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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

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

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 the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 51 and 35 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 (A6-0233/2009),

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

Text proposed by the Commission	*Amendment*
(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this	(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this

respect Article 95(3) of the Treaty explicitly requires that***, in achieving harmonisation,*** a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.	respect Article 95(3) of the Treaty explicitly requires that a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.

Justification

The aim of this directive should be to clarify patients' rights and not to harmonise the organisation of health care. This is a matter for which Member States bear sole responsibility.

Amendment 2

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 C 124 E, 25.5.2006, p. 543.

Amendment 3

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.

Amendment 4

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) This Directive respects and does not prejudice the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States.

Justification

Concerns have been raised that ethically controversial medical "services" like euthanasia, DNA-testing or IVF maybe have to be financed by the Member States even if the relevant service is not allowed, or at least not financed, in the relevant Member States. For services which are clearly illegal, like euthanasia, there should be no doubt, but it may be helpful to clarify this point. In other areas, like DNA-testing, the situation is more complicated because it is not banned in any Member State but the conditions are quite different, for example obligation to do counselling before testing is necessary in one Member State and not in the other.

Amendment 5

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	(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.

general and effective application of principles developed by the Court of Justice on a case by case basis.

Amendment 6

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community ***and*** to ***ensure*** patients mobility ***and freedom to provide healthcare and*** high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.	(8) This *Directive* aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community ***in relation to*** patients mobility ***as well as a to a*** high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and ***for*** the organisation and delivery of healthcare and medical care ***as well as of*** social security benefits in particular for sickness.

Justification

The proposed Directive applies only to patient mobility and not to free movement of providers of services.

Amendment 7

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does	(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does

not apply to assistance and support for families or individuals who are, over an extended period of time, in ***a*** particular ***state of*** need. ***It*** does not apply, for example, to residential homes or housing, or assistance provided to elderly people or children by social workers or volunteer carers or professionals other than health professionals.	not apply to assistance and support for families or individuals who are, over an extended period of time, in particular need ***of nursing, support or care in so far as this involves specific expert treatment or help provided by a social security system. This covers above all such long-term care services as are considered necessary in order to provide the person in need of care with as full and independent a life as possible. This Directive*** does not apply, for example, to residential homes or housing, or assistance provided to elderly people or children by social workers or volunteer carers or professionals other than health professionals.

Justification

This amendment serves to clarify the fact that services in the area of social assistance or care, rehabilitation with a view to resuming work and long-term care are excluded from the scope of this directive.

Amendment 8

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) This Directive does not apply to organ transplantations. Due to their specific nature, they will be regulated by a separate directive.

Amendment 9

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" ***only*** covers the ***use of healthcare in a Member State other than that where the patient is***

	an insured person. 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;	
– 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).	

Amendment 10

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 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	(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 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. ***In view of these common values it is nevertheless accepted that Member States take different decisions on ethical grounds as regards the availability of certain treatments and the concrete access conditions. This Directive is without prejudice to ethical diversity.***

Amendment 11

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 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	(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.	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. ***In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, Member States shall ensure that patients receive on request the relevant information on health and quality standards enforced in the Member State of treatment as well as on the characteristics of healthcare provided by a specific healthcare provider. Such information shall also be made available in formats accessible to persons with disabilities.***

Amendment 12

Proposal for a directive
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) Member States should ensure that in the application of this Directive patients are not encouraged against their will to receive treatment outside of their Member State of affiliation.

Amendment 13

Proposal for a directive
Recital 13 b (new)

Text proposed by the Commission	*Amendment*
	(13b) It is also important to put in place measures to ensure that women have equitable access to public health schemes and care that is specific to them, particularly gynaecological and reproductive healthcare.

Amendment 14

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved, in line with the Council Conclusions of 1-2 June 2006 on Common values and principles in European Union Health Systems and taking into account advances in international medical science and generally recognised good medical practices as well as taking into account new health technology;

Justification

Health systems in the European Union should be governed by the Common Values and Principles as defined by the European Council and follow developments in medical science, technology and practice.

Amendment 15

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) Research suggests that harm arises	(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. 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.

from healthcare in around 10% of cases. Ensuring ***that Member States of treatment have systems in place (including provision of aftercare)*** to deal with ***alleged*** harm arising from healthcare ***as defined by the Member State of treatment*** 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 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.

Amendment 16

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(17) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example in	(17) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example in

the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive.	the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive. ***The patient should be able to stop the release of his data at any point and receive confirmation that his data have been deleted.***

Amendment 17

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 restrictions on the exercise of that***	(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. Community law does not detract from the power of the Member States to organise their healthcare and social security systems.

freedom in the healthcare sector.

Amendment 18

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 ***and goods connected with healthcare provided in another Member State*** at least at the level provided for ***treatment which is*** the same or ***equally effective,*** had they been provided ***or purchased*** 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.

Justification

Part of the amendment incorporated in the report without vote, on the basis of Rule 47.

Amendment 19

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 ***or goods purchased*** in another Member State***.*** The assumption of costs should *therefore be* limited only to ***the*** actual costs. ***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.***

Justification

Part of the amendment incorporated in the report without vote, on the basis of Rule 47. The Directive applies not only to services but also to the purchase of goods in the context of cross-border health care. The amendment also formulates the recital better.

Amendment 20

Proposal for a directive
Recital 25

Text proposed by the Commission	*Amendment*
(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such a treatment ***is*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions.	(25) This Directive does not aim either to create entitlement for reimbursement of treatment ***or of the cost of purchasing goods*** in another Member State, if such a treatment ***or such goods are*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare ***and goods*** provided in another Member State according to its provisions. ***This Directive recognises that entitlement to treatment is not always determined nationally by Member States and that Member States may organise their own healthcare and social security systems to provide for***

entitlement to treatment to be determined at a regional or local level.

Justification

Part of the amendment incorporated in the report without vote, on the basis of Rule 47. The Directive applies not only to services but also to the purchase of goods in the context of cross-border health care. The amendment also formulates the recital better.

Amendment 21

Proposal for a directive
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) 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, even if they are not available in the patient's Member State of affiliation.

Amendment 22

Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.	(27) This Directive provides also for the right for a patient to receive any medicinal product ***or medical device*** authorised for marketing in the Member State where healthcare is provided ***in the Member State of treatment***, even if the medicinal product ***or medical device*** is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining ***this specific*** effective treatment ***for the patient*** in another Member State.

Justification

Incorporated in the report without vote, on the basis of Rule 47. For reasons of legal certainty and the practical consequences as regards the provision of medicinal products, this directive should not depart from the principle enshrined in Article 6 of Directive 2001/83/EC that only medicinal products authorised in the Member State concerned may be placed on the market.

Amendment 23

Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(30) There is no definition of what constitutes hospital care throughout the different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases). ***A regularly updated list of such treatments shall be specifically defined by the Commission through the comitology procedure.***	(30) There is no definition of what constitutes hospital care throughout the different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases).

Justification

Differences in entitlements and clinical practices between Member States mean that, in practice, having a single EU list of treatments for which prior authorisation may be required would only cause confusion for patients.

Amendment 24

Proposal for a directive
Recital 32

Text proposed by the Commission	*Amendment*
(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation 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. However, when the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.	(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had ***treatment which is*** the same or ***equally effective for the patient*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with

the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 25

Proposal for a directive
Recital 32 a (new)

Text proposed by the Commission	*Amendment*
	(32a) Prior authorisation should only be refused in the context of a fair and transparent procedure. The rules laid down by the Member States for submitting an authorisation request and the possible reasons for refusal should be made known in advance. Refusals should be limited to what is necessary, and should be proportionate to the objectives of setting up a prior authorisation system.

Amendment 26

Proposal for a directive
Recital 33

Text proposed by the Commission	*Amendment*
(33) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This applies also to the actual reimbursement of costs of healthcare incurred in another Member State after the patient's return. ***It is appropriate that*** patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days. However, that period should be shorter where warranted by the urgency of the treatment in question.	(33) Procedures regarding cross-border healthcare established by the Member States should give patients guarantees of objectivity, non-discrimination and transparency, in such a way as to ensure that decisions by national authorities are made in a timely manner and with due care and regard for both those overall principles and the individual circumstances of each case. This applies also to the actual reimbursement of costs of healthcare incurred in another Member State after the patient's return. Patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days. However, that period should be shorter where warranted by the urgency of the treatment in question. In any event,

In any event, recognition procedures and rules on the provision of services as provided for by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications should not be affected by these general rules.	recognition procedures and rules on the provision of services as provided for by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications should not be affected by these general rules.

Justification

There is a small yet considerable demographic group which live between more than one member state. Therefore, these individuals should have the right to non-hospital care such as convalescence, residential care and so on, only provided that they are insured for the same menu of care in their member state of affiliation.

Amendment 27

Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross-border healthcare. They should also provide information about options available in case	(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross border healthcare**.** They should also provide information about options available in case

of problems with cross-border healthcare, in particular about out-of-court schemes for settling cross-border disputes.	of problems with cross-border healthcare, in particular about out of court schemes for settling cross border disputes. ***In developing arrangements for the provision of information on cross-border healthcare, the Member States should give consideration to the need to provide information in accessible formats and to potential sources of additional assistance for vulnerable patients, disabled people and people with complex needs.***

Justification

It is vital that information about cross border healthcare is available in accessible formats.

Amendment 28

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

Amendment 29

Proposal for a directive
Recital 36

Text proposed by the Commission	*Amendment*
(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. ***The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Community level, such as through the European Health Portal.*** The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.	(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. ***The Member States should ensure the participation of bodies representing health professionals in these activities.*** The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system. ***The national contact points should be able to provide patients with relevant information on cross-border healthcare and to assist them. This should not include legal advice.***

Amendment 30

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	(37) Cooperation ***is required*** between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure

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

Justification

As this Directive concerns all forms of care, it is illusory to mention an internal market for cross-border healthcare.

The part is moved to a new Recital 37 a, where it is to be formulated more precisely.

Amendment 31

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, ***including the future legislation on falsified medicinal products (Directive XXXX/XX/EC) and pharmacovigilance (Directive ZZZZ/ZZ/EC),*** and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be recognised ***medically or in pharmacies*** 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 ***and without prejudice to the validity of national pricing and payment rules***. 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.

Amendment 32

Proposal for a directive
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) The interoperability of e-health solutions should be achieved whilst respecting national regulations on the provision of health services adopted in order to protect the patient, including legislation on internet pharmacies, in particular national bans on mail order of prescription-only medicinal products in accordance with the case-law of the European Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 2007 on the protection of consumers in respect of distance contracts[1].
	[1] OJ L 144, 4.6.1997, p. 19.

Justification

In line with the case-law of the European Court of Justice (judgment of 11 December 2003, C-322/01, Deutscher Apothekerverband) and Article 14 of the Distance Selling Directive (97/7/EC), it should be made clear that this directive does not affect the permissibility of bans on mail order of prescription-only medicinal products on the grounds of dangers to public health.

Amendment 33

Proposal for a directive
Recital 43

Text proposed by the Commission	*Amendment*
(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This will***	(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***However, the assessment of health technologies and the possible restriction of access to new technologies by certain decisions by administrative bodies raise a number of fundamental social issues which require contributions from a wide range of stakeholders and the***

also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant authorities of all the Member States, building on existing pilot projects.	***establishment of a viable governance model. Accordingly any cooperation should involve not only the competent authorities of all the Member States but also all the stakeholders concerned, including health professionals and representatives of patients and industry. Moreover, this cooperation should be based on viable principles of good governance such as transparency, openness, objectivity and the impartiality of procedures.***

Justification

Exchanges of information between health technology assessment bodies presuppose and require the application of good practice principles (for example good governance, transparency and participation by stakeholders) in the assessments performed by Member States. Health technology assessments must therefore meet criteria regarding openness and objectivity and be based on dialogue and the involvement of stakeholders, including patients and representatives of industry.

Amendment 34

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the	***deleted***

addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Justification

This amendment corresponds to the amendment by the same author to Article 8 and Article 15.

Amendment 35

Proposal for a directive
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) The Member State of affiliation and the Member State of treatment should by prior bilateral cooperation and in consultation with the patient ensure that appropriate aftercare and support is made available in either Member State following the authorised medical treatment and that clear information is available to patients about aftercare options and costs. To do this, Member States should adopt measures to ensure that:
	(a) the necessary medical and social care data is transferred with due regard to patient confidentiality; and
	(b) medical and social care professionals in both countries are able to consult each other to ensure the highest quality treatment and aftercare (including social support) for the patient.

Amendment 36

Proposal for a directive
Recital 46 b (new)

Text proposed by the Commission	*Amendment*
	(46b) By facilitating the freedom of movement for patients within the European Union, this Directive is likely to lead to competition between healthcare providers. Such competition is likely to contribute to an increase in the quality of the healthcare, for all and to the establishment of centres of excellence.

Justification

When the Directive has this as an outcome it would have a positive contribution to the healthcare systems in the Member States, but careful monitoring is needed to check the results of the Directive.

Amendment 37

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive ***establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare.***	This Directive ***lays down rules for access to safe and high-quality healthcare in another Member State and establishes cooperation mechanisms on healthcare between Member States, whilst fully respecting national competencies in the organisation and delivery of healthcare.*** ***In the application of this Directive, Member States shall take into account the principles of good quality care and equity.***

Amendment 38

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.	This Directive shall apply to provision of ***cross-border*** healthcare regardless of how it is organised, delivered and financed or whether it is public or private. ***It shall be without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EEC) No 1408/71 and its successor Regulation (EC) No 883/2004***. ***This Directive shall not apply to health services whose main focus is in the field of long-term care, including services provided over an extended period of time whose purpose is to support people in need of assistance in carrying out routine, everyday tasks.*** ***This Directive shall also not apply to organ transplantation.***

Amendment 39

Proposal for a directive
Article 3 - paragraph 1 - points - a a and - a b (new)

Text proposed by the Commission	*Amendment*
	(-aa) Directive 2005/36/EC on the recognition of professional qualifications;
	(-ab) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;

Amendment 40

Proposal for a directive
Article 3 - paragraph 1 - point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;

Amendment 41

Proposal for a directive
Article 3 - paragraph 1 - point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

Amendment 42

Proposal for a directive
Article 3 - paragraph 1 - point g c (new)

Text proposed by the Commission	*Amendment*
	(gc) Directive 92/49/EEC on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance, as regards the implementing powers conferred on the Commission;

Amendment 43

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. ***However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.***	2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, ***including when the conditions for granting an authorisation under Regulation (EEC) No 1408/71 and, from its date of application, Regulation (EC) No 883/2004 are fulfilled but the authorisation is not granted,*** Articles 6, 7, 8 and 9 of this Directive *shall* apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply.

Amendment 44

Proposal for a directive
Article 3 - paragraph 3

Text proposed by the Commission	*Amendment*
3. If the provisions of this Directive conflict with a provision of another Community act governing specific aspects of healthcare, the provision of the other Community act shall prevail and shall apply to those specific situations concerned. These include:	***deleted***

(a) Directive 2005/36/EC on the recognition of professional qualifications;

(b) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.

Amendment 45

Proposal for a directive
Article 4 – point a

Text proposed by the Commission	*Amendment*
(a) "healthcare" means ***a health service*** provided by ***or under the supervision of a health professional in exercise of his profession, and*** regardless of the ways in which ***it is*** organised, delivered and financed at national level or whether ***it is*** public or private;	(a) "healthcare" means ***health services or goods, such as pharmaceuticals and medical devices*** provided ***or prescribed*** by ***health professionals to patients to assess, maintain or restore their state of health or prevent them from becoming ill,*** regardless of the ways in which ***they are*** organised, delivered and financed at national level or whether ***care is*** public or private;

Amendment 46

Proposal for a directive
Article 4 - point b

Text proposed by the Commission	*Amendment*
(b) "cross-border healthcare" means healthcare provided in a Member State other than that where the patient is an insured person ***or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established***;	(b) "cross-border healthcare" means healthcare provided in a Member State other than that where the patient is an insured person;

Amendment 47

Proposal for a directive
Article 4 - point c

Text proposed by the Commission	*Amendment*
(c) "use of healthcare in another Member State" means healthcare provided in the Member State other than that where the patient is an insured person;	***deleted***

Amendment 48

Proposal for a directive
Article 4 - point d

Text proposed by the Commission	*Amendment*
(d) "health professional" means a ***doctor of medicine*** or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC;	(d) "health professional" means a ***medical practitioner*** or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC***, or a person legally exercising healthcare activities in the Member State of treatment;***

Justification

For obvious reasons, the term medical practitioner appears more appropriate since a doctorate in medicine is not a necessary requirement for healthcare professionals to be able to exercise a healthcare activity.

