



Q&A FOR THE TRANSPPOSITION OF THE DIRECTIVE ON CROSS-BORDER CARE



Version 1

Information compiled by EURORDIS

The Directive on Patients' Rights for Cross-Border Care has been officially adopted on 9 March 2011. Since its publication in the Official Journal of the European Union, member states have a period of 30 months to transpose it in their national legislations.

This document is intended to respond to some of the main questions patients' representatives may have to best understand the new legislation and to advocate at national level in the best interest of patients for the transposition in national law.

Q&A for the transposition of the Directive on Cross-Border Care

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

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INTRODUCTION

The newly adopted Directive represents a step forward to improve access to care for European citizens. Not only it proposes solutions for healthcare professionals to better collaborate across Member States (telemedicine, European Reference Networks...) but also it indicates to Member States which initiatives they should implement to facilitate access to care in other Member States than the Member State of affiliation (where a patient pays his taxes to the health care system).

The European Court of Justice has confirmed¹ that the right to seek cross-border healthcare already exists in the Treaty. Therefore this Directive is not creating any new right for the patients, they already exist.

However, the Directive will only be useful if all Member States transpose it in their national legislation, in full respect of patients' rights, and this should be achieved by 25 October 2013.

As a consequence, patients and their organisations have an opportunity to discuss with their health authorities how to best implement the Directive with their health authorities, during the next two years.

One characteristic of this Directive is that it proposes many options, for each Member State to decide to use these options or not.

Below is what EURORDIS has been advocating since 2006:

1. For rare diseases, patients should have the right to receive treatment in another country than their country of affiliation when the treatment is not available in their country of residence
2. All costs should be reimbursed, including travel and accommodation costs
3. Patients should not pay up front and wait for the reimbursement to be processed
4. When prior-authorisation is requested, it should not be submitted to arbitrary decision, it should be proportional (no unrealistic request of information), and it should be rapid, with a possibility to appeal when the decision is negative (as laid down by the Directive).

During discussions with health authorities, some articles in this Directive are particularly important to highlight and are summarised in the table below.

Issue	What to object	
	Article or Recital of the Directive that support our case	Where to find explanation in this document
<p>Your health authority insists that patients should always use the S2 form (former E112) and systematically ask for prior-authorisation.</p> <p>This may happen when a government considers the Directive is not really needed and is not willing to modify in depth the administrative process for the Directive transposition.</p>		Question 4 page 5
<p>Your health authority states that patients can seek for a second medical opinion in a different country but only for diagnosis, not for treatment (and treatment is reimbursed in the country of affiliation).</p>	Recital 16, page 88/46	
<p>Your health authority agrees to facilitate cross-</p>	Recital 55, page 88/51	

border care but only for very rare diseases	<i>Rare diseases are those that meet a prevalence threshold of not more than five affected persons per 10 000, in line with Regulation EC- 141/2000</i> Article 13.b, page 86/62	
Your health authority claims the patient should pay in advance, and will be reimbursed at a later stage (only if prior-authorisation)	Article 7.4, page 88/57	Question 7, page 7
Your health authority is not proposing specific efforts for rare diseases compared to frequent diseases	Article 13, page 88/62	Question 8 page 7
Healthcare professionals are proposing a different cost for the same type of service, depending where the patient is coming from	Article 4.4, page 88/56	Question 9 page 7
Your health authority states travel and accommodation expenses are not in the scope of this Directive	Recital 34, page 88/49 Article 7.4, page 88/58	Question 10 page 7
Your health authority states the Directive does not foresee the reimbursement of full costs (main costs) but only in the limit of what would be reimbursed at home	Article 7.4, page 88/58	Question 13 page 9
Your health authority does not want to engage in a dialogue on the list of treatments for which prior authorisation is needed or is not as transparent as desired on this list	Article 8.7, page 88/59	Question 14 page 9
Your health authority is setting limits to the numbers of patients from other Member States who will be treated in the country	Recital 21, page 88/47 Article 7.9, page 88/58	Question 15 page 9

1 | one WHY DO WE HAVE BOTH A REGULATION AND A DIRECTIVE?

