EUROPEAN PARLIAMENT

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Committee on the Environment, Public Health and Food Safety

2008/0142(COD)

20.11.2008

***I
DRAFT REPORT

on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
(COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: John Bowis

Rapporteurs for opinion (*):
Iles Braghetto, Committee on Employment and Social Affairs
Bernadette Vergnaud, Committee on the Internal Market and Consumer Protection

(*) Associated committees – Rule 47 of the Rules of Procedure

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
(COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0414),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0257/2008),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs, the Committee on the Internal Market and Consumer Protection, the Committee on Economic and Monetary Affairs, the Committee on Committee on Industry, Research and Energy, Committee on Legal Affairs and the Committee on Women's Rights and Gender Equality (A6-0000/2008),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The European Parliament adopted on 9 June 2005, by 554 votes to 12, a resolution on Patient Mobility and Healthcare Developments in the European Union[1] , in which it called for legal certainty and clarity on rights and procedures for patients, health professionals and Member States.
	[1] OJ 124 E, 25.5.2006, p. 543.

Or. en

Amendment 2

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. ***They are also part of the wider framework of services of general interest.***	(4) The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development.

Or. en

Amendment 3

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. ***As healthcare was excluded from the scope of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market it*** is important to address these issues in a specific Community legal instrument in order to achieve a more general and effective application of principles developed by the Court of Justice on a case by case basis.	(6) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the care is resident, have been already addressed by the Court of Justice. ***It*** is important to address these issues in a specific Community legal instrument in order to achieve a more general and effective application of principles developed by the Court of Justice on a case by case basis.

Or. en

Amendment 4

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(10) For the purpose of this Directive, the concept of "cross-border healthcare" covers the following modes of supply of healthcare:	(10) For the purpose of this Directive, the concept of "cross-border healthcare" covers the following modes of supply of healthcare:
– Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';	– Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
– Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;	– Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services**.**
– Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,	
– Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).	

Or. en

Amendment 5

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating	(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating

principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving patients' mobility ***and free movement of provision of healthcare in the internal market*** as well as a high level of health protection.	principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving patients' mobility as well as a high level of health protection.

Or. en

Amendment 6

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive. Member States' authorities have	(12) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive. Member States' authorities have

to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement within the internal market, non-discrimination inter alia with regard to nationality ***(or in the case of legal persons, with regard to the Member State in which they are established),*** necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.	to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement of ***individuals*** within the internal market, non-discrimination inter alia with regard to nationality, necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.

Or. en

Amendment 7

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring clear common obligations to deal with ***circumstances of responding to*** harm arising from healthcare is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare.	(15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring clear common obligations to deal with ***alleged*** harm arising from healthcare is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. Coverage for harm and

Coverage for harm and compensation by the systems of the country of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.	compensation by the systems of the country of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.

Or. en

Amendment 8

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom ***to provide services include the freedom*** for the recipients of healthcare, including persons in need of medical treatment, to go to another Member Sate in order to receive it there. The same applies to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services. ***Whilst*** Community law does not detract from the power of the Member States to organise their healthcare and social security systems***, Member States must when exercising that power comply with Community law, in particular with the Treaty provisions on the freedom to provide services. Those provisions prohibit the Member States from introducing or maintaining unjustified***	(18) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions ***include*** the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member Sate in order to receive it there. The same applies to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services. Community law does not detract from the power of the Member States to organise their healthcare and social security systems.

restrictions on the exercise of that freedom in the healthcare sector.

Or. en

Amendment 9

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) ***It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (EC) No. 1408/71 should be able to benefit from the principles of free movement of services in accordance with the Treaty and the provisions of this Directive.*** Patients should be guaranteed assumption of the costs of ***that*** healthcare at least at the level provided for the same or similar healthcare had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial for the patient. This may be the case in particular for any treatment provided through European reference networks as mentioned in Article 15 of this Directive.	(21) Patients should be guaranteed assumption of the costs of healthcare ***provided in another Member State*** at least at the level provided for the same or similar healthcare had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial for the patient. This may be the case in particular for any treatment provided through European reference networks as mentioned in Article 15 of this Directive.