Amendment 49

Proposal for a directive
Article 4 - point e

Text proposed by the Commission	*Amendment*
e) "healthcare provider" means any ***natural*** or legal person legally providing healthcare on the territory of a Member State;	e) "healthcare provider" means any ***health professional in the sense defined in (d) above*** or legal person legally providing

	healthcare on the territory of a Member State;

Amendment 50

Proposal for a directive
Article 4 - point f

Text proposed by the Commission	*Amendment*
(f) "patient" means any natural person who receives or ***wishes*** to receive healthcare in a Member State;	(f) "patient" means any natural person who receives or ***seeks*** to receive healthcare in a Member State;

Amendment 51

Proposal for a directive
Article 4 - point g

Text proposed by the Commission	*Amendment*
(g) "insured person" means***:***	(g) "insured person" means a person who is insured ***under*** the provisions of ***the definition in*** Article 1(c) of Regulation (EC) No 883/2004***, or as defined in the policy conditions of private sickness insurance schemes;***
(i) until the date of application of Regulation (EC) No 883/2004: a person who is insured ***in accordance with*** the provisions of ***Articles 1, 2 and 4 of Regulation (EC) No 1408/71,***	
(ii) as from the date of application of Regulation (EC) No 883/2004: a person who is an insured person within the meaning of Article 1(c) of Regulation (EC) No 883/2004;	

Justification

Regulation (EC) No 883/2004 comes into force on 1 January 2009.

Amendment 52

Proposal for a directive
Article 4 - point h

Text proposed by the Commission	*Amendment*
(h) "Member State of affiliation" means the Member State where the patient is an insured person;	(h) "Member State of affiliation" means the Member State where the patient is an insured person ***or the Member State where the patient resides if this Member State is not the same as the former***;

Justification

In line with the provisions of Regulation 883/2004.

Amendment 53

Proposition de directive
Article 4 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) where, due to the application of Regulation (EEC) No 1408/71 and Regulation (EC) No 883/04 respectively, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits in accordance with the legislation of that state, then that Member State is regarded as the Member State of affiliation for the purposes of this Directive;

Amendment 54

Proposal for a directive
Article 4 - point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) "medical device" means a medical device as defined in Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC.

Justification

The purchase of goods in connection with health care (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments.

Amendment 55

Proposal for a directive
Article 4 - point i b (new)

Text proposed by the Commission	*Amendment*
	(ib) "goods used in connection with health care" means goods which are used to preserve or improve a person's health, such as medical devices and medicines;

Justification

The purchase of goods in connection with health care (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments.

Amendment 56

Proposal for a directive
Article 4 - point k a (new)

Text proposed by the Commission	*Amendment*
	(ka) "health technology" means a medicinal product or a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

Justification

This additional definition is required as Art. 5 and 17 refer to health technologies.

Amendment 57

Proposal for a directive
Article 4 - point l

Text proposed by the Commission	*Amendment*
(l) "harm" ***means adverse outcomes or injuries stemming from the provision of healthcare.***	(l) "harm" ***is defined in cross-border healthcare by reference to the existing legal framework of the Member State of treatment and understanding of what constitutes harm may vary from Member State to Member State.***

Amendment 58

Proposal for a directive
Article 4 - point l a (new)

Text proposed by the Commission	*Amendment*
	(la) "Patient's medical records" or "medical history" means all the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.

Justification

This term is used throughout the proposal for a directive, and it is therefore considered necessary to include a definition.

Amendment 59

Proposal for a directive
Article 5 – paragraph 1 and 1 a (new)

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	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 standards for healthcare provided on their territory, and ensure

ensure that:	***compliance with existing EU legislation on safety standards***, ***and*** 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, such healthcare is provided in accordance with 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 point (a) is provided in accordance with standards and guidelines on quality defined by the Member State of treatment;***
	(ba) patients and healthcare providers from other Member States are provided with information by the national contact point of the Member State of treatment, inter alia by electronic means, on quality standards and guidelines, including provisions on supervision, and on availability, quality and safety, treatment options, prices, outcomes of the healthcare provided, accessibility for persons with disabilities and details of the healthcare provider's registration status and insurance cover or other means of personal or collective protection with regard to their professional liability;
(c) healthcare providers provide all relevant information to enable patients to 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***;	(c) healthcare providers provide all relevant information to enable patients to make an informed choice;
(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 and ***the right to seek*** compensation when they suffer harm arising from the healthcare they receive ***and there are mechanisms in place to guarantee remedies***;
(e) systems of professional liability insurance or a guarantee or similar	(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;	arrangement, 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. ***However, this Directive shall not oblige healthcare providers in a Member State either to provide healthcare to an insured person from another Member State or to prioritise the provision of healthcare to an insured person from another Member State to the detriment of a person who has similar health needs and is an insured person of 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;
	1a. The public authorities in the Member State of treatment shall monitor regularly the accessibility, quality and financial state of their healthcare systems on the basis of the data collected under Article 18 of this Directive.

Amendment 60

Proposal for a Directive
Article 5 - paragraph 1b and 1c (new)

Text proposed by the Commission	*Amendment*
	1b. In order to maximise patient safety the Member States of treatment and affiliation shall ensure that:
	(a) patients have a means of making complaints, notably to a European Ombudsman who will treat patient complaints as regards prior authorisation, the quality of treatment and payments, and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;
	(b) the quality and safety standards of the Member State of treatment are made public in a language and format that is clear and accessible to all citizens;
	(c) there is a right to continuity of care, notably by means of the forwarding of relevant medical data concerning the patient with due respect to the provisions of paragraph 1 - point (e) and pursuant to Article 13 and 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;
	(d) in the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, the Member State of affiliation guarantees to provide healthcare equivalent to that received on its territory;
	(e) they immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services;
	1c. The Commission shall in accordance with the procedure referred to in Article

19(2), adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

**** OJ C 146, 22.6.2006, p. 1.***

Amendment 61

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any measures taken by Member States, when implementing this Article, shall respect the provisions of Directive 2005/36/EC on the recognition of professional qualifications and Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce.	***deleted***

Justification

These references have been moved to Article 3.

Amendment 62

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.

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 63

Proposal for a directive
Article 5 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. For the purposes of this Article, Member States shall have a transparent mechanism for the calculation of costs that are to be charged for the healthcare provided. This calculation mechanism shall be based on objective, non-discriminatory criteria known in advance and it shall be applied at the relevant administrative level in cases where the Member State of treatment has a decentralised healthcare system.

Amendment 64

Proposal for a directive
Article 5 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In view of the great importance, particularly to patients, of safeguarding the quality and safety of cross-border care, the organisations involved in drawing up standards and guidelines as referred to in paragraphs 1 and 3 shall at the minimum include patients' organisations (particularly those of a cross-border nature).

Amendment 65

Proposal for a directive
Article 6 – title

Text proposed by the Commission	*Amendment*
Article 6	*Article 6*
Healthcare provided in another Member State	***Responsibilities of authorities of the Member State of affiliation***

Justification

This amendment seeks to align the title of Article 6 with that of Article 5. There is a general problem throughout the proposal of titles of articles not reflecting the content of the article, and a widespread revision of titles is required.

Amendment 66

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, ***administrative regulations, guidelines and codes of conduct of the medical professions,*** of the Member State of affiliation to which the insured person is entitled. ***Without prejudice to Regulation (EEC) No 1408/71 and, as from its date of application, Regulation (EC) No 883/2004,*** 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 ***equally effective*** healthcare been provided in its

territory. ***If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision.*** 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.

Patients affected by rare diseases should have the right to access healthcare in another Member State and to get reimbursement even if the treatment in question is not among the benefits provided for by the legislation of the Member State of affiliation.

Amendment 67

Proposal for a directive
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) A national of a Member State may be affiliated to a health insurance scheme of a Member State other than that of residence, by paying contributions to that scheme.

Justification

Supporting the interests of citizens who are in a Member State other than that of residence means allowing them access to a health scheme of a Member State other than that of residence.

Amendment 68

Proposal for a directive
Article 6 – paragraph 2 and paragraph 2a

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	2. The costs of healthcare provided in another Member State shall be reimbursed ***or paid directly*** by the Member State of affiliation in accordance with the

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.

provisions of this Directive up to the level of costs that would have been assumed ***in respect of the same medical condition under the same conditions as laid down in paragraph 1*** 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 and accommodation and travel costs.***

2a. The extra costs which persons with disabilities might incur when receiving healthcare in another Member State due to one or more disabilities shall be reimbursed by the Member State of affiliation in accordance with national legislation and on the condition that sufficient documentation setting out these costs exists.

Amendment 69

Proposal for a directive
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and ***reimbursement of*** healthcare costs as it would impose if the ***same or similar*** healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of ***persons***.	3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities***, whether set at a local, national or regional level,*** for receiving healthcare and ***assumption*** of healthcare costs as it would impose if ***that*** healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of ***patients and goods, such as pharmaceuticals and medical devices, and are known in advance. This may include a requirement that the insured person is assessed for the purposes of applying those conditions, criteria or formalities by a health professional or healthcare administrators***

	providing services for the statutory social security system of the Member State of affiliation, where such an assessment would also be required for accessing health services in the Member State of affiliation.

Amendment 70

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be ***reimbursed to the insured person*** by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had ***the same or similar*** healthcare been provided in the territory of the Member State of affiliation.	4. ***For the purposes of this Article,*** Member States shall have a ***transparent*** mechanism for the calculation of costs that are to be ***assumed*** by the statutory social security system ***or other statutory public system*** for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had ***that*** healthcare been provided in the territory of the Member State of affiliation. ***The mechanism shall be applied at the relevant administrative level in cases where the Member State of affiliation has a decentralised healthcare system***.

Amendment 71

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Patients ***travelling to another Member State with the purpose of*** receiving healthcare ***there*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with	5. Patients receiving healthcare ***in a Member State other than their Member State of affiliation*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with

national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC. ***If the medical records are held in electronic form, patients shall have a guaranteed right to obtain a copy of these records or a right of remote access to these records. Data shall be transmitted only with the express consent in writing of the patient or the patient's relatives.***

Justification

Part of the amendment incorporated in the report without vote, on the basis of Rule 47.

Amendment 72

Proposal for a directive
Article 6 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The provisions of this Chapter shall not affect the conclusion of cross-border contractual arrangements for planned healthcare.

Justification

It is important to clarify that these provisions do not prevent the conclusions of cross-border contractual arrangements for planned healthcare. In the case of such contractual arrangements, contracting parties would follow the rules of the social security coordination or apply specific rules and tariffs established through negotiation between the contractual parties.

Amendment 73

Proposal for a directive
Article 7

Text proposed by the Commission	*Amendment*
The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would	The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State ***or the purchase of goods connected with healthcare which are purchased in another Member State***

have been paid for by its social security system.	subject to prior authorisation, where the cost of that care, if it had been provided in its territory, ***or of those goods, if they had been purchased in its territory,*** would have been paid for by its social security system.

Justification

The purchase of goods connected with health care (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments.

Amendment 74

Proposal for a directive
Article 8 – title

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

Amendment 75

Proposal for a directive
Article 8 – paragraphs 1 and 2

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, ***the definition of*** hospital care***, as established by the Member State of affiliation,*** shall ***be limited to***:
(a) healthcare which requires overnight accommodation of the patient in question for at least one night***.***	(a) healthcare which requires overnight accommodation of the patient in question for at least one night***; 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 ***which is highly specialised and/or requires use of cost-intensive medical infrastructure or medical equipment; or***
- healthcare that requires use of highly	***(ba)*** healthcare involving treatments

specialised and cost-intensive medical infrastructure or medical equipment; or

- healthcare involving treatments presenting a particular risk for the patient or the population.

presenting a particular risk for the patient or the population.

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).

Amendment 76

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:	3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:
(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and	(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and
(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine***:***	***(b) the absence of prior authorisation could*** seriously undermine ***or be likely to undermine:***
(i) the financial balance of the Member State's social security system; and/or	(i) the financial balance of the Member State's social security system; and/or
(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or	(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or

the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.	the maintenance of treatment capacity or medical competence on the territory of the concerned Member State. ***Such a system shall be without prejudice to Regulation (EEC) No 1408/71 and, as from its date of application, Regulation (EC) No 883/2004.***

Amendment 77

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***, shall be based on clear and transparent criteria***, and shall not constitute a means of arbitrary discrimination ***or an obstacle to freedom of movement of patients.***

Amendment 78

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that the patient is expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in the health system of their Member State of affiliation. Member States should seek to transfer funds directly between the funders and the providers of care for any other costs.

Justification

Incorporated in the report without vote, on the basis of Rule 47.

Amendment 79

Proposal for a directive
Article 8 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

Justification

Incorporated in the report without vote, on the basis of Rule 47.

Amendment 80

Proposal for a directive
Article 8 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Justification

Incorporated in the report without vote, on the basis of Rule 47. With the purpose of making the right of cross boarder health care a right for everyone, and in order to give patients the possibility to know for sure whether they will be reimbursed or not, it is important to give patients the right to apply for a prior authorisation in the Member State of affiliation. A system without this right to apply for prior authorisation would lead to great economical uncertainty for the patients. This uncertainty would make the right to cross boarder health care less attractive for those with a low income and thus not equally available to all.

Amendment 81

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***.

Amendment 82

Proposal for a directive
Article 8 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. With regard to any request for authorisation made by an insured person with a view to receiving healthcare in another Member State, the Member State of affiliation shall ascertain whether the conditions laid down in Regulation (EC) No 883/2004 have been met, and, if so, shall grant prior authorisation pursuant to that Regulation.

Justification

New paragraph 5, in line with the amendment deleting paragraph 2 of this article. The proposal for a directive conflicts with the existing regulation on the coordination of social security systems. The overlapping of directive and regulations has the effect of creating two parallel systems for cross-border healthcare, of which patients could choose one or the other. The proposal thus generates legal uncertainty.

Amendment 83

Proposal for a directive
Article 8 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5b. Patients with rare diseases shall not be

subject to prior authorisation.

Justification

In a context of global scarcity of knowledge and expertise at national level, patients affected by rare diseases, both diagnosed and undiagnosed, should be recognised the right to choose where to purchase healthcare, without prior authorisation. They also should be recognised the right for their care, often expensive, to be fully paid directly by the country of origin to the country of provision of care (without having to pay up-front), even and especially when the care they need does not exist in their country of affiliation, as this is often the reason for which they need to go abroad".

Amendment 84

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within time limits set out and made public in advance by the Member States.	2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within ***reasonable*** time limits set out and made public in advance by the Member States.

Amendment 85

Proposal for a directive
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation referred to in Article 8(3).	***deleted***

Amendment 86

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

Text proposed by the Commission	*Amendment*
	3a. Member States of affiliation shall ensure that patients who have received prior authorisation for the use of healthcare abroad will only be required to make upfront or top-up payments to the healthcare systems and/or providers in the Member State of treatment, to the extent that such payments would be required in the Member State of affiliation itself.

Justification

Member States have the obligation to facilitate patient mobility in those cases where this is appropriate and to ensure equal access to healthcare abroad. They therefore also have to take away any practical barriers for patients to use healthcare abroad, such as the need to make upfront or top-up payments to the healthcare systems or providers in the Member State of treatment.

Amendment 87

Proposal for a directive
Article 9 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:	4. Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with ***and, when considering these requests***, take into account:
(a) the specific medical condition,	(a) the specific medical condition,
	(aa) individual circumstances,
(b) the patient's degree of pain,	(b) the patient's degree of pain,
(c) the nature of the patient's disability, and	(c) the nature of the patient's disability, and
(d) the patient's ability to carry out a professional activity.	(d) the patient's ability to carry out a professional activity.

Amendment 88

Proposal for a directive
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Prior authorisation application systems shall be made available at the level appropriate for the administration of the Member State's health service and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

Justification

It is important to guarantee the accessibility of prior authorisation application systems.

Amendment 89

Proposal for a directive
Article 9 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ensure that any administrative decisions regarding the use of healthcare in another Member State are subject to administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.	5. Member States shall ensure that any administrative ***or medical*** decisions regarding the use of healthcare in another Member State are subject***, on a case-by-case basis, to a medical opinion or an*** administrative review and also capable of being challenged in judicial proceedings, which include provision for interim measures.

Amendment 90

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.

Amendment 91

Proposal for a directive
Article 9 a (new)

Text proposed by the Commission	*Amendment*
	Article 9a
	Prior notification
	Member States may offer patients a voluntary system of prior notification whereby, in return for such notification, the patient shall receive a written confirmation of the maximum amount that will be paid. That written confirmation can then be taken to the hospital of treatment and reimbursement would then be made directly to that hospital by the Member State of affiliation.

Amendment 92

Proposal for a directive
Article 9 b (new)

Text proposed by the Commission	*Amendment*
	Article 9b
	European Patients Ombudsman
	The Commission shall present a legislative proposal to establish a European Patients Ombudsman within 18 months after the entry into force of this

Directive. The European Patients Ombudsman shall consider, and if appropriate, mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. The European Patients Ombudsman shall only be engaged once all the complaint options within the relevant Member State have been exhausted.

Amendment 93

Proposal for a directive
Article 10 – paragraphs 1 and 2

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 State.	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 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,*** and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State. ***This information shall be published in formats accessible to persons with disabilities. Member States shall consult stakeholders, including patients' organisations, to ensure information is clear and accessible. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from regulations on coordination of social security schemes as referred to in Article 3(1)(f).***
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.

