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

**Commission Report 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**

Directive 2011/24/EU<sup>1</sup> (hereafter 'the Directive') on the application of patients' rights in cross-border healthcare came into force on 24 April 2011. It was due to be transposed by Member States by 25 October 2013. It clarifies the rights of patients to seek reimbursement for healthcare received in another Member State.

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

This report sets out the current state of play of transposition, and covers the most important and relevant provisions, such as the use of prior authorisation, the level of patient mobility, reimbursement practices, information to patients and cooperation under the Directive. It also reports on the use of delegated powers pursuant to Article 17(1) of the Directive, which requires the Commission to report on these by 24 October 2015.

### **Chapter 1: State of play of transposition**

The transposition deadline for the Directive was 25 October 2013. Infringement proceedings were launched against 26 Member States on the grounds of late or incomplete notification of such measures.

As of 1 July 2015, four infringement proceedings remained open, and all four Member States concerned had made firm commitments to address the outstanding issues.

These infringements relate only to the completeness of transposition measures. The next stage for the Commission is to assess whether Member States have transposed the Directive correctly.

### **Chapter 2: Patient mobility**

#### **2.1 Prior authorisation: background**

Article 8(2)(a) of the Directive allows Member States to use a system of prior authorisation 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. Articles 8(2)(b) and (c) also allow them to require prior authorisation for treatments presenting a particular risk to patients or the population or for

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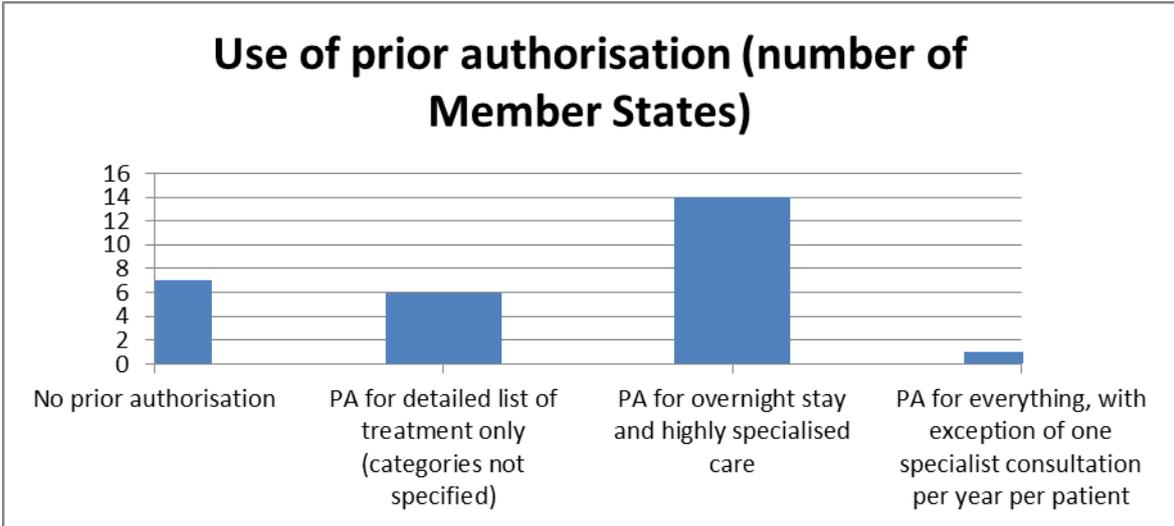
<sup>1</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

care provided by a healthcare provider that gives rise to serious concerns relating to the quality and safety of care. However, in practice, prior authorisation systems are based almost entirely on Article 8(2)(a), on which this report will therefore focus.

Any system of prior authorisation must be 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 patients.

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

Member States have introduced prior authorisation systems as follows.



Fourteen countries therefore use both the “overnight stay” and the “highly specialised” care criteria for requiring prior authorisation.

None of the 14 countries which have used the ‘overnight stay’ criterion has specified which treatments are covered by this criterion.

Several Member States require prior authorisation if the healthcare requires an overnight stay in the Member State of treatment. It is questionable whether this is in line with the criterion in Article 8(2)(a), which relates to the way treatment is provided in the Member State of affiliation rather than the Member State of treatment.

Nine of the 14 Member States have set out which treatments they consider to meet the ‘highly specialised’ criterion, whilst five have not.

In these 14 Member States, therefore, it is unclear for patients exactly which treatments are subject to prior authorisation, since the use of at least one of these criteria — and sometimes both — has not been elucidated by national authorities.

Interviews with 20 health insurers as part of an evaluative study<sup>2</sup> on behalf of the Commission found that 15 of them thought that patients in their country do not know whether a treatment is subject to prior authorisation or not, and that patients therefore tended to request prior authorisations even when this was not necessary.