Or. en

Amendment 10

Proposal for a directive
Recital 24

Text proposed by the Commission	*Amendment*
(24) The patient should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to actual costs of healthcare received.	(24) The patient should, in any event, not derive a financial advantage from the healthcare provided in another Member State and the assumption of costs should be therefore limited only to actual costs of healthcare received. ***Member States may decide to cover other related costs, such as therapeutic treatment provided that the total cost does not exceed the amount payable in the Member States of affiliation.***

Or. en

Amendment 11

Proposal for a directive
Recital 35

Text proposed by the Commission	*Amendment*
(35) When healthcare is received by a patient in a Member state, which is not the country where he is insured, it is essential for the patient to know in advance which rules shall be applicable. An equivalent level of clarity is needed ***in case where healthcare providers temporarily move to another Member State to provide their medical services there or*** when healthcare is provided cross-border. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment in accordance with the general principles set out in Art.5, given that in accordance with Art. 152(5) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient in making an informed	(35) When healthcare is received by a patient in a Member state, which is not the country where he is insured, it is essential for the patient to know in advance which rules shall be applicable. An equivalent level of clarity is needed when healthcare is provided cross-border***, such as telemedicine***. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment in accordance with the general principles set out in Art.5, given that in accordance with Art. 152(5) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish

choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.

a high level of trust between the patient and the healthcare provider.

Or. en

Amendment 12

Proposal for a directive
Recital 37

Text proposed by the Commission	*Amendment*
(37) Realising the potential of ***the internal market for*** cross-border healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of ***services*** may be the most efficient way of organising ***health services*** for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Community law, be restricted for any reason relating to professional	(37) Realising the potential of cross-border healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of ***healthcare*** may be the most efficient way of organising ***healthcare*** for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Community law, be restricted for any reason relating to professional qualifications. This Directive

qualifications. This Directive should be without prejudice to those provisions of Directive 2005/36/EC.

should be without prejudice to those provisions of Directive 2005/36/EC.

Or. en

Amendment 13

Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(39) Where medicinal products are authorised within the patient's Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be medically recognised and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products.	(39) Where medicinal products are authorised within the patient's Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be medically recognised and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. ***Where a prescription is issued in the Member State of treatment for drugs which are not normally available on prescription in the Member***

State of affiliation it should be for the latter to decide whether to authorise exceptionally or to provide an alternative drug deemed to be similar.

Or. en

Amendment 14

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare**.** In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:	1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare**.** In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:
(a) ***mechanisms are in place for ensuring that healthcare providers are able to meet such standards, taking into account international medical science and generally recognised good medical practices;***	(a) ***when healthcare is provided in a Member State other than that where the patient is an insured person, or in a Member State other than that where the healthcare provider resides, is registered or established, such healthcare is provided according to the legislation of the Member State of treatment.***
(b) ***the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;***	(b) ***healthcare referred to in paragraph 1(a) is provided according to standards and guidelines on quality and safety defined by the Member State of treatment ensuring that:***
	(i) patients and healthcare providers from other Member States can be provided with information on such standards and guidelines, including provisions on supervision, inter alia by electronic means;
(c) healthcare providers provide all relevant information to enable patients to	***(ii) patients and healthcare providers from other Member States can be provided with***

make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of ***their*** insurance cover or other means of personal or collective protection with regard to professional liability;	***information*** on availability, prices and outcomes of the healthcare provided and details of ***the healthcare provider's*** insurance cover or other means of personal or collective protection with regard to their professional liability;
(d) patients have a means of making complaints and are guaranteed remedies and compensation ***when they suffer harm arising from the healthcare they receive***;	(d) patients have ***the*** means of making complaints ***when they suffer harm arising from the healthcare they receive*** and are guaranteed remedies and ***the right to seek*** compensation;
(e) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;	(e) systems of professional liability insurance or a guarantee or similar arrangement, which are equivalent or essentially comparable as regards their purpose and which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;
(f) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;	(f) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;
(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.	(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.
	(ga) patients who have received treatment are entitled to a written or electronic record of such treatment and of any medical advice for the continuity of their care;

Or. en

Justification

Article 5 should be merged with article 11, since they deal with two aspects of the same subject matter.