Amendment 94

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

Text proposed by the Commission	*Amendment*
	2a. In addition to the information outlined in paragraph 1, information on health professionals and healthcare providers shall be made easily available via electronic means by the Member State in which the health professionals and healthcare providers are registered, and shall include the name, registration number and practice address of the healthcare professional, and any restrictions on their practice;

Justification

In the interests of patients availing of cross-border services, there is also a need for greater transparency of health professional and health service regulation. Public registers of health professionals and health service providers should be available in Member states so that patients can easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of the health professionals providing care. The international evidence illustrates that the most practical way for patients to have access to information on their current or prospective healthcare providers is via the publication of public registers of such practitioners. Such registers should now be available via the Internet and should allow the patient to access the relevant data by searching either via the name or via the registration number of the healthcare provider (or indeed by searching via geographical area). The relevant data that should be in the public domain should be, at a minimum, the name, registration number and practice address of the healthcare professional, the date of their first registration on that register, the expiry date of their current registration, and any conditions or restrictions on their practice or suspensions should this be the case. Healthcare professionals, who are not registered, be it for voluntary reasons or if struck off for whatever reason, should not appear on such register.

Amendment 95

Proposal for a directive
Article 10 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission may, in accordance with the procedure referred to in Article 19(2), develop a standard Community format for the prior information referred to in paragraph 1.	***deleted***

Justification

Information on cross-border healthcare should take into account the differences in the way healthcare systems are managed and organised in different Member States. A standard community format may therefore be counterproductive.

Amendment 96

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. 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 service is provided according to the legislation of the Member State of treatment in accordance with Art.5.	1. When healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare service is provided according to the legislation of the Member State of treatment in accordance with Art.5.

Justification

The proposed Directive is supposed to cover only cross-border cooperation and cases of patient mobility, i.e. the use of healthcare abroad by individual patients; the reference to other modes of supply of healthcare should therefore be deleted.

Amendment 97

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that patient organisations, sickness funds and healthcare providers are encompassed by national contact points.*** ***The national contact points should be established in an efficient and transparent way.***
	Information about the existence of the national contact points shall be disseminated across Member States, so that patients have easy access to the information.

Amendment 98

Proposal for a directive
Article 12 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The national contact points for cross-border health care may also be incorporated into existing information centres in the Member States.

Justification

Recital 36 of the preamble clearly states that national contact points may be incorporated into existing structures in the Member States, and this should be clearly expressed in the provisions of the directive. This will make it possible to avoid placing additional administrative burdens on the Member States in connection with the implementation of the directive.

Amendment 99

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The national contact point in the Member State of affiliation shall, ***in close cooperation with other competent national authorities, and with national contact points in other Member States, in particular in the Member State of treatment, and with the Commission***:	2. The national contact point in the Member State of affiliation shall provide and disseminate information to patients ***and health professionals, on a website if appropriate, on receiving healthcare in another Member State, and on the terms and conditions which apply***, in particular on ***patients'*** rights related to cross-border healthcare ***as laid down in Article 6***. ***The national contact point shall help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State;***
(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***;	
(b) ***help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State; the national contact point*** shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case ***and help patients to monitor their dispute where necessary;***	***2a. The national contact point in the Member State of treatment shall provide and disseminate information to patients, on a website if appropriate, on issues referred to in Article 5(1)(ba) and on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities, procedures for complaints and means of redress available for healthcare received in the Member State of treatment. It*** shall in particular inform patients ***and health professionals, where necessary,*** about ***the means by which professionals and providers are regulated and the means by which regulatory action can be taken,*** the options available to settle any dispute, ***and*** help to

identify the appropriate out-of-court settlement scheme for the specific case.

(c) gather detailed information on national bodies operating out-of-court settlement of disputes and facilitate co-operation with those bodies;

(d) facilitate the development of international out-of-court settlement scheme for disputes arising from cross-border healthcare;

2b. The national contact point in a Member State shall cooperate closely with other competent authorities, with national contact points in other Member States, with patients' organisations and with the Commission.

2c. The national contact points shall provide the information referred to in paragraphs 2 and 2a in formats easily accessible for people with disabilities.

Amendment 100

Proposal for a directive
Article 13

Text proposed by the Commission	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.	1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.	2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.
	2a. Member States, particularly neighbouring countries, may conclude agreements with one another concerning the continuation or potential further development of cooperation arrangements.

2b. Member States shall guarantee that registers in which health professionals are listed can be consulted by relevant authorities of other Member States.
2c. Member States shall exchange information about disciplinary and criminal findings against health professionals.

Amendment 101

Proposal for a directive
Article 14

Text proposed by the Commission	*Amendment*
1. If a medicinal product is authorised to be marketed on their territory in accordance with Article 6(1) of Directive 2001/83/EC, Member States shall ensure that prescriptions issued by an authorised person in another Member State for a named patient can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:	1. If a medicinal product is authorised to be marketed on their territory in accordance with Article 6(1) of Directive 2001/83/EC, Member States shall ensure that prescriptions issued by an authorised person in another Member State for a named patient ***in respect of that medicinal product*** can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:
(a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory or	(a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory or
(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription.	(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription, ***or the status of the prescriber.***
	The recognition of such prescription shall not affect:
	(i) national rules governing prescribing and dispensing, including generic substitution;
	(ii) national rules governing the reimbursement of Community cross-border prescriptions;
	(iii) any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued

	in the Member State of affiliation.
2. For facilitating the implementation of paragraph 1, the Commission shall adopt:	2. For facilitating the implementation of paragraph 1, the Commission shall adopt:
(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;	(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;
(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;***
	(ba) measures to ensure, if needed, contact between the prescribing party and the dispensing party in order to ensure complete understanding of the treatment, whilst maintaining confidentiality of patient's data;
(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.	
	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 as effective.
3. The measures referred to in points (a) ***and*** (b) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 19(2). ***The measures referred to in point (c) of paragraph 2, designed to amend non-essential elements of this Directive, by supplementing it,***	3. The measures referred to in points (a)***,*** (b), ***and (ba)*** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 19(2).

shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).

Amendment 102

Proposal for a directive
Article 15 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall facilitate the development of the European reference networks of healthcare providers. Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.	1. Member States shall facilitate the development of the European reference networks of healthcare providers***,, in particular in the area of rare diseases, which shall draw on the health cooperation experience acquired within the European groupings of territorial cooperation (EGTCs)***. Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.

Justification

EGTCs are a recent innovation, recognised at Community level in Regulation (EC) No 1082/2006 of the European Parliament and of the Council of 5 July 2006, and an important reference point for macro-scale regional activities.

Amendment 103

Proposal for a directive
Article 15 - paragraph 2 - point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) contribute to the pooling of knowledge regarding sickness prevention and the treatment of major commonly occurring disorders;

Justification

Cooperation within European reference networks must not be limited to rare disorders.

Amendment 104

Proposal for a directive
Article 15 - paragraph 2 - point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) to implement instruments which enable the best possible use to be made of existing healthcare resources in the event of serious accidents, particularly in cross border areas.

Justification

The European reference networks must cater for serious accidents requiring emergency medical care.

Amendment 105

Proposition de directive
Article 15 - paragraph 3 - introductory part

Text proposed by the Commission	*Amendment*
3. The Commission shall adopt:	3. The Commission***, in collaboration with relevant experts and stakeholders,*** shall adopt:

Justification

In the setting up of European reference networks, consultation with stakeholders will be essential in order to develop a sound and appropriate list of criteria to ensure their functioning.

Amendment 106

Proposition de directive
Article 15 - paragraph 3 - point a - introductory part

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	(a) a list of specific criteria and conditions that the European reference networks must fulfil, including ***also a list of rarer disease***

required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks:	***areas to be covered and*** 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:

Amendment 107

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.

Amendment 108

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Trial areas
	The Commission, in cooperation with the Member States, may designate border regions as trial areas in which innovative cross-border healthcare initiatives can be tested, analysed and evaluated.

Amendment 109

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), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field,	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.	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.

Amendment 110

Proposal for a directive
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Member States shall ensure that the use of e-Health and other telemedicine services:
	(a) adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision;
	(b) offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for practitioners similar to those in use for non-electronic healthcare provision.

Justification

This new technology provides not only progress but could also lead to potential misuse of information and communication technologies in healthcare, with associated potential risks to patients. Therefore, the same level of guarantee, in terms of quality and safety, must be applied to these services as compared to "standard" medical acts.

Amendment 111

Proposal for a directive
Article 17

Text proposed by the Commission	*Amendment*
Cooperation on management of new health technologies	Cooperation on management of new health technologies
1. ***Member States shall facilitate development and functioning of a network*** connecting the national authorities or bodies responsible for health technology assessment.	1. ***The Commission shall, in consultation with the European Parliament, facilitate the establishment of a network*** connecting the national authorities or bodies responsible for health technology assessment. ***This network shall be based on the principles of good governance including transparency, objectiveness, fairness of procedures, and broad and full stakeholder participation of all relevant groups, except in cases where national law precludes the participation of one or more of those groups.***
2. The objective of the health technology assessment network shall be:	2. The objective of the health technology assessment network shall be:
(a) to support cooperation between national authorities or bodies;	(a) to support cooperation between national authorities or bodies;
	(aa) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets;
(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.	(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.
	(ba) to analyse the nature and type of information that can be exchanged;
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.	3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.
4. The Commission shall, in accordance	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.***	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.

Amendment 112

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect statistical ***and other additional*** data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.	1. Member States shall collect statistical data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data***, and specifically Article 8(4) of Directive 95/46/EC***.

Justification

Article 8(4) of Directive 95/46 lays down specific requirements relating to subsequent use of health data.

Amendment 113

Proposal for a directive
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.	1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative. ***In doing so, the Commission shall ensure the consultation of experts from the relevant patient and professional groups in an appropriate manner especially in the***

context of the implementation of this Directive and shall provide a reasoned report on these consultations.

Justification

The implementation of this directive can only be achieved through the involvement of all relevant parties. Therefore, an appropriate mechanism of consultation should be set up in order to assist this "cross-border healthcare committee".

Amendment 114

Proposal for a directive
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.	2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months. ***Where implementing measures relate to the processing of personal data the European Data Protection Supervisor may be consulted.***

Justification

As recommended in the EDPS opinion, it is important the EDPS is consulted on these matters.

Amendment 115

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.

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 a system of voluntary prior notification, followed by a written confirmation of the maximum amount that will be paid. That written confirmation could then be taken to the hospital of treatment and reimbursement would then be made directly to that hospital by the Member State of affiliation..

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.

OPINION FROM THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

13.2.2009

Mr Miroslav Ouzký
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: 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).

Dear Mr Chair,

By letter of 29 January 2009, the Chair of the Committee on the Environment, Public Health and Food Safety has consulted the committee pursuant to Rule 35 of the Rules of Procedure on the legal basis for the above-mentioned proposal.

The committee considered the above question at its meeting of 12 February 2009.

Amendments have been tabled in the Environment Committee to change the legal basis from Article 95 of the EC Treaty to Article 152; Articles 16 and 152; Articles 42, 152 and 308; Articles 137 and 152, or Articles 95 and 152.

This question may be analysed as follows, starting from the principles set out in the case-law of the Court of Justice.

As we know, every Community legislative act has to have a legal basis specifying the competences conferred on the Community and indicating the type of act that may be adopted and the procedure to be followed for its adoption.

In opinion No 2/00 of 6 December 2001[1] on the choice of legal basis for the conclusion of an international agreement (specifically, the Cartagna Protocol), the Court of Justice put the matter clearly as follows:

"*The choice of the appropriate legal basis has constitutional significance. Since the Community has conferred powers only, it must tie the Protocol to a Treaty provision which empowers it to approve such a measure. To proceed on an incorrect legal basis is therefore*

[1][2001] ECR.I-9713.
Online: http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&newform=newform&jurcdj=jurcdj&docav=docav&alldocnorec=alldocnorec&docnoj=docnoj&docnoor=docnoor&typeord=ALL&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&numaff=2%2F00&ddatefs=&mdatefs=&ydatefs=&ddatefe=&mdatefe=&ydatefe=&nomusuel=&domaine=&mots=&resmax=100&Submit=Submit

liable to invalidate the act concluding the agreement and so vitiate the Community's consent to be bound by the agreement it has signed. That is so in particular where the Treaty does not confer on the Community sufficient competence to ratify the agreement in its entirety, a situation which entails examining the allocation as between the Community and the Member States of the powers to conclude the agreement that is envisaged with non-member countries, or where the appropriate legal basis for the measure concluding the agreement lays down a legislative procedure different from that which has in fact been followed by the Community institutions." (emphasis supplied)

On the one hand, the Court points to the "constitutional significance" of the choice of legal basis given that the Community is not a legal order with general ends, but is governed by the principle of conferral of powers. On the other hand, the Court is at pains to point to the problem where there is no legal basis capable of covering the Community action (where there is not "sufficient competence") or where changing the legal basis results in a change in the procedure for adoption. An eloquent example can be found in the Opinion of Advocate General Jacobs of 15 November 2001 in Case C-314/99 *Netherlands* v. *Commission*[1], where the change in the legal basis would have meant that the act would have had to have been adopted using a different procedure than the one by which it was actually adopted.

In that case, as Parliament's Legal Service also pointed out in the *British American Tobacco* case[2], an error as to the legal basis is more than a purely formal defect when it gives rise to irregularity in the procedure applicable to the adoption of the act and can result in its annulment, since it partakes of its substance, causing it to be unlawful.

According to the Court of Justice the choice of legal basis is not a subjective one, but "must be based on objective factors which are amenable to judicial review"[3], such as the aim and content of the measure in question[4]. Furthermore, the decisive factor should be the main object of a measure.[5]

According to the case-law of the Court of Justice, a general Treaty article constitutes a sufficient legal basis even though the measure in question also seeks, in a subordinate manner, to attain an aim sought by a specific Treaty article[6].

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[1] [2002] ECR I-05521.
online: http://eur-lex.europa.eu/Notice.do?val=353903:cs&lang=it&list=449394:cs,335881:cs,250906:cs,353903:cs,250621:cs,250591:cs,250603:cs,242077:cs,242014:cs,234659:cs,&pos=4&page=1&nbl=26&pgs=10&hwords=base%20giuridica~&checktexte=checkbox&visu=#texte

[2] Case C-491/2001 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd* [2002] ECR I-11453.
Online:
http://eur-lex.europa.eu/Notice.do?val=264374:cs&lang=it&list=405672:cs,287495:cs,264374:cs,132861:cs,&pos=3&page=1&nbl=4&pgs=10&hwords=british%20american%20tobacco~&checktexte=checkbox&visu=#texte

[3] Case 45/86, *Commission* v. *Council* [1987] ECR 1439, para. 5.

[4] Case C-300/89, Commission v. *Council* [1991] ECR I-287, para. 10.

[5] Case C-377/98, *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.

[6] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, paras 27-28; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paras 93-94.

However, if the view were to be taken that the two aims are indissolubly linked with each other without one being secondary and indirect in respect of the others, it might be considered that two legal bases would have to be used[1].

The long and short of all this is that the Court's preference is for a single legal basis, except where a given instrument has two equal-ranking aims.

In this case, the legal basis chosen by the Commission is Article 95 of the EC Treaty[2].

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[1] Case C-165/87 *Commission* v. *Council* [1988] ECR 5545, para. 11.

[2] *Article 95*

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior

The Commission justifies its choice of legal basis in a detailed discussion of the general legal aspects of the proposal. It sets out to establish a general legislative framework for cross-border healthcare consisting of (a) principles common for all the healthcare systems in the EU, (2) a specific framework for cross-border healthcare, and (3) forms of European cooperation on healthcare. In the final analysis, the objective is "*to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the European Union and to ensure free movement of health services and a high level of health protection, whilst fully respecting the responsibilities of the Member States for the organisation and delivery of health services and medical care*".

Various amendments have been moved to the legal basis. It now falls to consider them.

First and foremost, it is necessary to consider Article 152, which has been proposed either alone or in conjunction with other articles.

(a) Article 152[1] as the sole legal basis:

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harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure. (emphasis supplied)

[1] Article 152 reads as follows:

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

Although this article deals with public health, the scope of the measures which may be adopted in reliance on it is limited. Whilst paragraph 1 gives the Community competence to take action "*towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health"*, this competence is clearly stated to be complementary to national policies. It is further qualified in the following terms: "*Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention."* Article 152(2) refers to cooperation between the Member States in these areas, supporting their action and coordination of national policies and programmes, whilst Article 152(3) deals with fostering cooperation with third countries and the competent international organisations in the sphere of public health.

The sole legislative competence entailing the codecision procedure is that provided for in Article 152(4), which provides that, in order to contribute to the achievement of the objectives to which we have referred, measures can be adopted *setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives together with measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health and incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.* It is further noted that the Council may adopt recommendations.

