in border regions, a very significant part may also reflect patients' desires to receive healthcare in a place of their choice. Such choice may be driven by a desire to return 'home' to a country of birth for healthcare, or to bring a relative closer to a place where a family member can care for them or it may be driven by a desire to find expertise not available in their home country.

²⁶ Recall however that the flow from France to other Member States applies to 2016 data only since France was not able to provide this data in 2015 or 2017.

3. Information to patients

It is important that information on cross-border healthcare should be easily available to those patients and families who need or want it. The National Contact Points (NCPs) have an essential role to play in relation to this, providing information to citizens upon demand and, more generally, in raising awareness on patient rights and responding to information needs.

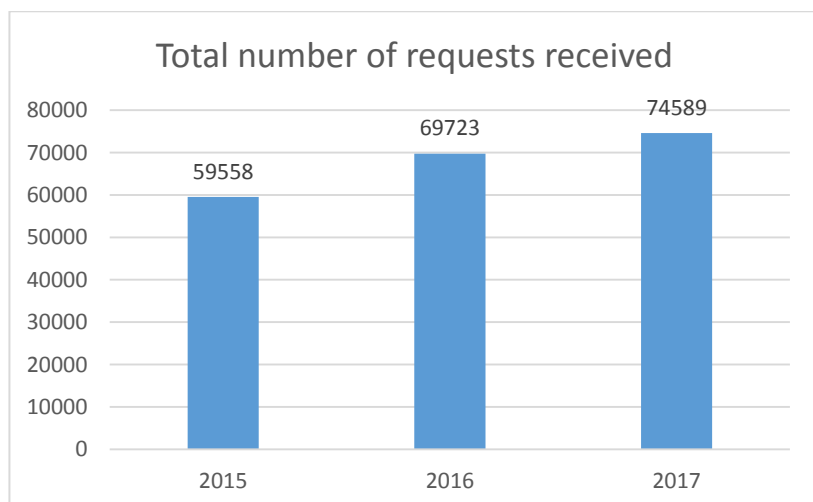
3.1. Data from Member States on information requests received by National Contact Points

In 2017 a total of 74,589 enquiries were received across 22 Member States and Norway, reflecting a very similar use of NCPs to that reported for 2016 when a total of 69,723 enquires were counted across 28 Member States and Norway and in 2015 when a total of 59,558 requests were received in 19 Member States.

Taking into account the variation in the number of Member States providing feedback on the number of requests received, and noting the limited variation in the spread of requests (in all three years the total number of requests was dominated by Poland and Lithuania which together accounted for more than 50% of all requests for information across all Member States), there has been little change in the level of enquiry about access to cross-border healthcare made by citizens.

However, the fact that there has been a slow but steady increase in the number of citizens travelling to receive care suggests that the increase of information available on NCP websites has reduced the number of requests patients made to NCPs. Similarly, as doctors have become more knowledgeable about the scheme, they are to provide information themselves directly to the patients.

Figure 3: Requests for information made to NCPs



3.2. Enhancing information to patients and information needs for persons with disabilities

A recent study of the Commission on the information provided to patients²⁷ shows that in-depth information on patients' rights is generally lacking on NCP websites, including insight into what

²⁷ https://ec.europa.eu/health/cross_border_care/key_documents_en

to do in the case of undue delay. Information on complaint procedures and settlement of disputes was also scarce, as well as information on the time period required to process reimbursements and prior authorisation requests. Information was variable also on which treatments are reimbursed. The findings show that, while information provision through NCP websites was well taken care of for several categories, there remains a need to further improve the websites.

The Directive calls on NCPs to provide patients and health professionals with information on accessibility of hospitals for persons with disabilities (Article 4(2)(a)). Information should be made available by electronic means and in formats accessible for persons with disabilities (Article 6(5)) and additional costs for persons with disabilities may be taken into account (Article 7(4)). A recent small-scale survey by IF SBH²⁸ relating mostly to one Member State (Denmark) found that an overwhelming majority of respondents had not even heard about the existence of NCPs. However, the few people who did exercise their rights under the Directive were mostly satisfied, had their expenses fully or partially covered and would consider using this mechanism again. This reflects findings of the previous [Commission report](#)²⁹ and echoes its past conclusions that knowledge of the existence of the Directive among the surveyed groups remains scarce.