The issue of defining standards on quality and safety should be dealt with purely as a matter of applicable law. This will make the proposal more in line with the principles of subsidiarity and proportionality, and the respect for Member State competence on healthcare. Instead, Member States shall provide information on their standards and guidelines on quality and safety to patients and healthcare providers.

Patients should be guaranteed the right to seek compensation when they suffer harm, not guaranteed compensation when they suffer harm. This because harm sometimes is an unavoidable outcome/side effect of certain healthcare treatments.

The provision on guidelines is not necessary since the Commission has a general mandate to issue guidelines for implementing Community law.

Amendment 15

Proposal for a directive
Article 5 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, ***shall*** develop guidelines to facilitate the implementation of paragraph 1.	3. In so far as it is necessary to facilitate the provision of cross-border healthcare and taking as a basis a high level of protection of health, the Commission, in cooperation with the Member States, ***may*** develop guidelines to facilitate the implementation of paragraph 1.

Or. en

Justification

The issue of defining standards on quality and safety should be dealt with purely as a matter of applicable law. This will make the proposal more in line with the principles of subsidiarity and proportionality, and the respect for Member State competence on healthcare. Instead, Member States should provide information on their standards and guidelines on quality and safety to patients and healthcare providers.

Amendment 16

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.	1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to ***the Member State of treatment or*** the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. ***If there are several methods available for treating a certain disease or injury, the patient shall have the right to reimbursement for all methods of treatment that are sufficiently tried and tested by international medical science, even if they are not available in the patient's Member State of affiliation.*** In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. en

Justification

It is for each Member State to organise its national social security system and to determine the conditions governing entitlement to benefits. Accordingly, if patients are entitled to a certain health care benefit in their home Member State they should have the right to be reimbursed for equivalent healthcare provided in other Member States. However, according to ECJ case law, Member States must not disregard Community law when determining which

treatments will be paid for by it's social security system.[1] Therefore, if there are several methods available for treating a certain disease or injury, the patient should have the right to reimbursement for all methods of treatment that are sufficiently tried and tested by international medical science,[2] even if they are not offered in the patient's home Member State. This will give patients a greater opportunity of receiving a treatment that suits their individual condition.

Amendment 17

Proposal for a directive
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.	2. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States may decide to cover other related costs, such as therapeutic treatment, provided that the total cost does not exceed the amount payable in the Member States of affiliation.***

Or. en

Amendment 18

Proposal for a directive
Article 8 – title

Text proposed by the Commission	*Amendment*
Hospital ***and specialised*** care	Hospital care

Or. en

[1] Case C-157/99, Smits/Peerbooms, p 87-88.
[2] Ibid, p 94.

Amendment 19

Proposal for a directive
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:	1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:
(a) healthcare which requires ***overnight accommodation of the patient in question for at least one night.***	(a) healthcare which ***is highly specialised and/or*** requires ***use of cost-intensive medical infrastructure or medical equipment; or***
(b) healthcare***, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:***	(b) healthcare ***involving treatments presenting a particular risk for the patient or the population.***
- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or	
- healthcare involving treatments presenting a particular risk for the patient or the population.	

Or. en

Amendment 20

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).	***deleted***

Or. en

Amendment 21

Proposal for a directive
Article 8 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.	4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination ***or an obstacle to freedom of movement of persons***.

Or. en

Amendment 22

Proposal for a directive
Article 8 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3.	5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3***, including appeal procedures in the event of a refusal to give authorisation***.

Or. en

Amendment 23

Proposal for a directive
Article 9 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States may offer patients a voluntary system of prior authorisation whereby, in return for such authorisation,

	the patient shall receive a voucher indicating the maximum reimbursable cost. This voucher can then be taken to the hospital of treatment and reimbursement would then be made direct from the Member State of affiliation.