Typical measures adopted in recent years using the legal basis of Article 152 include laying down health rules as regards animal by-products not intended for human consumption (COD/2008/0110); placing on the market and use of (animal) feed (COD/2008/0050); laying down a prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta agonists (COD/2007/012), and laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (COD/2007/0064), to name just a few typical examples.

The aim of the proposed directive on patients' rights has to do with establishing a general legislative framework for cross-border healthcare and has little or nothing to do with

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(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

improving public health, preventing human illness and diseases, and obviating sources of danger to human health, being concerned with how cross-border healthcare should be organised and operate. Article 152 is therefore out of the question as the sole legal basis. The incompatibility of the objects of the proposed directive with Article 152 is further underscored by the fact that that article goes out of its way to exclude any harmonisation of the laws and regulations of the Member States when it comes to incentive measures designed to protect and improve human health, the only aspect of Article 152 which has a link, albeit an extremely tenuous one with the object of the Commission's proposal.

The question arises as to whether the adoption of amendments in the Environment Committee would be such as the change the centre of gravity of the proposed directive to such an extent as to warrant a change in the legal basis to Article 152 alone. Although it cannot be predicted which of the over 700 amendments tabled in that committee will be adopted, it is not considered that any of them would have that effect.

Article 152 can therefore be ruled out as the sole legal basis.

(b) Combined legal bases

Article 95 with Article 152

Since only a tenuous link if any has been found between the proposal for a directive and the legislative competence conferred by Article 152 (action "*towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health"*), it cannot be said that the proposed instrument has two aims that are indissolubly linked with each other without one being secondary and indirect in respect of the others. It has to be underlined, however, that this analysis is based on the Commission's proposal. Further analysis of the legal basis could be necessary if amendments adopted in the vote in committee substantially altered the aim and content of the proposal.

It is therefore considered that the combined legal basis of Article 95 with Article 152 can be ruled out.

Article 152 with Article 16[1]

Article 16 does not found any competence. It is merely declaratory and interpretative. If, therefore - as has already been argued - Article 152 cannot serve as the legal basis alone, adding Article 16 will not save it.

[1] Article 16 of the EC Treaty reads as follows:

Article 16
Without prejudice to Articles 73, 86 and 87, and given the place occupied by services of general economic interest in the shared values of the Union as well as their role in promoting social and territorial cohesion, the Community and the Member States, each within their respective powers and within the scope of application of this Treaty, shall take care that such services operate on the basis of principles and conditions which enable them to fulfil their missions.

The combined legal basis of Article 152 with Article 16 can therefore be ruled out.

Articles 42, 152 and 308

As far as Article 42[1] is concerned, it is trite case-law that the choice of legal basis must be determined by objective factors which can be subject to judicial review[2], such as the aim and content of the measure in question[3]. Furthermore, the decisive factor should be the main object of a measure[4].

It is evident that the centre of gravity of the proposal is not social security for migrant workers and the explanatory memorandum is absolutely clear that the mechanism provided for therein is alternative to the machinery provided for migrant workers in Regulation No 1408/71[5]. Patients receiving cross-border healthcare under the proposed directive will be reimbursed by their national health schemes, paying any difference themselves. Whilst migrant workers may benefit from the system to be set up by the directive, it is not aimed at them, but is more general in scope ("patient" is defined in Article 4(f)) as "any natural person who receives or wishes to receive healthcare in a Member State").

Article 152, as has been shown, does not come into consideration as a legal basis.

As for Article 308[6], the Court of Justice has stated that Article 308 of the EC Treaty is an appropriate legal basis only where no other article of the Treaty gives the Community its necessary powers[7]. Thus, before choosing this provision as a legal basis, the Community legislator must establish that there are no other Treaty provisions conferring the necessary powers for the proposed measure. This is patently not the case here. Moreover, it would seem difficult to postulate a situation in which Article 308 could be used as a legal basis together with other articles of the Treaty.

Lastly, it should be observed that the three legal bases (Arts 42, 152 and 308) are incompatible since they provide for mutually incompatible procedures and voting majorities in the Council.

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[1] *Article 42*
The Council shall, acting in accordance with the procedure referred to in Article 251, adopt such measures in the field of social security as are necessary to provide freedom of movement for workers; to this end, it shall make arrangements to secure for migrant workers and their dependants:
(a) aggregation, for the purpose of acquiring and retaining the right to benefit and of calculating the amount of benefit, of all periods taken into account under the laws of the several countries;
(b) payment of benefits to persons resident in the territories of Member States.
The Council shall act unanimously throughout the procedure referred to in Article 251.

[2] Case 45/86, *Commission* v. *Council* [1987] ECR 1439, para. 5.

[3] Case C-300/89, *Commission* v. *Council* [1991] ECR I-287, para. 10, and Case C-42/97, *European Parliament* v. *Council* [1999] ECR I-869, para. 36.

[4] Case C-377/98, *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.

[5] OL 149, 05.07.1971.

[6] *Article 308*
If action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community, and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament, take the appropriate measures.

[7] Case C-45/86, *Commission* v. *Council* [1987] ECR 1493, para. 13.

The idea of a combined legal basis consisting of Articles 42, 152 and 308 must therefore be rejected.

Articles 137 and 152

Article 137[1] has to be read in conjunction with Article 136, which reads as follows:

"The Community and the Member States, having in mind fundamental social rights such as

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[1] *Article 137*
1. With a view to achieving the objectives of Article 136, the Community shall support and complement the activities of the Member States in the following fields:

(a) improvement in particular of the working environment to protect workers' health and safety;
(b) working conditions;
(c) social security and social protection of workers;
(d) protection of workers where their employment contract is terminated;
(e) the information and consultation of workers;
(f) representation and collective defence of the interests of workers and employers, including codetermination, subject to paragraph 5;
(g) conditions of employment for third-country nationals legally residing in Community territory;
(h) the integration of persons excluded from the labour market, without prejudice to Article 150;
(i) equality between men and women with regard to labour market opportunities and treatment at work;
(j) the combating of social exclusion;
(k) the modernisation of social protection systems without prejudice to point (c).

2. To this end, the Council:
(a) may adopt measures designed to encourage cooperation between Member States through initiatives aimed at improving knowledge, developing exchanges of information and best practices, promoting innovative approaches and evaluating experiences, excluding any harmonisation of the laws and regulations of the Member States;
(b) may adopt, in the fields referred to in paragraph 1(a) to (i), by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.
The Council shall act in accordance with the procedure referred to in Article 251 after consulting the Economic and Social Committee and the Committee of the Regions, except in the fields referred to in paragraph 1(c), (d), (f) and (g) of this Article, where the Council shall act unanimously on a proposal from the Commission, after consulting the European Parliament and the said Committees. The Council, acting unanimously on a proposal from the Commission, after consulting the European Parliament, may decide to render the procedure referred to in Article 251 applicable to paragraph 1(d), (f) and (g) of this Article.

3. A Member State may entrust management and labour, at their joint request, with the implementation of directives adopted pursuant to paragraph 2.
In this case, it shall ensure that, no later than the date on which a directive must be transposed in accordance with Article 249, management and labour have introduced the necessary measures by agreement, the Member State concerned being required to take any necessary measure enabling it at any time to be in a position to guarantee the results imposed by that directive.
4. The provisions adopted pursuant to this Article:
— shall not affect the right of Member States to define the fundamental principles of their social security systems and must not significantly affect the financial equilibrium thereof,
— shall not prevent any Member State from maintaining or introducing more stringent protective measures compatible with this Treaty.

5. The provisions of this Article shall not apply to pay, the right of association, the right to strike or the right to impose lock-outs.

those set out in the European Social Charter signed at Turin on 18 October 1961 and in the 1989 Community Charter of the Fundamental Social Rights of Workers, shall have as their objectives the promotion of employment, improved living and working conditions, so as to make possible their harmonisation while the improvement is being maintained, proper social protection, dialogue between management and labour, the development of human resources with a view to lasting high employment and the combating of exclusion.
To this end the Community and the Member States shall implement measures which take account of the diverse forms of national practices, in particular in the field of contractual relations, and the need to maintain the competitiveness of the Community economy.
They believe that such a development will ensue not only from the functioning of the common market, which will favour the harmonisation of social systems, but also from the procedures provided for in this Treaty and from the approximation of provisions laid down by law, regulation or administrative action.

In view of the fact that the proposed directive is concerned with “patients’ rights” and patients need not be workers ("patient" is defined as "any natural person who receives or wishes to receive healthcare in a Member State" in Article 4(f) of the proposal for a directive) and bearing in mind that, according to the preamble, the proposed directive is to cover “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'; – 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)”, it does not fall within the scope of Article 136, which is concerned with the promotion of employment, and improved living and working conditions, so as to make possible their harmonisation while the improvement is being maintained, proper social protection, dialogue between management and labour, the development of human resources with a view to lasting high employment and the combating of exclusion.

Given that Article 152 has already been rejected as the legal basis, it cannot be used in conjunction with Article 137, which is itself not suitable as a legal basis for the proposal for a directive.

Conclusion

The sole legal basis possible is Article 95 alone. It has to be underlined, however, that this analysis is based on the Commission's proposal. Further analysis of the legal basis could be necessary if amendments adopted in the vote in committee substantially altered the aim and content of the proposal.

At its meeting of 12 February 2009 the Committee on Legal Affairs accordingly decided, by 8 votes in favour, 5 votes against, with 1 abstention[1], to recommend that the proposal for a directive should be based on Article 95 of the EC Treaty.

Yours sincerely,

Giuseppe Gargani

[1] The following were present for the final vote: Alin Lucian Antochi (acting Chair), Rainer Wieland (Vice-Chair), Lidia Joanna Geringer de Oedenberg (Vice-Chair), Francesco Enrico Speroni (Vice-Chair), Monica Frassoni (rapporteur), Sharon Bowles, Brian Crowley, Kurt Lechner, Klaus-Heiner Lehne, Alain Lipietz, Manuel Medina Ortega, Georgios Papastamkos, Aloyzas Sakalas, Jaroslav Zvěřina.

4.3.2009

OPINION OF THE COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS (*)

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur (*): Iles Braghetto

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

SHORT JUSTIFICATION

Based on Article 95 of the Treaty the directive proposes to establish a Community framework for cross-border healthcare, including legal definitions and general provisions. The directive also describes the coherence with other Community policies. The proposed directive applies to the provision of healthcare, regardless of how it is organised, delivered or financed.

Generally the EMPL Committee supports the aim of the proposed directive. It stresses that, for citizens to be able to make a deliberate choice, it is of the utmost importance to ensure clear information and a transparent framework for the provision of cross-border healthcare within the EU. Furthermore, the provided care should be safe and of good quality.
Given that patients have to pay themselves for the treatment upfront, the procedures for reimbursement of costs should be clear and transparent.

The EMPL Committee has, given its tasks, paid specific attention to the following points:

Regulations for coordination of social security schemes

The aim of the directive is not to modify the existing framework for coordination of social security schemes and this framework will remain in place with all the general principles on which the regulations on coordination of social security schemes are based. The EMPL Committee supports this, but finds it strange that for the reimbursement of the costs, compared to the rules in the regulation on the coordination, separate rules are proposed. The main cause of concern is that a new administrative system will be needed, thus leading to an unnecessary and unwanted raise in ´red tape´ and unclear rules. Therefore the EMPL Committee proposes to apply the same rules for the reimbursement of the cost as put down in

the regulation.

Framework for mutual recognition of professional qualifications

The proposal would also apply without prejudice to the existing framework for mutual recognition of professional qualifications established by the Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. This fully supported by the EMPL Committee.

Racial equality

The EMPL Committee stresses that equal access for all should be one of the main targets of this directive.

Information

The opinion stresses the general importance of giving useful and clear information to the patients with regard to the quality of the care (including information regarding the hospitals). The importance of knowing what are the specialisations and results of the healthcare providers is also stressed; this in order to be able to make a deliberate choice on which hospital would be the best for a specific patient and to be able to establish a list of centres of excellence within Europe.

Evaluation

With regard to the data collection, monitoring (article 18) it is stresses that the collection of the data should help in assessing if the Directive accomplishes the aim of improving the quality of the healthcare in general and more specific if it supports the principle of access for all. Within the reports mentioned in (article 20) this should be one of the focus points.

Definitions

Both definition of ´healthcare´ and ´health care professional´ are not clear and lead to contradictions and/or ambiguity. Therefore the definition of ´benefits in kind´ has been introduced, in conformity with Regulation 883/04.

With respect to the definitions the EMPL Committee calls, in the recitals, on the Commission and Member States to consider the recognition of the positive impact of thermal cures on the convalescence and on preserving people's health.

Also in the recitals attention has been paid to the equal access to ´European Centres of Reference´.

General remarks

- The fundamental role played by health care services and general social services in the European social model. Therefore it calls on the Commission and Member States to recognise that role when applying internal market and competition law; emphasises the

inadequate funding of those services, especially in certain eastern European Member States.

- The liberalisation of health services which could lead to greater inequality of access to high-quality health care.
- The development of a high quality, community-based health care in cooperation with users and patients, which can play an important role in the fight against poverty and social exclusion;
- Inequalities in health outcomes, both between and within Member States, which remain wide and urges Member States to tackle them, notably by ensuring effective access to healthcare for all.

AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The Commission's Communication of 26 February 2007 on Social Reality Stocktaking - Interim report to the 2007 Spring European Council[1] observed that although the Member States are among the wealthiest countries in the world, new patterns of poverty and inequality affecting people's health are emerging, such as the rise in obesity and mental health problems.
	[1] COM(2007)0063.

Justification

Stresses that community-based health and social care can play an important role in the fight against poverty and social exclusion.

Amendment 2

Proposal for a directive
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) The existing disparities between health-policy objectives and objectives of the internal market in services makes it necessary, where a conflict arises, always to assign priority to health-policy objectives as overriding reasons relating to the public interest (i.e. public health, social-policy objectives, preservation of the financial balance of the social security system, etc.).

Justification

This will ensure, inter alia, that health-policy objectives have priority and that the Commission's aim of improving health care can be achieved.

Amendment 3

Proposal for a directive
Recital 3 c (new)

Text proposed by the Commission	*Amendment*
	(3c) The Commission White Paper of 23 October 2007, entitled Together for Health: A Strategic Approach for the EU 2008-2013[1] sets out a first EC Health Strategy for Community activities in health.
	[1] COM(2007)0630.

Justification

The Communication is based on the commitment by the Member States and the Community to respect the common values and principles of health policies. The resolution of the Parliament stresses that health is one of the key social and political issues on which the future of the European Union depends.

Amendment 4

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Healthcare services and general social services play a fundamental role in the European social model but receive inadequate funding in certain Member States. The Commission and Member States should recognise that fundamental role when applying internal market and competition law.

Justification

Reaffirms the general starting points when discussing the healthcare system.

Amendment 5

Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) Healthcare services and general social services play a fundamental role in the European social model but receive inadequate funding in certain Member States. The Member States and the Commission should take better account of this fundamental role of healthcare services in all law-making.

Amendment 6

Proposal for a directive
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(4c) The liberalisation of health services could lead to greater inequality of access to high-quality health care and is therefore not the aim of this Directive.

Amendment 7

Proposal for a directive
Recital 4 d (new)

Text proposed by the Commission	*Amendment*
	(4d) High-quality, community-based health care, developed, where possible, in cooperation with users and patients, could play an important role in the fight against poverty and social exclusion.

Justification

This is one of the central elements of the resolution mentioned in recital 1.

Amendment 8

Proposal for a directive
Recital 4 e (new)

Text proposed by the Commission	*Amendment*
	(4e) Inequalities in healthcare outcomes, both between and within Member States, remain wide. Member States should tackle those inequalities, in particular by ensuring effective access to healthcare for all.

Justification

Cornerstone of all policies that involve healthcare should have the aim of ensuring access for all.

Amendment 9

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(5) As confirmed by the Court of Justice on	(5) As confirmed by the Court of Justice on

several occasions, while recognizing their specific nature, ***all types of medical care fall within the scope of the Treaty***.	several occasions, while recognizing their specific nature, ***medical services provided for consideration fall within the scope of the EC Treaty's provisions on the freedom to provide services***.

Justification

Given the fact that the Directive specifically deals with free movement of services, it is important to refer to the relevant EC Treaty provisions. The amendment also specifies - in accordance with settled ECJ case-law - that medical services fall within the ambit of these EC Treaty provisions if they are provided for consideration (see e.g. C-372/04, Watts, par 86).

Amendment 10

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) This directive aims to ***establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting*** the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.	(8) This directive aims to ***provide rules for the access to safe and high-quality healthcare in another Member State and establish cooperation mechanisms on healthcare between Member States, in full respect of national competence in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control. It fully respects*** the responsibilities of the Member States for ***healthcare according to the Treaty, including for*** the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment 11

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8)This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.	(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure patients mobility***, a better balance between patients' individual rights in relation to mobility and the maintenance of national regulatory capabilities, for the benefit of all,*** and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Amendment 12

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) In defining healthcare, the Commission and Member States should consider recognising the positive impact of thermal cures on convalescence and health maintenance.