As outlined in recital 43 of the Directive, the criteria attached to the grant of prior authorisation have to be duly justified. The data returns made by Member States, in general, do not suggest that extensive systems of prior authorisation are justified: the numbers of people applying for authorisation are simply too small. It seems hard to argue, for example, that a treatment should be subject to prior authorisation when not a single person has applied for authorisation for that treatment that year (with a possible exception for extremely specialised or expensive treatments, of course, where even a very small number of reimbursement claims could have significant consequences). The data in Annex A shows that some Member States with prior authorisation systems have received no requests for authorisation at all (and many others have received very few).

## **2.2 Reimbursement and administration**

Article 7(9) permits Member States to limit the application of the rules on reimbursement of cross-border healthcare for overriding reasons of general interest. However, Article 7(11) requires that such limitations be necessary and proportionate, and do not 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 7(9).

Although the Commission has received no specific notifications, some of the ways in which Member States have transposed the Directive could be considered as limiting reimbursement.

According to Article 7(4) of the Directive, the reference point for reimbursement for cross-border healthcare should be the amount borne by the system when that particular healthcare is provided by a public or contracted healthcare provider (depending on the way a given health system is organised) in the Member State of affiliation.

At least three Member States have adopted reimbursement practices for cross-border healthcare whereby the reimbursement tariff for patients is based on the costs that would be borne by the Member State of affiliation for care received from a private or non-contracted provider (which is considerably lower than the rate for public or contracted providers) had this healthcare been provided in its territory.

Three Member States appear to require any patient seeking reimbursement for cross-border healthcare to demonstrate why it is medically necessary for the particular episode of healthcare to be received in another country. It is questionable whether this is in line with the principle of free movement of patients and with the criteria set out in Articles 7(9) and 7(11).

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<sup>2</sup> [http://ec.europa.eu/health/cross\\_border\\_care/docs/2015\\_evaluative\\_study\\_frep\\_en.pdf](http://ec.europa.eu/health/cross_border_care/docs/2015_evaluative_study_frep_en.pdf).

A note on the evaluative study is attached in Annex B of this report.

Article 7(7) of the Directive allows Member States to impose the same conditions and formalities on patients seeking cross-border healthcare as they would impose if the healthcare were provided in their territory, provided that these are not discriminatory and do not constitute an unjustified obstacle to free movement.

Twelve Member States have used this provision with regard to their ‘gatekeeper’ structure, which is a system whereby a referral from a GP or family doctor is required for a patient to access specialist healthcare. Therefore such referrals are also required in order for patients to be reimbursed when they access such specialist healthcare in another Member State. According to the principle of mutual recognition of qualifications, however, Member States should recognise decisions about clinical need and appropriateness provided by an equivalent professional in another Member State. Yet five of these twelve Member States explicitly insist that the referral must be from a professional in their country.

At least four Member States require patients to provide a sworn translation of invoices (one even requiring patients to get all documents certified by their consul in the country of treatment). However, Article 10 of the Directive obliges National Contact Points to assist each other in understanding invoices. This requirement will therefore need to be analysed under the conditions of Article 7(7).

The application of the Directive to ‘telemedicine’ (i.e. health services provided remotely) has led to a certain lack of clarity. For example, some Member States reimburse or provide consultations with general practitioners at a distance, whilst others do not. If a patient from a Member State where such consultations are not provided or funded has a consultation via telemedicine with a GP in a Member State where such consultations are so provided, it is not clear whether the Member State of affiliation may, in such a case, refuse reimbursement. On the one hand, reimbursement for cross-border healthcare is to be provided if such healthcare is among the benefits to which the insured person is entitled in the Member State of affiliation (Article 7(1)) and the Member State of affiliation may impose, including in case of healthcare received through telemedicine, the same conditions and criteria of eligibility as for healthcare provided in its territory. On the other hand, Article 4(1)(a) lays down the principle whereby healthcare is provided in accordance with the legislation of the Member State of treatment and, in the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established (Article 3(d)). One relevant issue here is how the ‘basket of benefits’, i.e. the healthcare to which the patient is entitled, is defined.

### **2.3 Patient flows**

For this report, the Commission asked Member States to participate in a data collection exercise. Twenty-six Member States provided responses, covering the calendar year 2014.

Patient flows for healthcare abroad under the Directive are low. Of the 21 Member States who introduced a system of prior authorisation, 17 were able to supply data on numbers of requests for authorisation specifically under the Directive. In these Member States there were a total of only 560 applications for authorisation (of which 360 were granted). Two of these Member States reported that they had neither refused nor granted a single request, two reported only one each, and only two had more than 100 requests. In addition to these 17 Member States,

France reported granting 57 000 authorisations; however, this is an aggregate figure combining authorisations under both the Social Security Regulations<sup>3</sup> and the Directive.

For treatment not subject to prior authorisation, Finland, France and Luxembourg reported considerable activity, with 17142, 422680 and 117962 reimbursements respectively. However, again, these are aggregate figures combining data from both the Social Security Regulations and the Directive.