Or. en

Amendment 24

Proposal for a directive
Article 9 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Commission shall conduct a feasibility study into the establishment of a clearing house to facilitate the reimbursement of costs under this Directive across borders, healthcare systems and currency zones within two years of the entry into force of this Directive and shall report back to the European Parliament and the Council and, if appropriate, present a legislative proposal.

Or. en

Amendment 25

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member	1. The Member States of affiliation shall ensure that there are ***easily accessible*** mechanisms in place***, including by electronic means, promptly to*** provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, ***and shall include***

State.

information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements**,** inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Or. en

Amendment 26

Proposal for a directive
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.	***deleted***

Or. en

Amendment 27

Proposal for a directive
Article 10 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that information is available through a secure system to the health professionals advising a patient. This information shall include details of registered health professionals in the Member State of treatment and any disciplinary proceedings against them. Member States shall proactively notify each other of any such disciplinary proceedings and

subsequent findings immediately.

Or. en

Amendment 28

Proposal for a directive
Article 12 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and ***the guarantees of*** quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;	(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and ***information about*** quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Or. en

Amendment 29

Proposal for a directive
Article 12 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) facilitate patient access to European Patient Networks;

Or. en

Amendment 30

Proposal for a directive
Article 14 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible;	(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible***, including clarity as to different names used for the same medicinal product***;

Or. en

Amendment 31

Proposal for a directive
Article 14 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) measures to identify and prevent counterfeit medicinal products reaching pharmacies;

Or. en

Amendment 32

Proposal for a directive
Article 14 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where a prescription is issued in the Member State of treatment for medicinal products which are not normally available on prescription in the Member State of affiliation it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal

product deemed to be similar.

Or. en

Amendment 33

Proposal for a directive
Article 15 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) a list of specific criteria and conditions that the European reference networks must fulfil, including the conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks:	(a) a list of specific criteria and conditions that the European reference networks must fulfil, including the ***list of rarer disease areas to be covered and*** conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks:

Or. en

Amendment 34

Proposal for a directive
Article 15 – paragraph 3 – point a – point ix a (new)

Text proposed by the Commission	*Amendment*
	(ixa) have appropriate and effective relationships with technology providers.

Or. en

Amendment 35

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
The Commission shall, in accordance with the procedure referred to in Article 19(2),	The Commission shall, in accordance with the procedure referred to in Article 19(2),

adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data ***in accordance with the applicable law***. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.	adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall ***conform to the applicable data protection laws in each Member State and shall also*** reflect developments in health technologies and medical science, ***including telemedicine and telepsychiatry,*** and respect the fundamental right to the protection of personal data. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.

Or. en

Amendment 36

Proposal for a directive
Article 17 – title

Text proposed by the Commission	*Amendment*
Cooperation on management of ***new*** health technologies	Cooperation on management of health technologies

Or. en

Amendment 37

Proposal for a directive
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for health technology	1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for health technology

assessment.	assessment. ***Member States shall set up a system based on the principles of good governance including transparency, objectiveness, fair procedures, and full stakeholder participation of all relevant groups, including health professionals, patients, scientists and industry, for the operation of the network.***

Or. en

Amendment 38

Proposal for a directive
Article 17 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets.

Or. en

Amendment 39

Proposal for a directive
Article 17 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment ***and*** the management of this network ***and specifying the nature and type of the information to be exchanged.***	4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment***,*** the management ***and the transparent functioning*** of this network.

Or. en

Amendment 40

Proposal for a directive
Article 17 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall only allow such authorities to join the network which fulfil the principles of good governance as defined in paragraph 1.

Or. en

Amendment 41

Proposal for a directive
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.	The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive***, including statistics on patient outflows and inflows resulting from this Directive,*** and submit it to the European Parliament and to the Council.

Or. en

EXPLANATORY STATEMENT

"Jamais poete n'a interpreté la nature aussi librement qu'un juriste la realité" *Jean Giraudoux*
(No poet ever interpreted nature as freely as a lawyer interprets the truth.)