Justification

This amendment is linked to amendment 2. Thermal cures can play an important role in preventing health problems but also in solving them. Member States, Commission and healthcare insurance companies should investigate the values added by these kinds of provisions.

Amendment 13

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Member States should, when implementing this Directive, take into account the European Parliament resolution of 29 May 1997 on the status of non-conventional medicine[1].
	[1] OJ C 182, 16.6.1997, p. 67.

Justification

Given that a number of people in the Member States are making use of these kind of medicines and therapies the resolution calls on the Commission to launch a process of recognising non-conventional medicine.

Amendment 14

Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) In order to ensure that new barriers to the free movement of healthcare workers are not created and to ensure patient safety, equal standards of occupational safety for healthcare workers must be provided, in particular with a view to avoiding risks from infections resulting from accidents at the workplace such as needlestick injuries that can lead to potentially fatal infections, including Hepatitis B, Hepatitis C and HIV, as referred to in the European Parliament's resolution with recommendations to the Commission of 6 July 2006 on the protection of healthcare workers from blood-borne infections due to needlestick injuries[1].
	[1] OJ C 303 E, 13.12.2006, p.754.

Justification

The varying standards of occupational safety for healthcare staff can pose a significant barrier to the free movement of healthcare workers. The protection of healthcare workers from needlestick injuries needs to be particularly addressed as it represents a major and important difference in the standard of occupational safety across the European Union.

Amendment 15

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Member States should in particular ensure that a high level of protection is ensured to protect patients, staff and all other persons who have cause to enter healthcare establishments from healthcare-associated infections, as these constitute a major threat to public health especially considering cross-border healthcare. All appropriate preventive measures, including hygiene standards and diagnostic screening procedures, should be employed in order to avoid or minimise the risks of healthcare-associated infections.

Justification

The European Commission is expected to release its Communication on Patient Safety and Healthcare Associated Infections during 2008. The Council is also committed to a common text on this matter in the near future. The European Parliament should therefore ensure the inclusion of this subject given that healthcare associated infections do not respect geographical borders and hence should be reflected in a legislative text governing cross-border aspects of healthcare.

Amendment 16

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) It is appropriate to require that also	(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.	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 (*EEC*) 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 ***treatment which is*** the same or ***equally effective,*** 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. This may be the case in particular for any treatment provided through European reference networks as mentioned in Article 15 of this Directive.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on the coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 17

Proposal for a directive
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) This Directive recognises that entitlement to treatment is not always determined by Member States at national

level and that not all Member States have a defined list of the services they do or do not provide. Member States must retain the right to organise their own healthcare and social security systems in such a way that availability of treatments and entitlement to them, can be determined at a regional or local level.

Justification

A number of healthcare systems do not have national level eligibility criteria for determining access to particular treatments or a defined "basket of care" which all people they cover are automatically entitled to receive. The Directive should fully recognise that some Member States rely on sub-national decision-making arrangements for planning and financing their healthcare systems.

Amendment 18

Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(30) There is no definition of what constitutes hospital care throughout the different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases). A regularly updated list of such treatments shall be specifically	(30) There is no definition of what constitutes hospital care throughout the different health systems of the Community, and different interpretations could therefore constitute an obstacle to the freedom for patients to receive healthcare. In order to overcome that obstacle, it is necessary to provide a Community definition of hospital care. Hospital care generally means care requiring the overnight accommodation of the patient. However, it may be appropriate to submit to the same regime of hospital care also certain other kinds of healthcare, if that healthcare requires use of highly specialised and cost-intensive medical infrastructure or medical equipment (e.g. high-technology scanners used for diagnosis) or involving treatments presenting a particular risk for the patient or the population (e.g. treatment of serious infectious diseases) ***and for which planning is necessary in order to maintain***

defined by the ***Commission through the comitology procedure***.	***a balanced geographical distribution of health care services, to control costs and to prevent any significant wastage of financial, technical and human resources***. A regularly updated list of such treatments shall be specifically defined by the ***competent authorities of the Member State of affiliation***.

Justification

In accordance with ECJ case-law, the amendment reflects the idea that hospital care is inextricably linked with the need for planning, which ensures that there is sufficient and permanent access to a balanced range of high-quality hospital treatment whilst controlling costs and safeguarding the sustainability of the social security system. Provided that the Member State of affiliation is responsible for the assumption of costs, it is up to that Member State to draw up the list of hospital care.

Amendment 19

Proposal for a directive
Recital 31

Text proposed par la Commission	*Amendment*
(31) ***The evidence available indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems. However, the*** Court of Justice has recognised that ***it cannot be excluded that the possible*** risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which	(31) ***The*** Court of Justice has recognised that ***there is a*** risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for ***health***care received in another Member State***. Prior authorisation is essential for all hospital and specialised care as it***

they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for ***hospital*** care received in another Member State***, where the following conditions are met: had the treatment been provided on its territory, it would have been assumed by its social security system and the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, the Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in Article 8.***

provides a guarantee for patients that they will be treated and that the treatment will be covered by their social security system.

Amendment 20

Proposal for a directive
Recital 32

Text proposed by the Commission	*Amendment*
(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation 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. However, when the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.	(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had ***treatment which is*** the same or ***equally effective for the patient*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 21

Proposal for a directive
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33a) Refusals to grant prior authorisation cannot be based merely on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in each individual case an objective medical assessment of the patient's medical condition, the history and probable course of the illness, the degree of pain the patient is in and/or the nature of the disability at the time when the request for authorisation was made or renewed.

Justification

The amendment clarifies the conditions under which prior authorization can be refused (see C-372/04, Watts case).

Amendment 22

Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account	(34) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights to cross-border healthcare in practice. For cross-border healthcare the most efficient mechanism for providing such information is to establish central contact points within each Member State to which patients can refer, and which can provide information on cross-border healthcare taking into account

also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross-border healthcare. They should also provide information about options available in case of problems with cross-border healthcare, in particular about out-of-court schemes for settling cross-border disputes.	also the context of the health system in that Member State. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, these central contact points should also constitute a network through which such questions can be most efficiently addressed. These contact points should cooperate with each other and should enable patients to make informed choices about cross border healthcare**.** They should also provide information about options available in case of problems with cross-border healthcare, in particular about out of court schemes for settling cross border disputes. ***In developing arrangements for provision of information on cross-border healthcare, the Member States should give consideration to the need to provide information in accessible formats and to potential sources of additional assistance for vulnerable patients, disabled people and people with complex needs.***

Justification

It is vital that information about cross border healthcare is available in accessible formats.

Amendment 23

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) In particular, power should be conferred on the ***Commission*** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive***; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for***	(45) In particular, power should be conferred on the ***Member States' competent authorities*** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive.

establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Amendment 24

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.	(45) In particular, power should be conferred on the Commission to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; ***the list of services which fall under the headings of telemedicine services, laboratory services and remote diagnosis and prescription;*** accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Council Decision 1999/468/EC.

Justification

It is important also to make it clear what services qualify as telemedicine services, laboratory services and remote diagnosis and prescription. In this way the directive will become more clear and comprehensive and therefore more effective.

Amendment 25

Proposal for a directive
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) By facilitating the freedom of movement for patients within the European Union, this Directive is likely to lead to competition between healthcare providers. Such competition is likely to contribute to an increase in the quality of the healthcare, for all and to the establishment of centres of excellence.

Justification

When the Directive has this as an outcome it would have a positive contribution to the healthcare systems in the Member States, but careful monitoring is needed to check the results of the Directive.

Amendment 26

Proposal for a directive
Recital 46 b (new)

Text proposed by the Commission	*Amendment*
	(46b) Everyone should have access to a European Centre of Reference (ECR).

Justification

The discussion on the ECRs is still going on. It is important to stress that this discussion needs to come to a conclusion and that the aim of the Centres is equal access for all. The reimbursement should therefore be part of the regulation on coordination of social security schemes.

Amendment 27

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive establishes a general framework for the provision of safe, *high quality* and efficient cross-border healthcare.	This Directive establishes ***common rules to ensure patient mobility and access to***safe, *high-quality****, sustainable, effective*** and efficient cross-border healthcare***, whilst fully respecting the Member States' responsibility for the definition of social security benefits related to health and the organisation and delivery of healthcare, medical care and social security benefits in accordance with the principles of universal access, solidarity, access to good quality care, equity, affordability, equal territorial accessibility and democratic control***.

Justification

In order to prevent citizens from having to move to another Member State for their healthcare it is important that the system is also effective.

Amendment 28

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.	This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private. ***This Directive shall apply to statutory, private and combined sickness insurance schemes.***

Amendment 29

Proposal for a directive
Article 3 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) Regulations on coordination of social security schemes, in particular ***Article 22*** of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.	(f) Regulations on coordination of social security schemes, in particular ***Articles 19, 20, 22 and 25*** of Regulation (*EEC*) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and ***Articles 17, 18, 19, 20, 27 and 28 of*** Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Amendment 30

Proposal for a directive
Article 3 – paragraph 1 – point ga (new)

Text proposed by the Commission	*Amendment*
	(ga) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive)[1].
	[1] OJ L 228, 11.8.1992, p. 1.

Amendment 31

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation	2. ***Until the date of application of Regulation (EC) No 883/2004, the rule shall apply that*** when the circumstances under which an authorisation to go to

(EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation *(EC)* No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation *(EC)* No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

another Member State in order to receive appropriate treatment under Article 22 of Regulation *(EEC)* No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Regulation (*EEC*) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment 32

Proposal for a directive
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. From the date of application of Regulation (EC) No 883/2004, the rule shall apply that when the circumstances, under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 20 of Regulation (EC) No 883/2004 must be granted, are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 20 of Council Regulation (EC) No 883/2004 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 20(2) of Regulation (EC) No 883/2004 are fulfilled, the

	authorisation shall always be accorded, and the benefits provided, in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment 33

Proposal for a directive
Article 4 – point a

Text proposed by the Commission	*Amendment*
(a) "healthcare" means a health service provided ***by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private***;	(a) "healthcare" means a health service provided ***to patients in order to assess, maintain or restore their state of health***. ***For the purpose of Articles 6, 7, 8, 9, 10 and 11of this Directive, healthcare means treatments that are among the healthcare benefits provided for by the legislation of the Member State of affiliation***;

Amendment 34

Proposal for a directive
Article 4 – point b

Text proposed by the Commission	*Amendment*
(b) "cross-border healthcare" means healthcare ***provided in a*** Member State ***other*** than that where the patient is an insured person ***or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established***;	(b) "cross-border healthcare" means healthcare ***received by a patient in another*** Member State than that where the patient is an insured person;

Amendment 35

Proposal for a directive
Article 4 – point c

Text proposed by the Commission	*Amendment*
(c) "use of healthcare in another Member State" means healthcare ***provided*** in the Member State other than that where the patient is an insured person.	(c) "use of healthcare in another Member State" means healthcare ***received*** in a Member State other than that where the patient is an insured person.

Amendment 36

Proposal for a directive
Article 4 – point g – subpoint ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) an insured person as defined in the policy conditions of private sickness insurance schemes;

Amendment 37

Proposition de directive
Article 4 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) where, due to the application of Regulation (EEC) 1408/71 and Regulation (EC) 883/04 respectively, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits according to the legislation of that state, then that Member State is regarded as the Member State of affiliation for the purposes of this Directive;

Amendment 38

Proposal for a directive
Article 4 – point l

Text proposed by the Commission	*Amendment*
(l) ***"harm"*** means ***adverse outcomes or injuries stemming from*** the provision of healthcare.	(l) ***"adverse event"*** means ***an unintended injury or complication, which would not ordinarily be an outcome of the condition treated or*** the provision of healthcare ***required***.

Justification

The definition of "harm" as "adverse outcomes or injuries stemming from the provision of healthcare" in the Commission's proposal is far too broad as all surgery carries some risk of harm (no matter how small) even if it is performed to the highest standard. A reasonable element of risk of harm must be recognised by the Directive as a natural aspect of the treatment process. The wording in this section of the text should only address exceptional adverse events where serious injury or complication occurs far beyond any minor ailments which may ordinarily result from treatment. It seems therefore more appropriate to replace the word "harm" with "adverse event".

Amendment 39

Proposal for a directive
Article 5 – paragraph 1 – introductory part

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 ***take into account*** that:

Justification

Requiring Member States to "ensure" specific points cuts across their responsibility for determining their own quality and safety standards. In light of article 152 of the Treaty, which states that Member States are responsible for the organisation, funding and delivery of healthcare to their citizens, it seems more appropriate to say that Member States should "take into account" rather than "ensure".

Amendment 40

Proposal for a directive
Article 5 – paragraph 1 – introductory part

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 ***compliance with*** principles of ***general interest***, universality, access to good quality care, equity and solidarity***, and the public-service missions that derive therefrom, as conferred upon health service providers***, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Justification

It should be specified that health services are services of general interest and cannot be equated with ordinary services subject to the general provisions regulating the internal market, in compliance with Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market.

Amendment 41

Proposal for a directive
Article 5 – paragraph 1 - point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) such quality and safety standards are made publicly available in a clear and accessible format for citizens;

Amendment 42

Proposal for a directive
Article 5 -paragraph 1 - point b

Text proposed by the Commission	*Amendment*
(b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken	(b) the application of such standards by healthcare providers in practice is regularly monitored ***and assessed*** and corrective

when appropriate standards are not met, taking into account progress in medical science and health technology;	action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;

Justification

The assessment of the results of the monitoring is important in order to show on what the corrective action are constructed. Furthermore, the results of the assessment can be used to create, in the coming years, a network of accredited and recognised healthcare providers.

Amendment 43

Proposal for a directive
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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) the application of such standards by healthcare providers ***and the competence of health professionals*** in practice is regularly monitored and corrective action taken when appropriate ***to promote excellence and to ensure*** appropriate standards are met, taking into account progress in medical science and health technology;

Justification

It is vital for patient safety that health professionals are competent to practice.

Amendment 44

Proposal for a directive
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) healthcare providers provide all relevant information to enable patients to 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;	(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on ***quality,*** 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***, and with***

	regard to the reimbursement of other expenses for which the patient is liable, such as travel and accommodation costs for parents accompanying their children;

Justification

This is to make sure that the patients are informed about the reimbursement rules that apply to them.

Amendment 45

Proposal for a directive
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) healthcare providers provide all relevant information to enable patients to 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;	(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, ***quality, safety,*** 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;

Amendment 46

Proposal for a directive
Article 5 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(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***, health providers and the public*** have a means of making complaints and are ***given*** guaranteed ***recourse to appropriate*** remedies and compensation when they suffer harm ***or become aware of harm caused*** arising from ***cross-border*** healthcare. ***This is set in the context of an effective health system and professional regulation.***

Amendment 47

Proposal for a directive
Article 5 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(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. ***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.***

Justification

For the sake of clarity and consistency, it would seem useful to include a statement in main body of the Directive confirming, as set out in Recital 12, that healthcare providers are not required to accept for planned treatment or prioritise patients from other Member States to the detriment of patients from the Member State of treatment.

Amendment 48

Proposal for a directive
Article 5 – paragraph 1 - point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) Member States shall define clearly patients' rights and people's rights in relation to healthcare, in accordance with the European Charter of Fundamental Rights.

Amendment 49

Proposal for a directive
Article 5 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In view of the major importance, particularly to patients, of safeguarding the quality and safety of cross-border care, the organisations involved in drawing up norms and guidelines as referred to in paragraphs 1 and 3 shall at the minimum include patients' organisations (particularly those of a cross-border nature).

Amendment 50

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 ***deliberately*** travelling to another Member State with the purpose of receiving healthcare ***(planned care)*** there or seeking to receive healthcare ***(planned care)*** 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 ***competent institutions of the*** Member State of affiliation ***(without prejudice to Regulation (EEC) No 1408/71 and, as of its date of application, Regulation No 883/2004)*** shall reimburse the costs which would have been paid for by its statutory social security system had the same ***treatment*** or ***treatment which is equally effective*** 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.

Justification

It is desirable to state specifically that this article refers to planned care which is the reason for travelling abroad.

Amendment 51

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 ***or paid for*** by ***the social security system or competent institution of*** the Member State of affiliation ***(without prejudice to Regulation No 1408/71 and as of its date of application,Regulation No 883/2004)*** in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same ***treatment*** or ***treatment which is equally effective*** 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 accommodation and travel costs***.

Justification

Clarification that it is not the Member State but the social insurance institution(s) concerned that should reimburse the costs.

Amendment 52

Proposal for a directive
Article 6 - paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may	3. The Member State of affiliation may

impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or ***similar healthcare*** was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons	impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same ***treatment*** or ***treatment which is equally effective*** was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion "or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 53

Proposal for a directive
Article 6 - paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or ***similar healthcare*** been provided in the territory of the Member State of affiliation.	4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same ***treatment*** or ***treatment which is equally effective*** been provided in the territory of the Member State of affiliation.