Twenty Member States reported data on reimbursement made exclusively under the Directive. For these, a total of 39 826 reimbursements were made, of which 31 032 were reported by Denmark alone. In total, only four of these Member States reported more than 1 000 reimbursements. At the other end of the scale, 14 Member States had made fewer than 100 reimbursements (of which six had made no reimbursements at all). This seems to be due to low numbers of claims rather than large numbers of refusals: the available data suggests that roughly 85 % of reimbursement claims are granted.

This generally low volume of patient mobility for planned healthcare appears to be equally the case for care under the Social Security Regulations. In 2013 there were 1.6 million claims for reimbursement for unplanned healthcare but only 30 172 applications for planned healthcare abroad under the Regulations (via the S2 form used in such cases). Of the latter, 29 115 were accepted<sup>4</sup> — 17 358 in Luxembourg alone.

A detailed breakdown of data may be found in Annex A, which also sets out various qualifications regarding the data collection exercise, not least that the Directive was implemented at different times in different Member States and data may not therefore cover all of 2014).

The report under Article 20(3) of Directive 2011/24/EU which the Commission adopted in early 2014,<sup>5</sup> noted that the coming into operation of the Directive could affect the use of the Social Security Regulations. That report set out in detail the data which would be needed to assess whether this had, in fact, happened. As things stand, that data is unavailable and the Commission is, therefore, unable to make any further analysis at this time.

### **Chapter 3: National Contact Points and Information to patients**

Some Member States have different National Contact Points (NCPs) for ‘incoming’ and ‘outgoing’ patients. Others have regional NCPs under one ‘umbrella’ NCP. Some NCPs are based in the Ministry of Health, others in the healthcare insurer, and others in independent bodies.

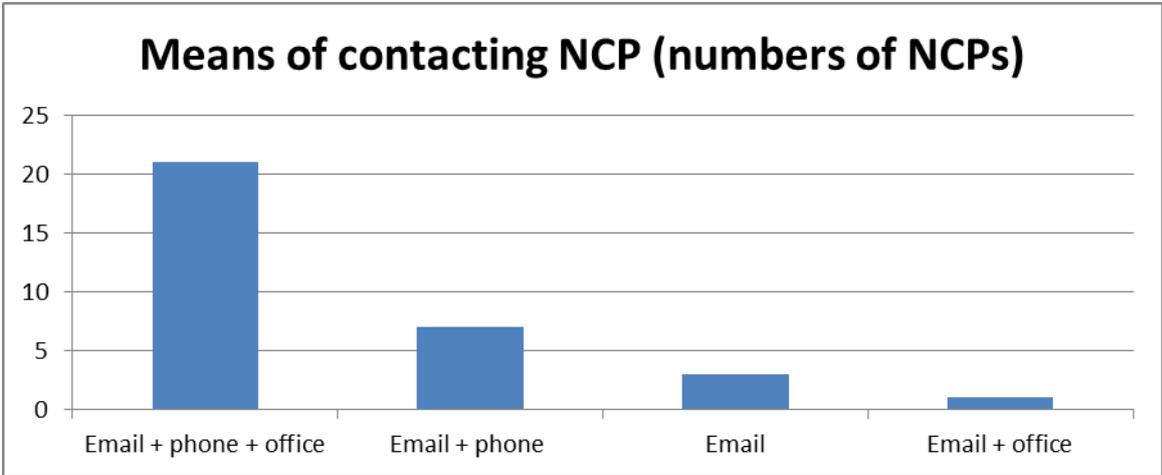
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<sup>3</sup> Regulations (EC) No 883/2004 and No 987/2009 on the coordination of social security systems.

<sup>4</sup> Note that the data for planned healthcare via the S2 forms covers only 22 Member States as data for the others was not available.