Sense and Sensitivity

Lawyers or politicians. For the past ten years, since the 1998 Kohll and Dekker judgement at the European Court of Justice (ECJ), the lawyers of Europe have been deciding policy on patient mobility, because the politicians of Europe have failed to do so. If we do nothing, the Court will continue to interpret the Treaties, where patient mobility rights are concerned. They will provide the clarity that we politicians have failed to provide. If we are content to leave policymaking to lawyers, then we need do nothing - except of course pay the resulting unpredictable bills. But if we believe it is our job, as elected politicians to give legal and policy certainty, then we should do so without further delay. Our electors like the idea of patient mobility as an option; but they want and expect it to be properly managed and they want and expect to be offered sound guidance on policy and procedures.

The Commission's long-awaited proposal, following the overwhelmingly majority in the Parliament for our Patient Mobility Report of 2005 (A6-0129/2005), is welcome, including its imaginative provisions that go beyond the ECJ judgements on European Reference Networks for rarer diseases. It does however leave some areas of uncertainty that this Report seeks to clarify and address.

Opportunity for Patients. We should make it crystal clear that this is an opportunity for patients. It is patient centred; issues about the mobility of health professionals and of health services are for another day. So, regrettably, is the urgently needed proposal on patient safety. Nor, as it makes clear, does this proposal amend or touch the Social Security route, which remains in place, although perhaps we need greater clarity as to when each would apply. We should make it no less clear that it is an opportunity for patients, based on need and not means and on informed choice and not compulsion.

Court Judgements. It is equally clear we are not starting with a clean sheet of paper; this is not a time for 'blue sky' drafting. The Treaties have provided the ECJ with the legal basis for its judgements and the Court has written its draft of consequent policy. They have set in motion a process which has the potential to empower patients and enhance the health of Europe's citizens. In its original ECJ essence, this confirmed that patients, facing 'undue delay' for treatment, have the right to go to another Member State for treatment and have the bill paid by the home country's health funder, so long as two conditions apply :- the treatment must normally be available in the home country and the cost must be comparable. In a series of ECJ judgements it has been established that there can be no requirement on the patient to seek prior approval for non-hospital treatment or other health benefits, such as the original spectacles and orthodontics. It leaves open however the possibility of some form of prior authorisation or notification when in-patient hospital treatment is concerned, if the home country ('Member State of Affiliation') can show that, without it, the management of healthcare for other patients would suffer. The judgements were not so much about the authorisation process but about the use of this process unreasonably to decline or place

obstacles in the way of a person's right to travel for treatment. For that reason we have sought to put in place a system of prior authorisation that has a light touch, where patients are concerned, but a sensible advance warning of exceptional costs, where healthcare managers are concerned.

Needs not Means. When we say the policy should be about patients with needs, not patients with means, we should make it clear we do not wish to see patients having to travel, clutching cash or credit card to pay upfront for often expensive in-hospital treatment. We should put in place a system of reimbursement direct from home funder to receiving hospital, either through a Central Clearing House to manage the cross-border, cross-currency, cross-system (Beveridge/Bismark) complications, or by a bi-lateral voucher system for the patient to take to the hospital and guaranteeing the latter payment by the Member State of Affiliation.

Either option would remove arguments between the patient and the hospital over payment and the latter option would also simplify matters between the two Member States about issues such as exchange rates. A Clearing House could take time to establish and so, as an additional and swifter mechanism to put in place, we suggest a patient who chooses to use the prior authorisation process established by his or her home country, should receive a voucher to take to the treating hospital, guaranteeing payment up to a given amount. With such a voucher the patient would not personally have to pay for the treatment and the hospital would be guaranteed payment by the patient's home country. Without such a voucher, and pending the establishment of a Central Clearing House, the patient would have to pay and claim back.

Packages. The question arises of whether the ECJ's ruling with regard to cost means a Member State of Affiliation can only be liable for the actual cost of treatment. A package of treatment, with extras such as convalescence or physiotherapy, could be offered at a total cost less than would have been paid for the treatment alone at home. If such packages bring added health benefit to the patient, for example making relapse less likely, that must be good and should be welcomed, so long as the whole package is within the cost that would have been paid for treatment in the home country. Member States should be as flexible as possible on this.