3.3. Interaction with the social security coordination Regulations

The main difference between the Directive and the Regulations as regards the reimbursement rights is that under the Regulations, patients are entitled to healthcare abroad as if they were insured under the social security system of the Member State of treatment. Under the Directive, they are reimbursed for treatment abroad as if the treatment was provided in their home countries (Member State of affiliation). However, as explained in recital 46 to the Directive, in certain cases, the benefits should be provided under the Regulations, unless otherwise requested by the patient.

According to a survey of NCPs, a number of Member States³⁰ continue to express concern about communicating the complexities of the current legal situation. A little less than half of the NCP websites provide information on both pieces of legislation. National experts have been trained in explaining the two routes, firstly via the [Conference of October 2016](#)³¹ on awareness of rights under the Directive and secondly via the NCP Capacity Building Workshop on 8 March 2018 which were both organised by the Commission. By using the toolbox disseminated during the Workshop, all NCPs should now be able to explain the distinction between the two legal routes via their websites and to proactively bring them up in contact with patients.

²⁸ IF SBH (International Federation for Spina Bifida and Hydrocephalus) and EDF (European Disability Forum), "[Impact of Cross-border Healthcare on Persons with Disabilities and Chronic Conditions](#)", 2017

²⁹ https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf

³⁰ 14 out of 37 NCP staff admitted in 2017 to facing difficulties communicating the Directive's relationship with the Regulations to the patient.

³¹ https://ec.europa.eu/health/cross_border_care/events/ev_20161024_en

4. Cooperation between Health Systems

4.1. Health Technology Assessment

Health Technology Assessment (HTA) is an important part of evidence-based decision-making on health in EU countries. Most of the Member States [reported](#)³² having in place a national HTA system for medicinal products (26 Member States and Norway) and/or medical devices (20 Member States and Norway)³³.

Today EU cooperation on HTA has two main components. Firstly, the [HTA Network](#)³⁴ which connects national authorities or bodies responsible for HTA. The rules concerning the HTA Network envisaged by Article 15 of the Directive are set out in Commission Implementing Decision 2013/329/EU³⁵. The Network provides strategic guidance and policy orientation for scientific and technical cooperation. Besides exchanging information on relevant policy developments in the area of HTA, in the past three years the HTA Network developed important policy papers such as the 'Added Value of the European Cooperation in the Joint HTA of Medical Devices' in October 2015 and a 'Reflection Paper on Synergies between Regulatory and HTA issues' in November 2016. In addition, a number of additional strategic documents are planned in its [Multi-Annual Work Programme 2016-2020](#)³⁶.

The second and complementary component is the scientific and technical cooperation represented by the [EUnetHTA Joint Actions](#)³⁷. The current Joint Action, EUnetHTA 3, launched in June 2016, runs until 2020 and includes more than 80 partners, relevant HTA bodies that carry out assessments and not-for-profit organisations contributing to HTA in Europe.

In response to the calls from the Council and the European Parliament to ensure sustainability of EU cooperation on HTA beyond 2020, the Commission launched an extensive reflection process, including stakeholder consultations and impact assessment in line with the Commission's Better Regulation Agenda³⁸. This reflection process culminated in the Commission's adoption of a [legislative proposal](#)³⁹ on 31 January 2018. The proposal seeks to build on the on-going project based cooperation on HTA and to address certain shortcomings identified in the reflection process. The proposed legislation aims at ensuring a better functioning of the internal market, while contributing to a high level of human health protection. Cooperation on HTA post 2020 in line with the proposal is expected to help to make innovative health technologies available to Europe's patients, make better use of available resources and improve business predictability. The proposal

³² https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2018_mapping_npc_en.pdf

³³ Mapping of HTA national organisations programmes and processes in EU and Norway, 2017, Contract nr. 17010402/2016/734820, ISBN: 978-92-79-77080-7

³⁴ https://ec.europa.eu/health/technology_assessment/policy/network_en

³⁵ Commission Implementing Decision 2013/329/EU of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the network of national authorities or bodies responsible for health technology assessment (OJ L 175, 27.6.2013, p. 71).

³⁶ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf

³⁷ <https://www.eunetha.eu/#tab-3-tab>

³⁸ https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

³⁹ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU, COM(2018)51 final, 31.01.2018.

https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

sets out a support framework and procedures for cooperation on HTA at Union level and common rules for clinical assessments of health technologies. In particular, it includes joint work on clinical assessments, joint scientific consultations and emerging health technologies.