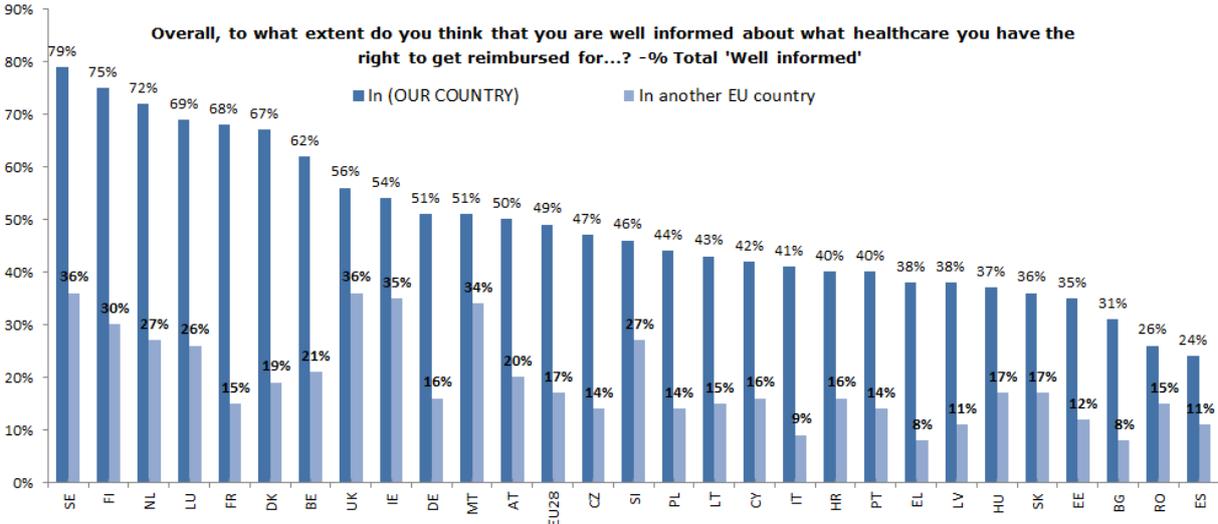
<sup>5</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0044&from=EN>.

There are also differences in the communication channels used by NCPs, as the following table (covering all 28 Member States and the separate contact points for England, Scotland, Wales, Northern Ireland, and Gibraltar)<sup>6</sup> shows.



This data is from the evaluative study, which also indicated significant variation in the activity of the NCPs. Of nine NCPs surveyed, three had fewer than 10 requests for information per month, four had between 10 and 100 requests, and only two had more than 100 requests per month. These findings are in line with the data reported by Member States on information requests (contained in Annex A)

This is not surprising, given EU citizens’ seemingly low awareness of their rights and the existence of the NCPs. A recent Eurobarometer survey<sup>7</sup> indicated that fewer than two out of ten citizens feel that they are informed about their cross-border healthcare rights:

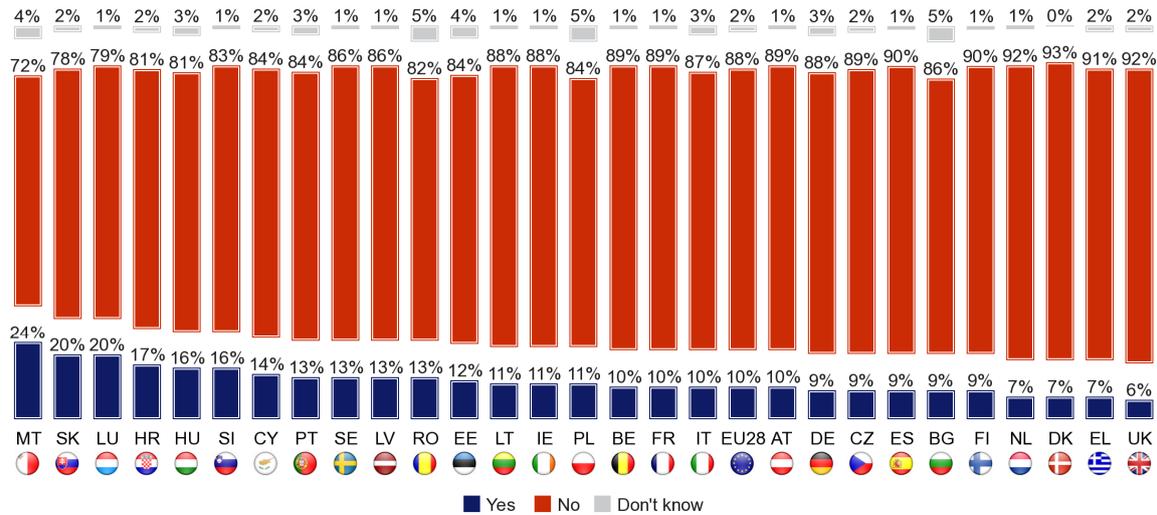


Whilst only one in ten knew about the existence of NCPs:

<sup>6</sup> The UK has no National Contact Point covering the whole UK, so it was necessary to examine the separate contact points. Other Member States also have regional contact points, but also one national NCP.

<sup>7</sup> [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_425\\_sum\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_425_sum_en.pdf).

QD12. In each EU Member State, there is a National Contact Point that provides information about cross-border healthcare inside the EU. Did you know that it existed?



Via a series of conferences organised on behalf of the Commission by the European Patients’ Forum, patient organisations have reported their concern that patients are faced with ‘a labyrinth of confusing, sometimes insufficient and sometimes too detailed information’ with regard to cross-border healthcare. They have identified NCPs as having a crucial role in the success or failure of the Directive, recommending that NCPs could provide ‘checklists’ for individuals considering planned care abroad, and more detailed individual timelines of procedures, costs and reimbursement rates. They stressed the desirability of facilitating ‘comparability and reliability of information provided to patients on quality and safety, across institutions and across Member States’.