Justification

ECJ case law does not include the reference to "or similar healthcare." For reasons of legal certainty and coherence with the rules on coordination of social security schemes, the notion

"or similar" should be replaced by "or equally effective for the patient." This is in line with the ECJ interpretation of the notion of "treatment" in Article 22 of Regulation 1408/71 (new Article 20 of Regulation 883/2004) (see e.g. C-372/04, Watts, par 61).

Amendment 54

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***to*** the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.	4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***for*** the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

Justification

Equal access to care abroad can be compromised by the need for a patient to pay for the care first from his own pocket before being able to seek reimbursement. Member States of affiliation and treatment could set up swift reimbursement schemes between them (at least for economically disadvantaged patients, if not for all). By specifying that the costs will be reimbursed to the insured person, this possibility is excluded.

Amendment 55

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives	5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives

95/46/EC and 2002/58/EC.	95/46/EC and 2002/58/EC. ***If the medical records are held in electronic form, patients shall have a guaranteed right to obtain a copy of these records or a right of remote access to these records.***

Amendment 56

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Patients ***travelling to another Member State with the purpose of*** receiving healthcare ***there*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	5. Patients receiving healthcare ***in a Member State other than their Member State of affiliation*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.

Justification

The Commission proposal on the reimbursement of health care costs might discriminate in practice against the principle of 'equal access for all' to cross-border health services and the principles of equity and equal treatment regardless of patients' income and treatment costs. People with lower incomes would be unlikely to be able to take advantage of the Commission's much-vaunted 'internal market freedom' in view of upfront payments to be made, the costs of travel and accommodation, and because language barriers and uncertainty over the legal situation in other EU countries would make the risks of seeking treatment in another Member States too daunting. And for insured persons from poorer Member States such as e.g. Romania or Bulgaria it is hardly likely that they can obtain treatment in richer Member States such as e.g. Sweden or France on this basis, as their own health insurance scheme would pay only a small fraction of the costs of any such treatment. In order to strengthen patients' rights in cross-border health care, therefore, the already existing framework of the coordination of social protection schemes exclusively should be used.

Amendment 57

Proposal for a directive
Article 7

Text proposed by the Commission	*Amendment*
The Member State of affiliation shall not	The Member State of affiliation shall not

make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.	make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its ***statutory*** social security system.

Justification

The principles on the assumption of healthcare costs apply in so far it concerns costs of that care which, if it had been provided in its territory, would have been paid under the statutory social security system of the Member State of affiliation. It corresponds to the term used in Article 6 of the Directive.

Amendment 58

Proposal for a directive
Article 8 – paragraph 1 – introductory part

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 ***and specialised care*** shall mean ***healthcare defined as such by the Member State of affiliation and which requires:***

Amendment 59

Proposal for a directive
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) ***healthcare which*** requires overnight accommodation of the patient in question for at least one night***.***	(a) ***it*** requires overnight accommodation of the patient in question for at least one night; ***or***

Justification

The definition provided by the Commission does not correspond to the real nature of the services provided in the Member States. It does not, for example, take account of outpatient surgery.
In order to correspond to the real nature of the services provided in practice, the definition of hospital care should refer to the definition in force in the patient's Member State of affiliation.

Amendment 60

Proposal for a directive
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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:	
- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or	***(b) it*** 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.	***(c) it involves*** treatments presenting a particular risk for the patient or the population.

Amendment 61

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***

Justification

This amendment recognises that prior authorisation systems can are valuable to patients in terms providing them with clarity on matters such as what reimbursement they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong. These considerations apply equally to care provided in hospitals and in other settings, as do issues about the need to plan services and manage financial resources for those who run health systems.

Amendment 62

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where ***the following conditions are met:***	3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where ***it could affect important aspects of its healthcare system, including its scope, cost or financial structure. Such a system shall be without prejudice to Regulation(EEC) No 1408/71 as of its date of application, (EC) No 883/2004.***
(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and	
(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:	
(i) the financial balance of the Member State's social security system; and/or	
(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.	

Justification

This amendment recognises that prior authorisation systems are valuable to patients in terms of providing them with clarity on matters such as what reimbursement they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong. Member States should be able to decide the circumstances in which prior authorisation systems are mandatory for patients seeking healthcare abroad, provided these systems meet criteria such as transparency and proportionality, are simple and straightforward, and provide timely responses to requests.

Amendment 63

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 apply without prejudice to Article 3(2) and*** shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

Amendment 64

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Prior authorisation application systems must be made available at a local/regional level and must be accessible and transparent to patients. The rules for application and refusal of prior authorisation must be available in advance of an application so that the application can be made in a fair and transparent way.

Amendment 65

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that the patient is expected only to pay upfront any costs that they would be expected to pay in this manner had their care been provided in

their home health system. Member States should seek to transfer funds directly between the funders and the providers of care for any other costs.

Amendment 66

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Patients seeking to receive healthcare provided in another Member State shall be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Justification

With the purpose of making the right of cross boarder health care a right for everyone, and in order to give patients the possibility to know for sure whether they will be reimbursed or not, it is important to give patients the right to apply for a prior authorisation in the Member State of affiliation. A system without this right to apply for prior authorisation would lead to great economical uncertainty for the patients. This uncertainty would make the right to cross boarder health care less attractive for those with a low income and thus not equally available to all.

Amendment 67

Proposal for a directive
Article 8 – paragraph 6 (new)

Text proposed by the Commission	*Amendment*
	6. The Member State of treatment may take appropriate measures to address the inflow of patients and to prevent it from undermining the healthcare system. The Member State of treatment shall refrain from discriminating with regard to nationality and shall ensure that the measures restricting free movement shall be limited to what is necessary and

proportionate.

Amendment 68

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.	1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. ***Until the date of application of Regulation (EC) No 883/2004, the rule shall apply that,*** in any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation *(EEC) No*1408/71 are met. ***From the date of application of Regulation (EC) No 883/2004, the rule shall apply that when the circumstances referred to in Article 20 of Regulation (EC) No 883/2004 are met, an insured person shall always be granted authorisation by virtue of the regulations concerning coordination of social security schemes as referred to in Article 3(1)(f).***

Amendment 69

Proposal for a directive
Article 9 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:	Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account ***and set out criteria by which they measure***:

Amendment 70

Proposal for a directive
Article 9 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the urgency of the treatment or of the medical procedure in question;

Justification

Although many medical conditions could not be painful, they might require urgent treatment or intervention though specific medical procedures.

Amendment 71

Proposal for a directive
Article 9 -paragraph 4 -point d a (new)

Text proposed by the Commission	*Amendment*
	(da) accreditation of the healthcare providers in the Member State of treatment.

Justification

Accreditation is an important element in order to assess the quality of the healthcare providers in other Member States.

Amendment 72

Proposal for a directive
Article 9 - paragraph 4 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the medical history of the patient.

Justification

The Court of Justice holds that, in order to determine whether a treatment which is equally effective for the patient can be obtained without undue delay in the Member State of residence, the competent institution is also required to take due account of the medical history of the patient (see C-372/04, Watts, paragraph 62).

Amendment 73

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 State.	1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with ***impartial, comparative and complete*** 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 State. ***1a. The Member State of treatment shall ensure that there are mechanisms in place to make impartial, comparative and complete information publicly available including information on receiving healthcare and on registered health professionals and providers in that Member State, on the quality and safety standards that apply, the regulatory system in place, and the process for making complaints where harm is caused as a result of healthcare received in that Member State.*** ***1b. In information about cross-border care, a clear distinction shall be made between the rights which patients have by***

virtue of this Directive and rights arising from regulations on the coordination of social security schemes as referred to in Article 3(1)(f).

Justification

In order to be able to make a well balanced choice for a hospital the information mentioned in the amendment is needed.

Amendment 74

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.	2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, ***in formats easily accessible to people with disabilities at no extra cost,*** 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.

Amendment 75

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

Text proposed by the Commission	*Amendment*
	2a. In addition to the information outlined in paragraph 1, information on health professionals and healthcare providers shall be made easily available via electronic means by the Member State in which the health professionals and healthcare providers are registered, and shall include the name, registration number, practice address of the healthcare professional, and any restrictions on their practice;

Justification

In the interests of patients availing of cross-border services, there is also a need for greater transparency of health professional and health service regulation. Public registers of health professionals and health service providers should be available in Member states so that patients can easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of the health professionals providing care. The international evidence illustrates that the most practical way for patients to have access to information on their current or prospective healthcare providers is via the publication of public registers of such practitioners. Such registers should now be available via the Internet and should allow the patient to access the relevant data by searching either via the name or via the registration number of the healthcare provider (or indeed by searching via geographical area). The relevant data that should be in the public domain should be, at a minimum, the name, registration number and practice address of the healthcare professional, the date of their first registration on that register, the expiry date of their current registration, and any conditions or restrictions on their practice or suspensions should this be the case. Healthcare professionals, who are not registered, be it for voluntary reasons or if struck off for whatever reason, should not appear on such register.

Amendment 76

Proposal for a directive
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	The Member State of treatment shall ensure that:
	(a) patients receive upon their request information on guarantees of quality and safety of healthcare provided.
	(b) healthcare providers in the Member State of treatment provide information on availability, prices and outcomes of healthcare provided, including procedures for complaints and means of redress available for healthcare provided.

Justification

Patients must be supplied with the most relevant and most useful information. To this end, it is for the Member State to provide the information on its own healthcare system. If the Member States were required individually to provide information on the other 26 Member States, there would be a risk that the information is not relevant and the information system could be

unreliable.

Amendment 77

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that patients' organisations, health insurance funds and care providers are involved in these national contact points.***

Amendment 78

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***They may also draw up national lists of centres for hospital and specialised care, for the benefit of stakeholders.***

Amendment 79

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	(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;	of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, on the terms and conditions applicable***, and on centres of excellence or healthcare centres specialised in certain diseases***;

Justification

The patient right on information must be completed with information on centres of excellence and specialised healthcare centres to be able to make a well balance choice.

Amendment 80

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 quality and safety ***standards***, protection of personal data, procedures for complaints***, the means by which professionals and providers are regulated and the means by which regulatory action can be taken, the*** means of redress available for healthcare provided in ***that*** Member State, and the terms and conditions applicable;

Amendment 81

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	(a) provide and disseminate information to patients ***and healthcare professionals*** in particular on ***patients'*** rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means

healthcare provided in another Member State, and on the terms and conditions applicable;	of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Justification

Health professionals are the patients' first point of contact and need information about patient's rights in order both to observe all the rights and to guide the patients to get the help they need.

Amendment 82

Proposal for a directive
Article 12 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The national contact point in the Member State of treatment shall register all activities in the Member State of treatment pursuant to Articles 6, 7, 8, 9 and 15 and notify the competent authorities of the Member State of treatment and the national contact point of the Member State of affiliation thereof. Health service providers shall supply the necessary information to the national contact point of their Member State as soon as they receive it.

Justification

To ensure that the procedure runs as smoothly as possible.

Amendment 83

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.	1. Member States shall render such mutual assistance ***for the promotion of the quality and safety of healthcare*** as is necessary for the implementation of this Directive.

Amendment 84

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.	1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive ***and shall conclude agreements on this subject***.

Amendment 85

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.	Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation***, and shall conclude agreements on this subject***.

Amendment 86

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.	2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and ***communication between healthcare providers in the Member States of treatment and affiliation respectively in order to better ensure continuity of care***, as well as through information and

communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Justification

Continuity of care is vital to patient safety. Medical teams from the patients' country of origin should cooperate closely with the medical and specialists teams of the country of treatment to ensure continuity of care.

Amendment 87

Proposal for a directive
Article 13 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States, particularly neighbouring countries, may conclude agreements among themselves as referred to in paragraphs 1 and 2 concerning, inter alia, worthwhile cooperative frameworks which should remain in existence or be allowed more scope for development, concerning the inflow and outflow of patients between these Member States, and concerning planning systems and certain intramural forms of care.

Justification

De verplichting tot samenwerking van artikel 13 is niet voldoende uitgewerkt, waardoor instellingen in grensgebieden in hun plannen te zeer afhankelijk blijven van de toevallige patiëntenbewegingen en de willekeur van verzekeraars/lidstaten om e.e.a. toe te laten. Voor structurele samenwerking en investeringen daarin hebben instellingen nu eenmaal enige zekerheid nodig, dat het ook zal gaan lopen en ook gefinancierd gaat worden. Door deze toevoeging kunnen instellingen, verzekeraars en patiënten terugvallen op afspraken die zijn toegesneden op bestaande problematiek en mogelijkheden in de grensregio's. Deze samenwerkingsovereenkomsten kunnen per lidstaat meer of minder vergaand zijn.

Amendment 88

Proposal for a directive
Article 13 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member states shall immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services.

Amendment 89

Proposal for a directive
Article 14 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) are limited to what is necessary ***and*** proportionate to safeguard human health and are ***non-discriminatory*** or	(a) are ***not*** limited to what is necessary***, are not*** proportionate to safeguard human health and are ***discriminatory*** or

Justification

The sentence is wrong in the Commission's version. Point (a) enumerates the exceptions which permit Member States not to abide by the general rule: bans on any limit on recognition of individual prescriptions are accepted in cases where prescriptions are not limited to what is necessary and proportionate with the aim of safeguarding human health, or are discriminatory.

Amendment 90

Proposal for a directive
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The recognition of prescriptions issued in another Member State shall not imply a modification to the right of Member States to determine the benefits which the Member States themselves decide to grant.

Justification

The directive is not intended to invalidate the subsidiarity principle, which allows the Member States to determine which benefits they wish to grant.

Amendment 91

Proposal for a directive
Article 14 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Reimbursements regarding individual prescriptions shall be based only on the relevant provisions of the Member State of afiliation..

Justification

The issue of mutual recognition of prescriptions has to be clarified in conjunction with the question of reimbursement. It is important that reimbursement is only possible for medicinal products that are part of the basket of benefits in the Member State of affiliation of the patient.

Amendment 92

Proposal for a directive
Article 14 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. The Member State of affiliation shall be obliged to reimburse the costs of a medical prescription from another Member State only if these costs would also be borne in the Member State of affiliation (e.g. in accordance with a reimbursement code or a positive list).

Justification
Otherwise there would be a contradiction with Article 11.

Amendment 93

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

Text proposed by the Commission	*Amendment*
(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;	(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a ***standardised*** Community prescription template, and supporting interoperability of ePrescriptions;

Justification

The monitoring of trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care will enable Member States and the Commission to identify some of the problems that will arise following the implementation of this Directive.

Amendment 94

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; ***prescriptions issued using this Community form must be formulated in accordance with the international non-proprietary name (INN) system;***

Justification

In order to be readable anywhere in Europe, prescriptions made out on the basis of a Community form should use a common language, the International Non-proprietary Name (INN) system, which identifies medicinal products by their molecules and not by their commercial names, which may vary from one country to another.

Amendment 95

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

Text proposed by the Commission	*Amendment*
(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.	(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article ***where the conditions referred to in paragraph 1 above apply or*** where necessary in order to safeguard public health.

Justification

In the interests of greater clarity, it is desirable to recall the conditions which enable Member States not to prohibit any limit on the recognition of individual prescriptions.

Amendment 96

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

Text proposed by the Commission	*Amendment*
	(ca) measures to ensure that prescriptions issued and information given about medicinal products prescribed are accessible to people with disabilities.

Amendment 97

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15a
	Trial areas
	In order, in future, to establish as effective a care policy as possible, the Commission shall designate border regions as trial areas where innovative initiatives relating to cross-border care can be thoroughly tested, analysed and assessed.

Amendment 98

Proposal for a directive
Article 15 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall facilitate the development of the European reference networks of healthcare providers**.** Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria	1. Member States shall facilitate the development of the European reference networks of healthcare providers ***and enhance the experience of cooperation as regards healthcare within the European cross-border cooperation groupings.*** Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria

Justification

The EGCC is, on the level of cross-border health cooperation, an important and already existing instrument. Best practices from the EGCC could be used for further developments in the field of this directive.

Amendment 99

Proposal for a directive
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) to help ensure effective access to healthcare for all, in particular with a view to combating inequalities in healthcare outcomes, both between and within Member States;

Justification

This is one of the central elements of the healthcare policies.

Amendment 100

Proposal for a directive
Article 15 – paragraph 2 – point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) to establish a database of all healthcare providers and information on the specific specialisations, in order to establish a list of centres of excellence;

Justification

This can help patients to make the right choice for a specific hospital.

Amendment 101

Proposal for a directive
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States purchasing e-health services from providers and professionals in other Member States shall ensure that such providers and professionals are appropriately regulated and qualified and that they have demonstrated, via the relevant competent authority, that they are fit to practise and to provide e-health services.

Amendment 102

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting	1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. ***They shall also monitor trends and patterns in relation to adverse***

healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.	***incidents or systems failures in respect of cross-border care.*** They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.

Justification

The monitoring of trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care will enable Member States and the Commission to identify some of the problems that may arise following the implementation of this Directive.