The proposal has been sent to the Council and the European Parliament.

4.2. eHealth

The eHealth Network is a voluntary network composed of national authorities responsible for eHealth that works towards interoperable applications and enhanced continuity of and access to care⁴⁰.

The work of the eHealth Network plays an important role in overcoming legal, organisational, technical, and semantic interoperability challenges in the context of cross-border exchange of personal health data. The Network laid the foundations for the eHealth Digital Service Infrastructure (eHDSI), an IT system funded by the Connecting Europe Facility⁴¹ and the Member States, and adopted guidelines on Patient Summaries (November 2013)⁴² and on ePrescriptions (November 2014)⁴³.

Under the eHDSI Infrastructure, the first wave of voluntary cross-border exchanges of patient summaries and ePrescriptions is set to begin by a few pioneering countries by the end of 2018; with around 20 Member States expected to participate by 2020. So far, 16 Member States have received EUR 10.6 million of CEF funding to make the necessary technical preparations for this cross-border exchange. An additional call took place in 2018 allowing more Member States to participate in the eHDSI.

On 25 April 2018 the Commission adopted a Communication, which inter alia seeks to ensure appropriate governance of the eHDSI and its financial basis and to improve the interoperability of patient data and access by the citizen⁴⁴. The intention is to review the management and functioning of the eHealth network to clarify its role in the governance of the eHealth digital service infrastructure and its operational requirements.

4.3. The European Reference Networks

The European Reference Networks (ERNs) are virtual, voluntary cross-border networks, bringing together healthcare providers across Europe. Their aim is to help diagnose and treat patients suffering from rare, complex and low prevalence diseases that require highly specialised healthcare and a concentration of knowledge and resources.

⁴⁰ 2011/890/EU: Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth

⁴¹ Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010, OJ L 348, 20.12.2013, p. 129.

⁴² https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

⁴³ https://ec.europa.eu/health/sites/health/files/ehealth/docs/eprescription_guidelines_en.pdf

⁴⁴ Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, COM(2018) 233 final, 25.4.2018.

Since the last report, the Member States within the ERN Board have approved 24 thematic Networks which were launched in March 2017 in Vilnius at the third ERN Conference. The Networks bring together more than 900 highly specialised healthcare units located in around 300 hospitals of 25 Member States (plus Norway). A key principle of ERNs is to let the knowledge travel rather than the patient. ERNs are not directly accessible by individual patients; instead, healthcare providers refer patients to the relevant Network, with their consent and in accordance with the national health systems rules.

Their clinical operation started in November 2017, when the dedicated IT platform, the Clinical Patient Management System, became operational, allowing for the first virtual panels on patient cases to take place. The virtual panels are convened to review a patient's diagnosis and treatment and are attended by medical specialists from different centres of expertise across the EU. By June 2018 165 panels had been opened, the number growing daily, with the first patients directly benefiting.

4.4. Recognition of prescriptions

The Commission adopted⁴⁵ Implementing Directive 2012/52/EU⁴⁶ to give effect to the principle of mutual recognition of medical prescriptions. Twenty-one infringement procedures were started for non-communication of national transposal measures. They have all been closed on the grounds of subsequent transposition by the Member States.

4.5. Mapping and building cross-border and regional cooperation

The Commission should encourage Member States to cooperate in cross-border healthcare provision in border regions⁴⁷. The latter should be seen as an opportunity to improve access to care for patients, to capitalise on economies of scale and to use resources efficiently. In its [Communication on Boosting Growth and Cohesion in EU Border Regions](#)⁴⁸, the Commission highlights ways in which Europe can reduce the complexity, length and costs of cross-border interaction and promote the pooling of services along internal borders. The Communication proposes a set of actions to enhance the competitive situation of border regions by showcasing successful practices. At the end of 2018, the Commission plans to organise a strategic event focused on healthcare with stakeholders from border regions to explore ways in which information exchange and best practices can be further developed throughout the Union.

At the Informal Ministerial Council in 2015, Member States called upon the Commission to prepare a study to map cross-border co-operation. [The subsequent study](#)⁴⁹ provides a picture of EU-funded projects implemented in the period of 2007 to 2017 and shows that geographical and cultural-societal factors remain decisive for policy-makers to establish and maintain cooperation initiatives across borders. Among more than 400 initiatives analysed in the mapping exercise, the

⁴⁵ Based on Article 11(2)(a), (c) and (d) of the Directive.