‘Patients have high expectations ...the prevailing sentiment is that the NCP must be a gateway to healthcare, not a gatekeeper blocking access.’ — *Patient organisation*

The Directive requires Member States to provide information on their quality and safety systems. Some Member States provide links to different legal documents; others give a general description of quality assurance strategies; a few provide detailed information (including links to hospital evaluation systems featuring typical safety parameters, e.g. mortality rate, number of cases treated with complications); others direct citizens to specific sources — websites or a named person. Some do not mention safety and quality at all.

A number of Member States continue to express concern about communicating the complexities of the current legal situation, where cross-border healthcare is covered by two distinct sets of EU legislation (the Directive and the Social Security Regulations), despite the stipulation in Article 2(m) of the Directive, whereby the former applies without prejudice to the Social Security Regulations (see also recitals 28-31 to the Directive).

## **Chapter 4: Cross-border cooperation**

### **4.1 Recognition of prescriptions**

Article 11 of the Directive gives effect to the principle of mutual recognition of medical prescriptions between Member States and empowers the Commission to adopt practical measures to assist such recognition.

The majority of these measures were addressed in Implementing Directive 2012/52/EU<sup>8</sup>. This Directive established a list of common elements to be included in cross-border prescriptions. This list includes, among other elements and with limited exceptions, the “common name” of the product (which, in practice, means the International Non-proprietary Name for a large majority of products).

The deadline for the transposition of the Implementing Directive was the same as that for transposition of Directive 2011/24/EU, i.e. 25 October 2013. Twenty-one Member States either failed to make the deadline, or transposed the Implementing Directive incompletely, leading to infringement proceedings. Two of these infringement cases were pending as of 1 July 2015, the others having been closed on the grounds of subsequent transposition by the Member States concerned. In the two pending cases, the Member States concerned have committed to addressing the outstanding issues.

### **4.2 European Reference Networks**

Article 12 of the Directive requires the Commission to support the development of European Reference Networks (ERNs) of healthcare providers and centres of expertise (in particular in the area of rare diseases) by: adopting the criteria and conditions that such Networks, and providers wishing to join Networks, must fulfil; developing criteria for establishing and evaluating such Networks; and facilitating the exchange of information and expertise on the Networks. In March 2014 the legal framework for the establishment and evaluation of Networks (delegated<sup>9</sup> and implementing decisions<sup>10</sup>) was adopted, with unanimous support of the Member States.

The Commission has since begun the process of establishing ERNs, including the establishment of the Board of Member States, which will be charged with approving proposals for ERNs. The first call for networks will take place in early 2016, with the first networks expected to be approved during that year.

The Commission is working with healthcare providers and authorities to raise awareness of the possibilities offered by ERNs, and to gather support for potential networks or members of networks.

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<sup>8</sup> 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).

<sup>9</sup> 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).

<sup>10</sup> Commission Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

### **4.3 eHealth**

The Commission adopted Implementing Decision 2011/890/EU concerning the eHealth Network on 22 December 2011.<sup>11</sup> The eHealth Network aims to support cooperation between national authorities. It meets twice a year and is supported operationally by a joint action under the Health Programme established by Regulation (EU) No 282/2014<sup>12</sup>. The work of the eHealth Network is supported by a number of activities carried out under the eHealth Action Plan 2012 – 2020: Innovative healthcare for the 21st century<sup>13</sup>.

Since its inception, the eHealth Network has adopted guidelines on patient summaries data sets and on ePrescriptions, and position papers on: electronic identification, interoperability, the proposed Regulation on data protection; and eHealth investment to be supported by the Connecting Europe Facility (CEF). It is currently working on guidelines on effective methods for enabling the use of medical information for public health and research. Under the CEF Work plan 2015, EU funding has been allocated to implement the exchange of patient summaries, and ePrescriptions. The eHealth Network will review and, if necessary, update the guidelines in 2015-2016 in the light of the CEF experience.

### **4.4 Health Technology Assessment (HTA)**

The rules concerning the HTA Network envisaged by article 15 of the Directive are set out in Commission Implementing Decision 2013/329/EU<sup>14</sup>. The HTA Network aims to support cooperation between national authorities, including on the relative efficacy and short-/long-term effectiveness of health technologies. It meets twice a year, and is supported on scientific and technical issues by a joint action under the Health Programme, called EUnetHTA.

The Network adopted a Strategy for EU cooperation on HTA in October 2014, and a reflection paper on reuse of joint HTA work in national activities in April 2015.<sup>15</sup>

For the future, the HTA Network will continue its strategic role, but strong and efficient scientific cooperation will be essential. Member States have asked the Commission to propose measures to ensure long-term sustainability.<sup>16</sup>

### **4.5 Cross-border collaboration**

The Directive requires the Commission to encourage Member States to cooperate in cross-border healthcare provision in border regions. Initial work by the Commission shows that there is a limited number of existing cross-border projects which may provide valuable ‘lessons learned’ for future parties. It has also identified specific areas where greater cross-

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<sup>11</sup> [http://ec.europa.eu/health/ehealth/docs/decision\\_ehealth\\_network\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/decision_ehealth_network_en.pdf).