Amendment 103

Proposal for a directive
Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The aim of that data collection is to assess whether this Directive contributes to the mobility of patients, the quality of the healthcare in general, and the principle of access for all.

Justification

It needs to be stressed that, given the aim of the Directive, the collected data should help assessing if the Directive accomplishes this aim. Also in the report (Article 20) this should be one of the main elements.

Amendment 104

Proposal for a directive
Article 18 - paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The collection of data in the context of this Article shall be done in close cooperation with the collection of data provided for by the Administrative Commission on Social Security for Migrant Workers.

Justification

Close cooperation on the collection of data under this Directive and the collection of data under the rules on the coordination of social security schemes will allow drawing a more comprehensive image of cross-border flows of people in the field of healthcare.

Amendment 105

Proposal for a directive
Article 20 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall ensure that the requisite information is gathered to chart cross-border flows of patients and practitioners so as to be able to remedy any adverse effects promptly and to further encourage positive effects. The Commission shall include this information in the report referred to in paragraph 1.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	EMPL 2.9.2008
Associated committee(s) - date announced in plenary	23.9.2008
Rapporteur Date appointed	Iles Braghetto 9.9.2008
Discussed in committee	26.1.2009 10.2.2009
Date adopted	2.3.2009
Result of final vote	+: 35 –: 2 0: 4
Members present for the final vote	Jan Andersson, Edit Bauer, Iles Braghetto, Philip Bushill-Matthews, Milan Cabrnoch, Alejandro Cercas, Luigi Cocilovo, Jean Louis Cottigny, Jan Cremers, Richard Falbr, Joel Hasse Ferreira, Roger Helmer, Karin Jöns, Jean Lambert, Bernard Lehideux, Elizabeth Lynne, Thomas Mann, Siiri Oviir, Marie Panayotopoulos-Cassiotou, Rovana Plumb, Bilyana Ilieva Raeva, Elisabeth Schroedter, Gabriele Stauner, Ewa Tomaszewska, Anne Van Lancker, Gabriele Zimmer
Substitute(s) present for the final vote	Françoise Castex, Gabriela Creţu, Donata Gottardi, Anna Ibrisagic, Rumiana Jeleva, Sepp Kusstatscher, Jamila Madeira, Viktória Mohácsi, Georgios Toussas
Substitute(s) under Rule 178(2) present for the final vote	Glenn Bedingfield, Herbert Bösch, Maddalena Calia, Ljudmila Novak, Gianluca Susta, Silvia-Adriana Ţicău

10.3.2009

OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION (*)

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur(*): Bernadette Vergnaud

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

SHORT JUSTIFICATION

Healthcare services were excluded from the services directive as they involve tasks carried out in the public interest and must be covered by specific legislation which ensures absolute compliance with the principles of equal access, universality, quality, safety and solidarity.

Healthcare cannot be considered an ordinary product in the internal market because healthcare services make a strong contribution to the economic, social and territorial cohesion of the European Union.

A directive on patients' rights in cross-border healthcare must therefore take care not to be a tool for promoting 'medical tourism', which if it were to develop could create genuine inequality of access to care, leading to a two-speed healthcare system which would benefit only the best informed and better-off patients.

In accordance with the Treaties guaranteeing basic freedoms of movement, and in compliance with the subsidiarity principle acknowledging each Member State's authority to organise, manage and finance their own system of healthcare and social protection, the European Union can provide vital added value in the context of patient mobility. The complexity, variety and specific features of healthcare systems necessitate optimum cooperation between countries on research and medical and administrative information, as well as in-depth consideration as to how these specific features should be structured in order to ensure legal certainty, for patients and for health professionals and care providers.

The Commission proposal provides only a very partial answer to this equation, by merely codifying the decisions of the Court of Justice, which are precisely the consequence of an acknowledged legal vacuum.

As regards defining the key concepts (hospital and non-hospital care, healthcare provision, reasonable waiting times, harm, etc.), details as to how the directive links in with the existing regulations (1408/71 and 883/2004), assuming the costs of continuing care and responsibilities in the event of post-operation complications, and the mutual recognition of prescriptions, the text is totally insufficient, and increases the legal uncertainty rather than removing it.

It is important to clarify the rules on tariffs and reimbursement, as well as the conditions governing the system of requiring prior authorisation by the Member States for guaranteeing that healthcare costs are assumed, and thus not create inequalities between patients.

Prior authorisation should be viewed as an opportunity for patients to be better informed and advised when seeking the most appropriate care, in line with the principle of non-discrimination, rather than an obstruction to mobility.

Moreover, it ensures that the essential functions of public health services are preserved: social and territorial cohesion and maintaining the financial equilibrium of public social security systems, which are what guarantees a genuine policy of solidarity on healthcare.

For care which is not subject to authorisation, a prior declaration would make it possible to verify that the patient had received all the necessary information before departure.

In the context of an ageing population, which makes it difficult to distinguish the medical from the social, it is important to provide for the concept of long-term care, as many Member States are affected by this problem.

It is vital to structure the relationship between patient mobility and the issue of healthcare professionals, given the strong link which exists between the two parties, in order to ensure the quality and safety of care while ensuring that imbalances are not created in the medical demography of certain Member States. This absence of simultaneous reflection on the situation of professionals, their training and the recognition of their qualifications is a shortcoming which is damaging to the patients themselves, as the 2005 Directive on the recognition of professional qualifications is not appropriate for the healthcare sector.

Public health is key to economic development. Enabling citizens to better inform themselves and seek better care, without promoting consumerism or medical tourism, in a vision which is more mutually supportive and more aligned with the rights of patients, without increasing social and territorial inequalities, and providing a degree of legal certainty for both patients and professionals, maintaining our social protection systems and optimising and pooling advances in research: these are the challenges facing the EU in an area which is fundamental to the European social model, so that in their everyday life every citizen looks upon Europe as a solution, not a problem.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) This Directive respects the fundamental rights and observes the general principles of law as recognised in particular by the Charter of Fundamental Rights of the European Union The right of access to healthcare and the right to benefit from medical treatment under conditions established by national law and practices are recognised by Article 35 of the Charter of Fundamental Rights of the European Union.. Specifically, this Directive has to be implemented and applied with due respect for the rights to private and family life, protection of personal data, equality before the law and the principle of non-discrimination and the right to an effective remedy and to a fair trial, in accordance with the general principles of law, as enshrined in Articles 7, 8, 20, 21, 47 of the Charter.	(3) This Directive respects the fundamental rights and observes the general principles of law as recognised in particular by the Charter of Fundamental Rights of the European Union. The right of access to healthcare and the right to benefit from medical treatment under conditions established by national law and practices are recognised by Article 35 of the Charter of Fundamental Rights of the European Union. Specifically, this Directive has to be implemented and applied with due respect for the rights to private and family life, protection of personal data, equality before the law and the principle of non-discrimination***, the fundamental ethical choices of Member States*** and the right to an effective remedy and to a fair trial, in accordance with the general principles of law, as enshrined in Articles 7, 8, 20, 21, 47 of the Charter.

Justification

Concerns have been raised that ethically controversial medical "services" like euthanasia, DNA-testing or IVF maybe have to be financed by the Member States even if the relevant service is not allowed, or at least not financed, in the relevant Member States. For services which are clearly illegal, like euthanasia, there should be no doubt, but it may be helpful to clarify this point. In other areas, like DNA-testing, the situation is more complicated because it is not banned in any Member State but the conditions are quite different (for example obligation to do counselling before testing).

Amendment 2

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) This Directive respects and does not prejudice the freedom of each Member State to decide what type of health care it considers appropriate. No provision of this Directive shall be interpreted in a way as to undermine the fundamental ethical choices of Member States, in particular as regards the protection of the right to life of every human being.

Justification

Concerns have been raised that ethically controversial medical "services" like euthanasia, DNA-testing or IVF maybe have to be financed by the Member States even if the relevant service is not allowed, or at least not financed, in the relevant Member States. For services which are clearly illegal, like euthanasia, there should be no doubt, but it may be helpful to clarify this point. In other areas, like DNA-testing, the situation is more complicated because it is not banned in any Member State but the conditions are quite different (for example obligation to do counselling before testing).

Amendment 3

Proposal for a directive
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) In accordance with the case law of the Court of Justice of the EU, patients and care providers have the right to go to any Member State for medical assistance. It is therefore of the utmost importance that cross-border movement of patients and cross-border health services should be hampered as little as possible within the European Union.

Justification

The common standards of the internal market must always take priority. Although care

systems are a matter for the Member States, patients and care workers move across borders, so that the European Union needs to be active in these fields. At the same time, this movement of patients and care workers should be hampered as little as possible by restrictions in order to be able to guarantee the free movement of persons in the European Union .

Amendment 4

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community ***and*** to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.	(8) This directive aims to establish a general framework for provision of safe, high quality and efficient cross-border healthcare in the Community**,** to ensure patients mobility and freedom to provide healthcare and high level of protection of health ***and to facilitate the provision of cross-border healthcare***, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Justification

Legislation which aims to address the application of patients' rights to cross-border healthcare should be clear in recognising the benefits, in certain circumstances, of cross-border healthcare. This is especially the case in the area of rare diseases, quality treatment for which may not be available within the boundaries of a particular member state.

Amendment 5

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" ***shall mean***:

- 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';	***- The patient physically visits*** a healthcare provider in ***a*** Member State ***other than that where he has social security affiliation with the intention of seeking health services there;*** 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;	***- The health service itself crosses borders, virtually or otherwise: the patient does not physically go to another Member State but nonetheless receives health services from*** the territory of ***a*** Member State ***other than that where he has social security affiliation, such as telesurgery, a medical consultation, issuing of a*** prescription ***and remote*** laboratory services; ***this is what is referred to as 'telemedicine';***
- Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,	- 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)***.***	- Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services)***;***
	- The purchase of goods connected with health care, such as medical devices and medicines, in a Member State other than that where the purchaser has social security affiliation; this may be, but is not necessarily, accompanied by physical movement of the patient to the latter Member State.

Justification

The first part of the amendment is intended to improve the formulation. The second part refers to the purchase of goods connected with health care which were the subject, inter alia, of the Decker judgment, which should be incorporated into a directive intended to codify the Kohll and Decker judgments.

Amendment 6

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 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.	(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. ***In view of these common values it is nevertheless accepted that Member States take different decisions on ethical grounds as regards the availability of certain treatments and the concrete access conditions. This Directive is without prejudice to the ethical diversity. It does not impose on Member States to make treatments and services accessible their territory or to reimburse costs for those treatments (received in another Member State) which are not allowed according to national laws, regulations and codes of conduct of the medical professions.***

Justification

Concerns have been raised that ethically controversial medical "services" like euthanasia, DNA-testing or IVF maybe have to be financed by the Member States even if the relevant service is not allowed, or at least not financed, in the relevant Member States. For services which are clearly illegal, like euthanasia, there should be no doubt, but it may be helpful to clarify this point. In other areas, like DNA-testing, the situation is more complicated because it is not banned in any Member State but the conditions are quite different, for example obligation to do counselling before testing is necessary in one Member State and not in the other.

Amendment 7

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 *includes* 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 restrictions on ***the exercise of that freedom in the healthcare***	(18) The right to reimbursement of the costs of healthcare provided ***or goods purchased in connection with health care*** in another Member State from the statutory social security scheme ***to which*** patients ***are affiliated*** 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 ***and goods*** *include* the freedom for ***patients deliberately to receive health care services and deliberately to purchase goods connected with health care in*** another Member *State*. The same applies to recipients of healthcare seeking to receive health care ***services by means of telemedicine from a*** Member State ***other than that where they have social security affiliation***. 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 ***and goods***. Those provisions prohibit the Member States from introducing or maintaining unjustified

sector.	restrictions on ***these freedoms.***

Justification

This recital applies not only to services but also to the purchase of goods in the context of cross-border health care. The amendment also formulates the recital better.

Amendment 8

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) It is appropriate to require that patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by Regulation (EC) No 1408/71 should *also* be able to benefit from the principles of free movement of services ***and goods*** in accordance with the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare ***and those goods*** at least at the level provided for the same or similar healthcare ***or goods*** had they been provided ***or purchased*** 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.

Justification

The Directive applies not only to services but also to the purchase of goods in the context of

cross-border health care. The amendment also formulates the recital better.

Amendment 9

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 ***or goods purchased*** in another Member State***.*** The assumption of costs should *therefore be* limited only to ***the*** actual costs.

Justification

The Directive applies not only to services but also to the purchase of goods in the context of cross-border health care. The amendment also formulates the recital better.

Amendment 10

Proposal for a directive
Recital 25

Text proposed by the Commission	*Amendment*
(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such a treatment ***is*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions.	(25) This Directive does not aim either to create entitlement for reimbursement of treatment ***or of the cost of purchasing goods*** in another Member State, if such a treatment ***or such goods are*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare ***and goods*** provided in another Member State according to its provisions.

Justification

The Directive applies not only to services but also to the purchase of goods in the context of cross-border health care. The amendment also formulates the recital better.

Amendment 11

Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.	(27) This Directive provides also for the right for a patient to receive any medicinal product ***or medical device*** authorised for marketing in the Member State where healthcare is provided ***in the Member State of treatment***, even if the medicinal product ***or medical device*** is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining ***this specific*** effective treatment ***for the patient*** in another Member State.

Justification

For reasons of legal certainty and the practical consequences as regards the provision of medicinal products, this directive should not depart from the principle enshrined in Article 6 of Directive 2001/83/EC that only medicinal products authorised in the Member State concerned may be placed on the market.

Amendment 12

Proposal for a Directive
Recital 29

Text proposed by the Commission	*Amendment*
(29) Any healthcare which is not regarded as hospital care according to the provisions of this Directive should be considered as non-hospital care. In the light of the case-law of the Court of Justice on the free movement of services, it is appropriate not to set a requirement of prior authorisation for reimbursement by the statutory social security system of a Member State of affiliation for non-hospital care provided in another Member State. ***In so far as the reimbursement of such care remains within the limits of the cover guaranteed by the sickness insurance scheme of the***	(29) Any healthcare which is not regarded as hospital care according to the provisions of this Directive ***and the legislation of the Member State of affiliation*** should be considered as non-hospital care. In the light of the case-law of the Court of Justice on the free movement of services, it is appropriate not to set a requirement of prior authorisation for reimbursement by the statutory social security system of a Member State of affiliation for non-hospital care provided in another Member State. ***Setting up a prior declaration system for non-hospital care should make***

Member State of affiliation, the absence of a prior authorisation requirement will not undermine the financial equilibrium of social security systems.	***it possible to ensure that patients have received all the necessary information before they depart. Such a system must not, however, call into question the principle of authorisation for non-hospital care being automatic.***

Justification

In parallel with the system of prior authorisation which the Member States of affiliation can set up for hospital and specialised care, a system of prior declaration should also be put in place. The Member State of affiliation cannot refuse to assume the costs in the context of this procedure, which simply aims to ensure that the patient has received all the necessary information before departure.

Amendment 13

Proposal for a directive
Recital 32 a (new)

Text proposed by the Commission	*Amendment*
	(32a) Prior authorisation should only be refused in the context of a fair and transparent procedure. The rules laid down by the Member States for submitting an authorisation request and the possible reasons for refusal should be made known in advance. Refusals should be limited to what is necessary, and should be proportionate to the objectives of setting up a prior authorisation system.

Amendment 14

Proposal for a directive
Recital 36

Text proposed by the Commission	*Amendment*
(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is	(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is

clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Community level, such as through the European Health Portal. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.	clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. ***The contact point should not provide legal advice in individual cases.*** The Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Community level, such as through the European Health Portal. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system. ***Consequently, the contact points may be based within the competent professional organisations entrusted with this task by the Member States, as well as in the administrative authorities.***

Justification

Involving the relevant professional organisations would avoid the risk of duplication and the associated costs, since some of them are already familiar with these tasks of providing information. This would also make it possible to ensure that the contact points would benefit from the expertise of the professional organisations concerned. Legal advice in individual cases would go beyond the remit of the contact points and raise questions in relation to liability.

Amendment 15

Proposal for a directive
Recital 38 a (new)

Text proposed by the Commission	*Amendment*
	(38a) The Commission should reinforce reciprocal aid between national bodies responsible for monitoring quality, voluntary certification of activities, quality

certifications and cooperation of professional associations and should support the development of codes of conduct of healthcare service providers.

Amendment 16

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 recognised ***medically or in pharmacies*** 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 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 ***and without prejudice to the validity of national pricing and payment rules***. 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.

Justification

The recognition of prescriptions is not only medical recognition, but recognition when medicinal products are sold by pharmacists.

Amendment 17

Proposal for a directive
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39a) The European Commission should prepare a feasibility study on a common EU benchmark system on the quality of healthcare.