⁴⁶ Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (OJ L 356, 22.12.2012, p. 68).

⁴⁷ Article 10(3) of the Directive.

⁴⁸ COM(2017) 534 final.

⁴⁹ [“Study on Cross-Border Cooperation: Capitalising on existing initiatives for cooperation in cross-border regions”](#),

Gesundheit Österreich Forschungs und Planungs GmbH, SOGETI, Maastricht University, 2017

large majority took place between countries with similar welfare state traditions and concerned knowledge sharing and management and shared treatment and diagnosis of patients. There are several scenarios for developing cooperation, one of the most realistic ones being one which builds regional networks oriented towards addressing local and regional needs, as already indicated by previous studies⁵⁰. Annex A provides a detailed list of further studies in support of good implementation.

5. Delegated powers

According to Article 17 of the Directive, the power to adopt delegated acts envisaged therein shall be conferred on the Commission for a period of 5 years from its entry into force. It requires the Commission to prepare a report in respect of the delegated powers.

Under the mutual recognition of prescriptions between Member States, Article 11(5) empowers the Commission to adopt, by means of delegated acts, measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, where necessary, to safeguard public health. Member States agreed that no exclusion is needed; therefore, the Commission has not used the delegated power⁵¹. Should such a need arise in the future, it would be necessary to deal with it swiftly via a delegated act.

The Commission is also empowered under the Directive⁵² to adopt, by means of delegated acts, a list of the specific criteria and conditions that the European Reference Networks must fulfil, and the conditions and criteria required from healthcare providers wishing to join such Networks. The Commission worked closely with the Member States on the content of the delegated act before adopting it on 10 March 2014, for entry into force on 27 May 2014⁵³.

The Commission considers that it has exercised its delegated powers within the remit conferred to it by the Directive. Since neither the European Parliament nor the Council revoked the delegation of powers conferred by Articles 11(5) and 12(5), they were automatically extended, in accordance with Article 17(1) of the Directive, for another 5 years period.

6. Conclusions

Cross-border patient mobility within the EU shows a slight increasing trend over the last three years. This may partly be due to the gradual improvements in the information of citizens regarding the Directive and a better awareness on patient rights as a possible consequence. It may also be partly due to the collaboration between the Commission and the Member States regarding its proper implementation and the interaction between the Directive and social security coordination Regulations, not least via the work done with NCPs and through the own-initiative investigations of the Commission (see Chapter 1).

⁵⁰ See the General Secretariat of the Benelux Union studies, e.g. "[Barriers and Opportunities in the Benelux](#)", February 2018.

⁵¹ See more details in the Commission report on the operation of the Directive published on 4 September 2015 (COM(2015) 421 final).

⁵² Article 12(5), read together with Article 12(4)(a).

⁵³ Commission Delegated Decision 2014/286/EU of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (OJ L 147, 17.5.2014, p. 71).

At the same time, it may be concluded that the Directive has improved the legal certainty and clarity for cross-border as well as for domestic patients over their rights. The interpretation of the Directive has not been subject to a review by the Court of Justice of the European Union. Compliance checks and dialogues with Member States will continue over the next reporting period and more use will be made of mobility data.

Regarding the voluntary cooperation structure (eHealth, HTA, ERNs), the Directive provides the basis for the Commission and Member States to enhance cross-border cooperation and on how broader technological and societal challenges might be met. A number of developments regarding these new perspectives are already underway. First, the Commission has made a [legislative proposal on health technology assessment](#) (see Chapter 4.1). Second, in its Communication on the Digital Transformation of Health and Care, the Commission put forward further measures on eHealth (see Chapter 4.2). Last but not least, the [launch of the ERNs](#) clearly marked a major change for the delivery of quality and accessible cross-border healthcare to EU citizens (see Chapter 4.3). These virtual networks that bring together healthcare providers across Europe to tackle complex or rare medical conditions, so that it is the medical knowledge that travels and not the patient, are certainly an example of good practice.

Now, after five years of the operation of the Directive, it can be concluded that cross-border patient flows are showing a stable pattern, mostly driven by geographical or cultural proximity. Overall, patient mobility and its financial dimension within the EU remain relatively low and the Cross-border Healthcare Directive has not resulted in a major budgetary impact on the sustainability of health systems.