<sup>12</sup> [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2014.086.01.0001.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.086.01.0001.01.ENG).

<sup>13</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012DC0736>.

<sup>14</sup> 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).

<sup>15</sup> [http://ec.europa.eu/health/technology\\_assessment/docs/reuse\\_jointwork\\_national\\_hta\\_activities\\_en.pdf](http://ec.europa.eu/health/technology_assessment/docs/reuse_jointwork_national_hta_activities_en.pdf).

<sup>16</sup> Council conclusions on ‘innovation for the benefit of patients’ Employment, Social policy, Health and Consumer affairs Council meeting Brussels, 1 December 2014  
[http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/145978.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/145978.pdf).

border collaboration could make a significant difference to patient outcomes, for example in access to critical care for myocardial infarctions.

Successful cross-border collaboration requires significant buy-in from local-level actors, with the support of national authorities. The next step is to identify those EU activities and best practices which will help implement real cross-border collaboration which delivers added value. Geographical areas which might benefit from such collaboration also need to be identified.

## **Chapter 5: Conclusions**

Patient mobility for planned healthcare — under both the Directive and the Social Security Regulations — remains low, whilst patient mobility in terms of unplanned healthcare seems to be considerably higher. France, Luxembourg, and possibly Finland and Denmark appear to be exceptions to this general observation. The level of use of planned healthcare elsewhere is far below the potential levels suggested by the number of people indicating in the Eurobarometer survey that they would consider using cross-border healthcare.

There are a number of reasons why this may be the case. Firstly, a number of Member States were late implementing the Directive, which will impact on the numbers able to use it during 2014.

Secondly, as also indicated by the Eurobarometer, the number of citizens who are aware of their general rights to reimbursement is extremely low. Even where citizens are aware of their rights, there are a number of Member States where it is difficult for patients to find out more about how to use these rights in practice. The evaluation study cited above indicates considerable variation in the performance of National Contact Points in this regard.

Thirdly, whilst some Member States have implemented the Directive fully and are making considerable efforts to facilitate patients' rights to cross-border healthcare, there are a considerable number of Member States where the obstacles placed in the way of patients by health systems are significant, and which, in some cases at least, appear to be the result of intentional political choices: some of the current systems of prior authorisation are more extensive than the current numbers of requests would appear to justify; in many cases it is not clear exactly which treatments require prior authorisation; lower reimbursement tariffs than those used in the home Member State are a clear disincentive; there are a number of burdensome administrative requirements which may well deter patients.

It may be that the natural demand for cross-border healthcare is relatively low for a number of reasons: unwillingness of patients to travel (e.g. because of proximity to family or familiarity with home system); language barriers; price differentials between Member States; acceptable waiting times for treatment in the Member State of affiliation. It is also worth noting that some of the demand that does exist may be catered for under local bilateral arrangements, which exist in some Member States. However, given the points set out above, it is not possible to conclude now that use of cross-border healthcare accurately reflects potential demand.

However, the impact of the Directive should be considered more widely than simply cross-border healthcare. It has contributed to a number of important discussions going on in many Member States regarding healthcare reform.

Most obviously, the Directive contains a significant number of provisions relating to transparency for patients on their rights, and on the quality and safety of healthcare services. This subject of which information patients need, and how it should be provided, is likely to be on the agenda for some time to come. This is not due to the Directive itself, but reflects broader technological and societal changes: people's expectations are radically different now than they were just a few years ago (and health services are unlikely to be immune from the impact of, for example, user-generated reviews). But the Directive does provide a ready-made space (and forum, in the shape of the network of NCPs, which meets regularly) for the Commission and Member States to share ideas on how this challenge might be met.

So far, it is clear that there are significant differences between NCPs in the way they operate and the quality of the information they provide. There may well be merit in exploring common approaches or guidelines for the work of NCPs in future discussions.

Similarly, the pressures faced by health services are leading to increased interest in making better use of resources via cross-border collaboration. Whilst the initial work undertaken by the Commission so far has thrown up some suggestions for action at EU level (e.g. sharing of best practice from successful projects; development of checklists for those considering cross-border collaboration), it is clear that these would only work in support of national or local activities.

The chapter of the Directive on cooperation between health systems has created a new framework for Member States' cooperation. This could deliver tangible benefits to health systems across the EU. To take just one example, the European Reference Networks could seriously improve access to care for rare / low-prevalence and complex diseases where expertise is rare. To realise this potential, ongoing support and commitment from all sides will be needed.