'Health Brokers'. It is likely that we will see an increase in the number of 'health brokers' setting up to give patients independent advice on packages of treatment and care, in the same way as an insurance broker shops around on behalf of his client to find the best options to meet his or her needs. Clearly it is for each Member State to decide its policy in this area and each Member State will in due course also have to decide whether the role or training of the health broker needs to be regulated or self-regulated in some way.

Topping Up. It is also likely that, in some countries, the option of going abroad will be only possible if the patient is prepared to top up the amount payable by the home country. There is nothing intrinsically wrong with that. It is no different from patients paying for an amenity bed in a local hospital or to parents paying for extra tuition for their child at school. But it will only be an option. No pressure should be put on the patient to pay more and no hospital should charge more for foreign than domestic patients for the same treatment.

Numbers. The expectation is that we shall not see large numbers of patients seeking to use this route. Most people prefer to have treatment near their home, where friends and family can visit. If necessary they will go elsewhere within their home country – not least because

language. If they do decide to go abroad, they will probably opt first for the managed arrangements already well established bilaterally and trilaterally between Member States, regions or cities. If they want more flexibility however – perhaps because of family or friends in another part of the EU, where they can stay to convalesce after treatment, or because they have heard of a particularly good hospital team or other healthcare provider – then they may choose to use this Cross Border Health opportunity.

Of course, if a Member State wishes to avoid its citizens using this new opportunity and with it the outflow of resources, it will raise its standards of healthcare and waiting times, so that no one feels the need to go elsewhere. If it attracts patients from abroad – perhaps because its care and treatment are less expensive – it will attract resources into the country, which can be ploughed back into healthcare for the benefit of all patients. After five years we should review the experience of outflows and inflows to see what the impact has been and whether we need to relax or tighten the policy.

Information. Information will be key and each Member State will be expected to establish information centres (national contact points), where the patient and his or her medical advisers can find out what is available, whether eligibility criteria apply, what processes are necessary, what complaints and appeals procedures are in force and what help there may be with travel costs. The sensitive issue of healthcare standards is also relevant in this context. Clearly, if a Member State authorises, explicitly or implicitly by accepting the ECJ Judgements, its citizens to go abroad for treatment, it has a duty of care to its citizens. It will certainly want to have in place mutual assurances about patient safety. One risk to patient safety can result from poor quality healthcare. Member States are responsible for their healthcare delivery and no-one suggests the European Union should prescribe standards for this. What the Member State of Treatment can and should do is ensure that such standards are described publicly. The duty of the Member State of Affiliation is to ensure that its citizens have access to information, so that patients and their medical advisers can know what standards to expect, if they choose to go to another country. No more; no less.

Prescriptions. One issue raised by the proposal concerns the mutual recognition of prescriptions. Clearly it is desirable that a pharmacy in the home country should recognise and act upon a prescription issued by a doctor in another. This will need access to a register of medical practitioners qualified and permitted to issue prescriptions. The problem however goes deeper. It is broadly acknowledged that it is for member States to decide what drugs are available on prescription. If therefore a patient goes abroad and is prescribed a course of drugs that are not available in the home country, that patient will either have to make do with what is available or return to the treating country – or, riskily, obtain them over the internet. It would seem to be preferable that member States should accept, as part of a supplementary prescription list, drugs prescribed as part of treatment within the Cross Border Health context. That is a matter for Member States, but could be the source of future challenges to the ECJ, if not handled sensitively and sensibly.

Sense and Sensitivity. And that, in a nutshell, is what this Report is about: sense and sensitivity; a new opportunity for patients; one in which the Europe Union can claim to have benefited it citizens; clarity and legal certainty; not solving the inequalities of healthcare across Europe or within Member States - that is a question to re-direct to the Ministers of respective Member States - but equity and equality of opportunity; flexibility and not bureaucracy; a willingness to look at the 'how shall we?' issues and not the 'why we should

not' ones. One thing is already clear: increasing numbers of our citizens are becoming aware of the imminence of this policy opportunity. They may not in the end use it, but they want it to be there. The challenge to us in all three institutions is to put it in place as quickly as possible.