The Regulation 883/2004 was adopted to guarantee access to care in the state of residence for migrant workers and their dependants. It also covered treatment received outside the state of residence or affiliation, under the following conditions:

- Occasional care: when temporarily in another Member State, a person is entitled to care becoming necessary during their stay. To prove his/her entitlement in the home state, the patient should submit an E111 form in the host state (now replaced by the European Health Insurance Card EHIC).

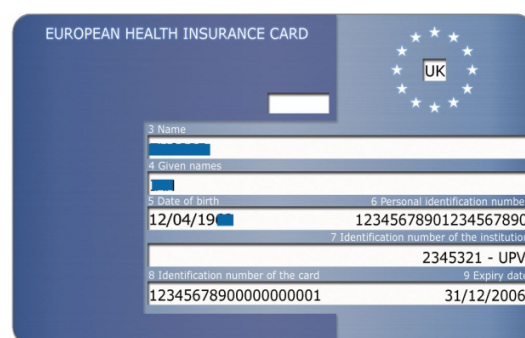


FIGURE 1: the European Health Insurance card

- Planned care: Patients moving to another Member State specifically to obtain care need to be granted prior authorisation from their competent institution in their home state. This authorisation, certified by a S2 form (former E112), must be given if the treatment is covered at home but cannot be provided there within medically justifiable time-limits, the so-called “undue delay”.

Directive 2011/24 was adopted in 2011 to codify the rights to healthcare abroad, which derived directly from the free movement provisions of the European Treaty, and which existed alongside the rights created by the Regulation. The existing Regulation 883/2004 has indeed been controversial, with a long series of law cases that overruled the requirement for prior authorisation in specific cases and patients have been refunded the costs of health care received abroad.

2 | two WHERE DO THEY DIFFER?

The Directive should provide clarity and legal certainty for patients. “The system must be patient focused. The requirement for prior authorisation of treatment and the closed list, where cross-border treatments are restricted, must not hinder patients getting the care they need” said Ireland East MEP Mairead McGuinness at the European Parliament in Strasbourg.

Prior authorisation can be envisaged:

- For healthcare which involves overnight hospital stay of at least one night;
- for highly specialised and cost-intensive healthcare;
- in serious and specific cases relating to the quality or safety the care provided abroad. In these 3 cases, patients may need to ask for permission in advance from their national health authority in charge of reimbursement.

Even with the passing of this piece of legislation, the Regulation 884/2004 will continue to exist and it may be that patients would find it better to apply for cross border health care under the existing rules than under the new Directive. Under regulation 883/2004 a patient may be reimbursed for reasonable travel costs. It will be up to Member States whether or not they pay for travel and accommodation.

The Directive provides that costs for medical treatment received in another Member State which exceeds the cost of the intervention in the home country would be borne by the individual, unless the home country agrees to pay the full cost of treatment.

The main differences are summarised below:

Regulation 883/2004 (E111/E112)

- *Prior authorisation to access care in a different country than country of affiliation: always required*
- *When OK: actual costs reimbursed*

Now Directive 2011/24

- *Prior authorisation not needed if treatment is on the « list »*
- *When on the list, reimbursement on the basis of their cost in country of affiliation*

3 | three IS THE S2 FORM USEFUL (FORMER E112)?

Yes, very! When you receive authorisation to obtain care in another country using the S2 form, not only all expenses linked to the provision of care are reimbursed (even if cost is higher than in country of affiliation), but also travel expenses are also reimbursed. S2 form characteristics:

- For planned care (not for emergencies or accidents)
- For free, given by patients' health insurance
- Letter explaining the medical need
- Prior authorisation (expert)
- Valid for one year
- Provides access to care under the conditions in the country of care
- The healthcare system of the country of care pays the hospital (not all costs)
- Part of costs: payment by the patient, and then reimbursement by his/her health insurance

4 | four WHY ISN'T A S2 FORM FULLY SATISFYING (FORMER E112)?