The HTA strategy adopted by the HTA Network has demonstrated the interest in joint work by the Member States but has also shown the need for permanent and well-founded arrangements. Such arrangements would need to facilitate joint work, and consequently enable Member States and other stakeholders to benefit fully from it.

Finally, the advance of technology means that 'telemedicine' services (including online pharmacies) are likely to become more common and more significant in the immediate future. It may therefore prove useful to consider whether and how the applicable rules (e.g. on applicable legislation; access to, and reimbursement for, treatment) need to be developed and clarified.

## **Chapter 6: Exercise of the power to adopt delegated acts conferred on the Commission pursuant to Article 17 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare**

### **6.1 Introduction**

Article 11 of Directive 2011/24/EU concerns 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.

Article 12 of Directive 2011/24/EU concerns the development of European Reference Networks (ERNs). Article 12(5), read together with Article 12(4)(a), empowers the Commission to adopt, by means of delegated acts, a list of the specific criteria and conditions that the ERNs must fulfil, and the conditions and criteria required from healthcare providers wishing to join such Networks, as envisaged in Article 12(4)(a).

Article 17 of Directive 2011/24/EU confers on the Commission the delegated powers for a period of 5 years from 24 April 2011. It requires the Commission to prepare a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegated powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes them in accordance with Article 18.

### **6.2 Exercise of the delegation**

Regarding Article 11(5), a meeting of Member State experts was convened on 14 February 2012 to discuss whether there was a need to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions. The conclusion of this meeting (and of the support study carried out) was that no exclusion was needed at that time. The Commission has therefore not yet used the delegated power.

Regarding Article 12(5), the Commission worked closely with the Member States on the content of the delegated act before adopting it on 10 March 2014 (see reference under 4.2, above). It entered into force on 27 May 2014.

### **6.3 Conclusion**

The Commission is of the view that the delegated powers conferred by Directive 2011/24/EU should remain in force.

The field of medicinal products and medical devices is one where change may occur rapidly. Although exclusions from the principle of mutual recognition of prescriptions are not currently needed, such a need may arise in the future, and would need to be dealt with swiftly via a delegated act in order to safeguard public health.

Regarding ERNs, the first Networks will be established in 2016, and will then need to be evaluated. This evaluation is likely to mean that it is desirable to adjust the content of the current Delegated Act in the future.

## **ANNEX A**

### **Data from Member States on the operation of the Directive**

A questionnaire was sent to all Member States in January 2015. The agreed final cut-off date for the exercise was 30 April 2015. The timeframe covered by the exercise was the calendar year 2014.

A total of 26 out of 28 Member States provided data (no returns were received from Latvia or Malta).

A selection of the data reported by Member States is presented here. A number of points should be noted:

Member States transposed Directive 2011/24/EU at different times and in many cases the data provided only cover part of 2014. Some Member States have difficulties dividing their cases between Directive 2011/24/EU and the Social Security Regulations (Regulations (EC) No 883/2004 and (EC) No 987/2009), particularly for claims for reimbursement of healthcare not subject to prior authorisation.

It has proved difficult for many Member States to provide data concerning information requests to NCPs broken down by medium and issue. It is also likely that requests relating to cross-border healthcare outside the scope of Directive 2011/24/EU have sometimes been included, e.g. questions relating to the European Health Insurance Card (EHIC) etc.

Some Member States — particularly those with insurance-based systems — have experienced difficulties in collecting information from the component parts of their system.

As this was the first time this questionnaire was used, a number of practical semantic issues were identified during the exercise (reflecting the variety of national situations and practices). Those will need to be addressed in future exercises, as they affect the comparability of the data.

The data is not, therefore, easily comparable between Member States: examples in this Annex are given by way of illustration only.

### **Information requests received by National Contact Points**

Of the 26 Member States who responded, all but Luxembourg and Sweden were able to provide data on the total number of unique requests. A total of 109 223 such requests were recorded in 2014. Five Member States had fewer than 100 requests for information (Portugal, for example, recorded just 6). Ten Member States recorded more than 1 000 information requests. Three Member States alone accounted for nearly 75% of the requests recorded: Germany (36 602); Finland (25 207); and Austria (15 536). These much larger figures are probably due to website visits being recorded as information requests in these three Member States.

Some Member States were able to divide their information requests by medium. In these cases the data indicate 74 050 via website (see point above), 15 461 via telephone, 5 436 via email, and 2 179 via face-to-face contact.

### **Use of prior authorisation**

Twenty-one Member States have introduced a system of prior authorisation (Austria, the Czech Republic, Estonia, Finland, Lithuania, the Netherlands and Sweden have not, although some of these have introduced legislation enabling them to introduce such a system at a later date, should they so wish). Of these 21, Latvia and Malta did not provide data returns. Germany did provide a data return but was unable to provide data on the use of prior authorisation.

Of the 18 Member States who provided data, France was a clear outlier with 57 000 authorisations granted; however, this is an aggregate figure for authorisation granted under both the Social Security Regulations and the Directive. The number of requests for prior authorisation specifically under the Directive which were either authorised or refused in the remaining 17 Member States was 560, of which 360 were authorised. Two Member States (Poland and Greece) reported that they had neither authorised nor refused any requests for prior authorisation in 2014 and two (Croatia and Portugal) received just one each. At the other end of the spectrum, Italy received 177 (103 authorised) and Slovakia 139 (121 authorised).

### **Reimbursement for treatment not subject to prior authorisation<sup>17</sup>**

Of the 26 Member States who responded, only 23 were able to provide complete data on reimbursements made for treatment not subject to prior authorisation (Germany and the Netherlands could not provide data; Belgium could not provide complete data). Of these 23, Finland, France and Luxembourg provided aggregate data for the Directive and the Social Security Regulations. Finland reported 17 142 reimbursement claims, France 422 680 and Luxembourg 117 962.

In the other 20 Member States, a total of 39 826 reimbursements were made specifically under the Directive: of this total Denmark alone accounted for 31 032. Four Member States made more than 1 000 reimbursements. Fourteen Member States made fewer than 100 reimbursements, of which six (Austria, Bulgaria, Cyprus, Estonia, Greece, and Portugal) recorded no reimbursements under the Directive.

### **Processing times**

Of the 16 responding Member States that had a system of prior authorisation and received requests for prior authorisation, nine (Bulgaria, Croatia, Denmark, Ireland, France, Luxembourg, Slovakia, Spain, and the UK) reported average times to process requests as 20 days or fewer. Only three had average processing times of 30 days or more: Hungary (30 days); Cyprus (40); and Slovenia (69).

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<sup>17</sup> This data may include a limited number of claims for treatment which was supposed to be subject to prior authorisation but for which the claim was made retrospectively and ultimately reimbursed.

Of the 19 responding Member States that actually received claims (and were able to provide the requested figures) for reimbursement for treatment not subject to prior authorisation, 15 were able to provide data on the average times for processing claims (Belgium, Lithuania, Greece and Romania were not able to provide this data). Of these, four had an average of fewer than 20 days (Denmark, Hungary, Luxembourg, and the UK) and three had average times of more than 80 days: Finland (82); Slovakia (84.3) and Sweden (150) (NB the Finnish figure relates to both the Regulations and the Directive).<sup>18</sup>

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<sup>18</sup> Reimbursement practices may vary considerably from Member State to Member State. For example, if a Member State decides to reimburse someone under the Regulations on the grounds that this is more beneficial to the patient, then the procedure for establishing the reimbursement amount can take several months.

## **ANNEX B**

### **The evaluative study on the Cross-border Healthcare Directive**

This study considers the effects of Directive 2011/24/EU. Its overall objective is to report on implementation to date on the basis of the sources at hand and to identify gaps and potential for improvement, as called for by Article 20(1) of the Directive. It draws on the situation on the ground and other valuable external sources (past studies, scientific literature, stakeholder input, etc.).

#### **Methodology**

In addition to desk research and a literature review, a detailed website review and widely used participatory research methods were used.

Building on previous research efforts, a website analysis was carried out on all the websites of the 32 NCPs (32 countries or territories as Scotland, Wales, England, Northern Ireland and Gibraltar were analysed for the UK). The analysis was carried out between 6 October 2014 and 6 November 2014.

The ‘pseudo-patient’ research method was used to take account of the ‘end-user’ perspective. NCPs in 12 EU Member States (Austria, Belgium, France, Germany, Hungary, Italy, Lithuania, Malta, the Netherlands, Slovenia, Spain, and Sweden) were approached in November 2014 by both email and telephone using three different pre-designed scenarios. These ‘focus countries’ are a representative sample, based on a host of criteria detailed in the report.

Subjective, opinion-based data was also collected in the focus countries and at European level via 59 stakeholder interviews and an online survey addressed to the 12 NCPs in the focus countries. Some 50% of stakeholders contacted agreed to be interviewed over the four-week period. They represented a range of health insurance providers, healthcare providers, patient ombudsmen, national and regional authorities, patient groups, audit bodies, trade unions and frontline healthcare prescriber organisations. All NCPs completed at least a part of the online survey.

A SWOT analysis focusing on the services provided to the patients complements the conclusions of the study.

#### **Limitations**

The study is not a formal evaluation. Complaints, infringements and transposition measures were not part of its remit. Given the recent adoption of the Directive and the scarcity of readily available data on patient mobility, a formal evaluation of the Directive would have been premature. An evaluative study does, however, deliver a meaningful, albeit qualitative contribution to the baseline assessment and to future evaluation efforts, in line with the ‘evaluate first’ principle.