The drawbacks of a S2 form are:

- It is arbitrary (prior authorisation, by advisors who are not necessarily expert in the rare disease in question)
- It is mainly for well-established care (hardly applicable to rare diseases)
- It is on a case by case basis (paperwork, delays)
- It needs to be repeated every time a patient travels to the country of care
- There is a partial payment by patient (who is then reimbursed but after long delays) that can be costly

5 | five WHAT IS IMPORTANT IN THE NEW DIRECTIVE?

The Directive invites:

Member State to define the list of treatments for which prior authorisation is required.

Every Member State will have to create a National Contact Point where the public can find information on which type of care is available in which European country and at what cost. These contact points will provide patients with information about their rights and entitlements, as well as practical aspects of receiving cross border healthcare, e.g. information about healthcare providers, quality and safety, accessibility of hospitals for persons with disabilities, to enable patients to make an informed choice.

Illustration:

	Example: patient lives in Italy and goes to Czech Republic to receive a specific treatment. This treatment is not on the list.	
Regulation or Directive	Regulation: S2 form (ex E112) and prior authorisation required	Directive: no prior authorisation
Cost of treatment, Czech Rep.	30 000 €	30 000 €
Cost of treatment, Italy	26 000 €	26 000 €
Advance payment by patient * Sometimes null	3 000 €* Remaining costs 27 000 € paid by Czech healthcare system to hospital	30 000 €* Health insurance Italy reimburses 26 000 € to patient, not 30 000 €
	Health insurance Italy reimburses 3 000 € to patient	
Cost for patient	0 €	4 000 €

6 | six WHAT TYPE OF CARE IS COVERED IN THE DIRECTIVE?

Care provided in country of care can include:

- Consultation
- Examination
- Surgery
- Treatment, including medicines
- And this is not restricted to diagnosis

Recital 6 clearly states that “As confirmed by the Court of Justice of the European Union (hereinafter the ‘Court of Justice’) on several occasions, while recognising their specific nature, all types of medical care fall within the scope of the Treaty on the Functioning of the European Union (TFEU)”.

Recital 16 defines precisely which rules govern the purchase of medicines or medical devices in a different country:

“For the purpose of reimbursing the costs of cross-border healthcare, this Directive should cover not only the situation where the patient is provided with healthcare in a Member State other than the Member State of

affiliation, but also the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service.

The definition of cross-border healthcare should cover both the situation in which a patient purchases such medicinal products and medical devices in a Member State other than the Member State of affiliation and the situation in which the patient purchases such medicinal products and medical devices in another Member State than that in which the prescription was issued.”

7 | seven CAN I SEEK HEALTHCARE ABROAD IF THE TREATMENT IS NOT AVAILABLE IN MY COUNTRY?

Prior authorisation is to do with reimbursement, not access to treatment. If a treatment is not available in a Member State, and is not included in the “health benefits package”, then the authorities may refuse prior authorisation. If a treatment is included in the “health benefits package” but is not available then “undue delay” probably applies and therefore authorities probably cannot refuse. In this case, treatment provided abroad will be reimbursed.

Usually, public benefit packages are defined rather generally, but if more precise lists exist (such as detailed medical billing codes), these must be used for the purpose of cross-border reimbursement.

8 | eight AS PATIENTS, DO WE NEED TO PAY FULL COSTS IN ADVANCE, AND BE REIMBURSED AT A LATER STAGE?

Instead of reimbursing the patient, member states of affiliation may also decide to pay the healthcare provider directly. This is not an obligation, but an option.

This is explained in Article 7.4:

“The costs of cross-border healthcare shall be reimbursed or paid directly by the Member State of affiliation 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 costs of healthcare received”.

For non-hospital care, patients will be able to seek healthcare abroad without prior authorisation or formalities, and claim reimbursement upon their return home.

9 | nine ON WHICH GROUNDS CAN PRIOR- AUTHORISATION BE REFUSED?

These grounds have to be explained, and are defined very clearly, to avoid arbitrary decisions as much as possible. A member state of affiliation may refuse to grant prior authorisation:

- if the patient seeking cross-border healthcare will be exposed to an unacceptable safety risk,
- if the general public will be exposed to a substantial safety hazard,
- if the healthcare is to be provided by a healthcare provider that raises serious concerns relating to compliance with standards and guidelines on quality and safety,
- or if the healthcare can be provided on its territory within a medically justifiable time-limit.

10 | TEN ANYTHING PARTICULARLY IMPORTANT FOR RARE DISEASES?

Article 13

This article says that the European Commission and Member States should be aiming to make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks;

And make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation.

In other words, the Europe institutions insist on the provisions defined by the Regulation and the utility of the S2 form.

11 | ELEVEN IS THERE A DIFFERENT PRICE, ONE FOR THEIR FELLOW CITIZENS AND ANOTHER ONE FOR FOREIGNERS?

In fact there should be no difference, as explained in Article 4.4:

“Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation, or that they charge a price calculated according to objective, non-discriminatory criteria if there is no comparable price for domestic patients.”

12 | TWELVE CAN WE ASK FOR TRAVEL AND ACCOMMODATION EXPENSES TO BE ALSO REIMBURSED?

Yes, reimbursement of « other costs » is mentioned in Recital 34 and article 7.4. Member States are free to do so, patients' organisations should advocate at national level for their Member State to use this option.

“Member States are free, for example, to reimburse extra costs, such as accommodation and travel costs, or extra costs incurred by persons with disabilities even where those costs are not reimbursed in the case of healthcare provided in their territory”.

13 | THIRTEEN WHERE CAN WE FIND INFORMATION ON CARE PROVIDED IN OTHER MEMBER STATES?

Information on cross border care is explained in Recital 48:

“Appropriate information on all essential aspects of cross- border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for providing such information is to establish national contact points within each Member State”.

14 | FOURTEEN IN CASE SOMETHING GOES WRONG, WHAT CAN I DO? WHO'S LIABLE?

Complaints & liability are explained in Article 4.2 (c):

“Transparent complaints procedures and mechanisms in place for patients, in order for them to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive”

15 | FIFTEEN CAN WE ADVOCATE FOR THE FULL COST (MAIN COSTS) TO BE REIMBURSED?

Yes! As provided for in Article 7.4:

“Where the full cost of cross-border healthcare exceeds the level of costs that would have been assumed had the healthcare been provided in its territory the Member State of affiliation may nevertheless decide to reimburse the full cost.”

Each Member State can decide (if invited to do so...) to reimburse the full cost, in cases where the actual costs are above the costs that would have been reimbursed in the country of affiliation. Member States who wish to support rare disease patients may opt for this option, however it is not mandatory.

16 | SIXTEEN WHICH HEALTHCARE IS SUBJECT TO PRIOR-AUTHORISATION?

Article 8.7:

“The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive, as well as all relevant information on the system of prior authorisation.”

The definition of the lists (which will decide for which diseases prior authorisation will not be requested) will be specific to each Member State, and will certainly depend on the capacity of patients' organisations to defend their cause at national level.

17 | SEVENTEEN CAN MEMBER STATES LIMIT CROSS-BORDER CARE?

Recital 21 explains that the inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health.

In fact Member States' government are responsible for planning healthcare services and allocate necessary budgets. If a Member State estimates 300 CT-scan equipment to be needed to serve its population and due to an inflow of many patients coming from other Member States these 300 CT-scan can no longer satisfy the demand or with too long delays, the Member State can decide to acquire more CT-scans, or to put a limit on the number of patients from other Member States.

18 | eighteen IMPORTANT ECJ JUDGEMENTS TO HAVE IN MIND

Since 1995, all European Court of Justice (ECJ) Judgments concluded systematically in favour of the patients under the EU Treaty principle of free movements of good, services and people:

- Decker 1995 and Kohll 1996
- Vanbraekel 1998
- Müller-Faurel 1999
- Geraets-Smits-Peerboms 2001
- Leichtle 2002
- Inizan 2003
- Idryma Koinonikon Asfaliseon 2003
- Watts 2004
- Elchinov 2010

These judgments can be found here: <http://eur-lex.europa.eu/en/index.htm>

19 | nineteen THE ECJ IN THE GERAETS-SMITS & PEERBOOMS CASE

On 10/12/1996, Mr Peerbooms fell into a coma following a road accident. On 22/02/1997 he was taken to hospital in the Netherlands, and then transferred in a vegetative state to the University Clinic in Innsbruck, Austria. The Innsbruck clinic gave Mr Peerbooms special intensive therapy using neuro-stimulation.

On 20/06/1997 Mr Peerbooms came out of his coma and left the Innsbruck clinic. Back in the Netherlands, reimbursement of care received in Austria was denied as neuro-stimulation was not part of the "Dutch care basket" (was not on the reimbursement list in the Netherlands).

The court said:

- Authorisation to purchase treatment in other Member State cannot be refused where it appears that the treatment concerned is sufficiently tried and tested by international medical science
- Authorisation cannot be refused if treatment can be obtained in country of residence but only with long delays

In other words, the court decided Mr Peerbooms should have been reimbursed. This Court's ruling cannot necessarily be used outside of the particular case of the Netherlands where the basket of healthcare is defined as "normal care in the professional circles involved".

20 | twenty THE ECJ IN THE ELCHINOV CASE

Mr Elchinov, Bulgarian, suffered from a rare form of eye cancer. On 9/03/2007 he asked for the S2 form (former E112) to NZOK to obtain advanced treatment in Berlin (attachment of radioactive applicators, proton therapy), as this treatment was not available in Bulgaria. He was admitted in Berlin on 15/03/2007 in an emergency as his state of health deteriorated, prior to receiving any response from NZOK.

On 18/04/2007, after treatment in Berlin, he received a negative response from NZOK, since the treatment was not one of the benefits provided for by the Bulgarian legislation and reimbursed by NZOK. In Bulgaria, only enucleation was available and thus reimbursed.

Mr Elchinov appealed to an expert who confirmed the advanced treatment was not yet available in Bulgaria. However NZOK appealed to Supreme Administrative Court and Mr Elchinov went to the Court of Justice of the European Union as last resort.

The Judgment said:

“authorisation cannot be refused:

If

- where the list of benefits does not expressly and precisely specify the treatment method applied
- but defines types of treatment reimbursed
- it is established that the treatment method in question corresponds to types of treatment included in that list,

and if

- no alternative treatment which is equally effective can be given without undue delay in the Member State on whose territory the insured person resides”.

In other words:

If Bulgarian list says: Type of treatment covered: « For eye cancer: radiological or surgical treatment »	If Bulgarian list says: Type of treatment covered: « For eye cancer, enucleation only »
Then reimbursement of proton-therapy as provided in Berlin cannot be refused	Then reimbursement of proton-therapy as provided in Berlin can be refused only the cost that is equivalent to the cost of enucleation to be reimbursed

The lesson is: the more precise the list of treatments that are reimbursed, the more difficult it is to obtain reimbursement for a different type of treatment obtained in another country than country of affiliation.

21 | twenty-one GLOSSARY

- **Cross-border healthcare:** means healthcare provided or prescribed in a Member State other than the Member State of affiliation.
- **Healthcare provider:** means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State. It can be a healthcare professional, or a hospital, clinic...
- **Insured person:** nationals of a Member State, stateless persons and refugees residing in a Member State who are or have been subject to the legislation of one or more Member States. It includes the members of their families and their survivors.

Nationals of a third country who satisfy conditions laid down in Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010 are also insured.

- **Member State of affiliation** (country of affiliation): defines the country where the insured person has to request a prior authorisation to receive appropriate treatment outside the Member State of residence.
- **Member State of residence** (country of residence): where the insured person lives.
- **Member State of treatment**: means the Member State on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the Member State where the healthcare provider is established.

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