Amendment 18

Proposal for a directive
Recital (40)

Text proposed by the Commission	*Amendment*
(40) European reference networks should provide healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, in order to provide affordable, high quality and cost-effective care and could also be focal points for medical training and research, information dissemination and evaluation. The mechanism for identification and development of the European reference networks should be established with the aim to organise at European level equal access to high level shared expertise in a given medical field for all patients as well as for health professionals.	(40) European reference networks should provide healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, in order to provide affordable, high quality and cost-effective care and could also be focal points for medical training and research, information dissemination and evaluation. The mechanism for identification and development of the European reference networks should be established with the aim to organise at European level equal access to high level shared expertise in a given medical field for all patients as well as for health professionals. ***Significant synergies could be achieved by combining the institutional framework for reference networks with the central contact points within Member States, pursuant to Recital 34.***

Justification

There is a dual gain to be achieved for patients by combining the co-ordinating infrastructure for both cross-border healthcare contact points and reference networks within a single institution within each Member State.

Amendment 19

Proposal for a directive
Recital 43

Text proposed by the Commission	*Amendment*
(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This ***will*** also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant ***authorities*** of all the Member States, building on existing pilot projects.	(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This ***may*** also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant ***stakeholders, including healthcare professionals, patients' representatives, researchers and producers as well as authorities*** of all the Member States, building on existing pilot projects***.*** ***In addition, such cooperation must also be based on sound principles of good governance such as transparency, openness, inclusiveness, objectiveness and fairness of procedures, which are responsive to patients' needs, preferences and expectations. The Commission should ensure that only Health Technology Assessment bodies which adhere to these principles can join the network.***

Justification

Health Systems and the process of Health Technology Assessment (HTA) should be open and inclusive. The views, experiences and expertise of patients should be integrated into the evaluation process to allow for a better evaluation of benefits, costs and risks. Physicians, health professionals, researchers and industry should also be involved. Stakeholders' positions must be represented in the decision-making phase of the HTA process. This amendment goes with an amendment to Article 17.

Amendment 20

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive establishes a general framework for ***the provision of*** safe, high quality and efficient ***cross-border*** healthcare.	This Directive establishes a general framework for ***EU citizens' access to*** safe, high quality and efficient healthcare ***under equitable conditions, and establishes cooperation mechanisms between Member States in the field of health, respecting national responsibility for organising and providing healthcare and is intended to improve the accessibility, quality and efficiency of health systems in the Member States. And for enhanced legal certainty for citizens regarding the reimbursement of the cost of healthcare provided in another Member State.***

Justification

The current proposal, focused on patient mobility, might be deemed beneficial to citizens with a certain profile (well-off, well-informed and familiar with foreign languages), but these citizens are a minority.

The proposal should not focus simply on dealing with patient mobility (which only affects a minority) but on improving healthcare quality and safety, and on cooperation between Member States, all of which will benefit citizens in general.

Amendment 21

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.	This Directive shall apply to provision of healthcare ***in a Member State other than that in which the patient resides or is an insured person,*** regardless of how it is organised, delivered and financed or whether it is public or private. ***The purpose of the Directive is to enhance access to cross-border healthcare.***

Amendment 22

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***When*** the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.	***2. In accordance with the case-law of the Court of Justice of the European Communities and when*** the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Justification

It should be stated explicitly that where Regulation No 1408/71 (Directive 883/2004) is not in line with the case-law of the Court of Justice of the European Communities, this case-law shall take precedence. All directives relating to the reimbursement of and conditions for healthcare, authorisation and monitoring of medicinal products, protection of personal data and other directives shall have precedence over this directive provided they are not at variance with the case-law of the Court of Justice, as is explicitly set out in Paragraph 2.

Amendment 23

Proposal for a directive
Article 4 – point a

Text proposed by the Commission	*Amendment*
(a) "healthcare" means ***a*** health ***service*** provided by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which ***it is*** organised, delivered and financed at national level or whether ***it is*** public or private;	(a) "healthcare" means health ***services or products, in particular medical or pharmaceutical services and medicinal products or medical devices,*** provided by***, prescribed by*** or under the supervision of a health professional in *the* exercise of his profession, and regardless of the ways in which ***they are*** organised, delivered and financed at national level or whether ***they are*** public or private;

Justification

The supply of medicinal products is covered by the free movement of goods. Pharmacists do far more than simple distribution, however, as they advise and care for their patients. In addition, the medicinal products they provide supplement the therapy provided by doctors and thus represent a key component of healthcare. Their activities should therefore be comprehensively covered by the scope of this directive.

Amendment 24

Proposal for a directive
Article 4 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) "health data" means any information which relates to the physical or mental health of an individual, or to the provision of health service to the individual, which may include: a)

	information about the registration of the individual for the provision of health services; b) information about payments or eligibility for healthcare with respect to the individual; c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; d) any information about the individual collected in the course of the provision of health services to the individual; e) information derived from the testing or examination of a body part or bodily substance; and f) identification of a person (healthcare professional) as provider of healthcare to the individual;

Justification

As recommended in the EDPS opinion, the definition of health data should be as broad as possible. This is the ISO 27799 definition.

Amendment 25

Proposal for a directive
Article 4 – point d

Text proposed by the Commission	*Amendment*
(d) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC;	(d) "health professional" means a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC; ***or a person legally exercising healthcare activities in the Member State of treatment.***

Justification
Amendment in line with the scope of the Directive (healthcare services and products).

Amendment 26

Proposal for a directive

Article 4 - point h

Text proposed by the Commission	*Amendment*
(h) 'Member State of affiliation' means the Member State where the patient ***is an insured person***;	(h) 'Member State of affiliation' means the Member State where the patient ***has social security affiliation in accordance with the coordination rules laid down in Regulation (EEC) No 1408/71***;

Amendment 27

Proposal for a directive
Article 4 - point i

Text proposed by the Commission	*Amendment*
(i) 'Member State of treatment' means the Member State on whose territory cross-border healthcare is actually provided;	(i) 'Member State of treatment' means the Member State on ***or from*** whose territory cross-border healthcare is actually provided;

Justification

- definition 'Member State of treatment': 'or from whose' should clarify that telemedicine is also included in the definition.

Amendment 28

Proposal for a directive
Article 4 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) 'medical device' means a medical device as defined by Directive 93/42/EEC or Directive 90/385/EEC or Directive 98/7/EC;

Justification

The purchase of goods in connection with healthcare (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments

Amendment 29

Proposal for a directive
Article 4 – point i b (new)

Text proposed by the Commission	*Amendment*
	(ib) 'goods used in connection with health care' means goods which are used to preserve or improve a person's health, such as medical devices and medicines;

Justification

The purchase of goods in connection with healthcare (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments

Amendment 30

Proposal for a Directive
Article 5 - title and paragraph 1 and point a

Text proposed by the Commission	*Amendment*
Responsibilities of authorities of the Member ***State of treatment***	Responsibilities of the authorities of the Member ***States***
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 ***on the basis of the*** principles of universality, ***geographical and financial*** access to good quality care, ***efficiency and effectiveness, continuity,*** 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) mechanisms ***which deliver high quality systematic education and training for healthcare professionals,*** are in place ***toensure*** that healthcare providers are able to meet such standards, taking into account international medical science and generally recognised good medical practices;

Amendment 31

Proposal for a directive
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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) the healthcare ***referred to in paragraph 1 is provided in accordance with the 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 are provided with information on such standards and guidelines, including provisions on supervision, inter alia by electronic means;
	(ii) patients and healthcare providers from other Member States are provided with information on available treatments, availability, average or, if applicable, mandatory prices of the healthcare provided and details on the rules regarding insurance cover or other means of personal or collective protection with regard to the professional liability of healthcare providers;

Justification

The provisions of Article 11 should be incorporated into Article 5 as they deal with the same subject matter. The deletion of Article 11 can be considered.

For reasons of subsidiarity and proportionality, the definition of quality and safety standards should be treated exclusively as a matter for the applicable law.

Patients and providers must be informed about Member States' quality and safety standards. However, patients must also be informed about therapeutic options in order to be able to make a choice.

Amendment 32

Proposal for a directive
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) healthcare providers provide all relevant information to enable patients to 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;	(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on ***treatment options,*** availability, prices and ***quality certifications and risks inherent in*** the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Justification

Patients must be told about the different therapeutic options in order to be able to make an informed choice.

Amendment 33

Proposal for a Directive
Article 5 - paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) patients have a means of making complaints and are guaranteed remedies and compensations when they suffer harm arising from the healthcare they receive;	***deleted***

Amendment 34

Proposal for a directive
Article 5 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(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 ***the*** territory;

Amendment 35

Proposal for a Directive
Article 5 - title and paragraph 1 – point f and g and paragraph 1a and 1b

Text proposed by the Commission	*Amendment*
(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) there is a right to continuity of care by means of*** the ***forwarding of relevant medical data concerning the patient. In this context*** the fundamental right to privacy with respect to the processing of personal data ***must be*** 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) systematic and continuous efforts shall be made to ensure that these standards are improved, in accordance with the Council Conclusions on common values and principles in European Union health systems*, and taking into account advances in international medical science, generally recognised good practice and new healthcare technologies;
	(gb) the public authorities of the Member States of treatment shall regularly check the accessibility, quality and financial state of their healthcare systems on the basis of the data gathered in accordance with Article 18; they shall, on a regular basis, take appropriate measures to maintain the level of public health and the financial viability of their social security

systems;

gc) healthcare providers shall not be required under this Directive to accept planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, in particular through increasing waiting times.

(gd) the right to written or electronic medical records, with a view to continuity of care, must be safeguarded;

(ge) the calculation of the costs of healthcare provided to patients from other Member States corresponds to the actual average costs charged to patients or to their health insurance companies in the Member State of treatment;

1a. In order to maximise patient safety the Member States of treatment and affiliation shall ensure that:

(a) patients have a means of making complaints notably to a European Ombudsman who will treat patient complaints as regards prior authorisation, the quality of treatment and payments, and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;

(b) the quality and safety standards of the Member State of treatment are made public in a language and format that is clear and accessible to all citizens;

(c) there is a right to continuity of care of notably by means of the forwarding of relevant medical data concerning the patient with due respect to provisions of paragraph 1 - point (e) and pursuant to article 13 and 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;

(d) in the event of complications resulting from healthcare provided abroad or if a

particular medical follow-up proves necessary, the Member State of affiliation guarantees to provide healthcare equivalent to that received on its territory;

(e) they immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services;

1b. The Commission shall in accordance with the procedure referred to in Article 19(2), adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

**** OJ C 146, 22.6.2006, p. 1.***

Amendment 36

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, shall develop ***proposals*** to facilitate the implementation of paragraph 1***. These guidelines will support Member States in defining clear quality and safety criteria for healthcare provided on their territory.***

Justification

The Commission is responsible only for the provision of cross-border healthcare. Developing guidelines would clearly encroach on Member States' responsibilities in relation to the healthcare system. Under the subsidiarity principle, the Member States are responsible for the organisation of their health services.

Amendment 37

Proposal for a directive – amending act
Article 6 – title

Text proposed by the Commission	*Amendment*
Healthcare provided in another Member State	Healthcare provided in ***or from*** another Member State

Amendment 38

Proposal for a directive – amending act
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 ***from*** another Member State ***without physically visiting that Member State or seeking to purchase goods connected with health care there are not*** prevented from receiving ***this*** healthcare ***or these goods*** where the treatment ***or goods*** in question ***are*** 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 ***or the same or similar goods been purchased in its territory***. ***This Directive shall not prevent Member States from adopting more favourable rules, for example that the costs of treatment shall be reimbursed at the (higher) rate which applies in the Member State where the treatment has been provided or the goods purchased. This may in particular be the case for treatments which can be provided through the European reference networks referred***

	to in Article 15 of this Directive. In any event, it is for the Member State of affiliation to determine ***what health care services and goods are*** paid for regardless of where ***they are*** provided ***or purchased***.

Justification

The proposal provides only for a way of enabling Member States to restrict the outflow of patients. A way must also be provided for achieving the converse, namely limiting the inflow of patients. Both the outflow and inflow of patients may jeopardise the financial balance of social security schemes and/or the capacity and accessibility of care.

Amendment 39

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***, to the extent that they are among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled,*** be reimbursed ***or paid*** by the ***social security system of 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 ***treatment which is equally effective for the patient*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States shall 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.***

Amendment 40

Proposal for a directive – amending act
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may impose on a patient seeking healthcare ***provided*** in another Member State, the same conditions***, criteria of eligibility*** and regulatory and administrative formalities ***for receiving healthcare and reimbursement of healthcare costs*** as it would impose if the same or similar healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom ***of movement of persons***.	3. The Member State of affiliation may impose on a patient seeking healthcare ***services or goods connected with health care*** in another Member State, the same conditions and regulatory and administrative formalities ***including codes of conduct of the medical professions*** as it would impose if the same or similar healthcare was provided ***or the same goods were purchased*** in its territory, in so far as they are neither discriminatory nor an obstacle to freedom ***to provide goods and services***.

Justification

It is not the free movement of persons that is relevant here (this principle underlies Regulation No 1408/71). Rather, it is freedom to provide goods and services that is relevant here.

Amendment 41

Proposal for a directive – amending act
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.	4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation. ***These costs shall also include travel, where a situation of undue delay, or unavailability of treatment in the case of rare diseases, arises, without prejudice to the case of treatments which are specifically proscribed in the Member State of affiliation***

Justification

If insured persons are forced to travel for healthcare in another Member State, due to undue delay or unavailability of treatment, which is particularly relevant in the case of rare diseases, travel costs should also be factored into the eligible costs to be reimbursed by the healthcare provider in the Member State of affiliation. However, this shall not apply in cases where treatments are specifically proscribed in the Member State of affiliation.

Amendment 42

Proposal for a directive – amending act
Article 7

Text proposed by the Commission	*Amendment*
7. The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.	7. The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State ***or the purchase of goods connected with health care which are purchased in another Member State*** subject to prior authorisation, where the cost of that care, if it had been provided in its territory, ***or of those goods, if they had been purchased in its territory,*** would have been paid for by its social security system.

Justification

The purchase of goods in connection with healthcare (e.g. medical devices) was the subject of the Decker judgment (the device to which that case applied being spectacles), and should therefore also be incorporated into a directive intended to codify the Kohll and Decker judgments.

Amendment 43

Proposal for a directive
Article 8 – Title

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

Amendment 44

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).	***2.*** This list shall be set up ***in cooperation and dialogue with Member States' health authorities*** 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).

Justification

It is good practice for there to be cooperation and dialogue with the competent health authorities of the Member States in setting up this specific list, given that diseases and their treatment are not the same in all Member States.

Amendment 45

Proposal for a directive
Article 8 – paragraph 3 – point (a)

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State ***where the following conditions are met:***	3. ***By way of exception,*** the Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State ***in the case where***:
(a) healthcare which requires ***overnight*** accommodation of the patient ***in question for at least one night.***	(a) healthcare which ***can be provided only within a medical infrastructure and which normally*** requires ***the*** accommodation of the patient.
(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:	(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:
(i) the financial balance of the Member State's social security system; and/or	(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation ***carried out*** in the hospital sector ***to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence*** on the territory of the concerned Member State.	(ii) the planning and rationalisation ***objectives of the Member State*** in the hospital sector ***to ensure that there is a sufficient and permanent access to a balanced range of high quality hospital treatment*** on the territory of the concerned Member State ***and to avoid wastage of financial, technical and human resources.***

Amendment 46

Proposal for a directive
Article 8 – paragraph 4 a – (new)

Text proposed by the Commission	*Amendment*
	4a. Where prior authorisation has been sought and given, the Member State of affiliation shall ensure that the patient is only expected to pay up front any costs that they would be expected to pay in this manner had their care been provided in their home health system. Member States should seek to transfer funds directly between the funders and the providers of care for any other costs.

Amendment 47

Proposal for a directive
Article 8 – paragraph 5 a – (new)

Text proposed by the Commission	*Amendment*
	5a. Patients who are on a waiting list for medical treatment in their Member State of affiliation shall not be subject to prior authorisation, if the time required to obtain it would be prejudicial to their state of health or their receipt of medical treatment, or where the treatment in question can not be provided for the person concerned in their Member State of affiliation, notwithstanding procedures which are specifically proscribed under

the law of the Member State of affiliation.

Justification

Patients facing undue delay should not require prior authorisation. This is the same for patients who can not access treatments due to their unavailability in their Member State of affiliation. However, this should not be construed as facilitating the provision and funding of treatments which are specifically proscribed under the law of the Member State of affiliation.

Amendment 48

Proposal for a directive
Article 8 – paragraph 5 b – (new)

Text proposed by the Commission	*Amendment*
	5b. Patients who are on a waiting list for medical treatment in their home country and are in urgent need of care shall not be subject to prior authorisation.

Justification

Patients who are on a waiting list in their home country and are in urgent need of care should be empowered to seek timely treatment in another Member State without being subject to prior authorisation. They also should be recognised the right for their care, often expensive, to be fully paid directly by the country of origin to the country of provision of care (without having to pay up-front).

Amendment 49

Proposal for a directive
Article 8 – paragraph 5 c – (new)

Text proposed by the Commission	*Amendment*
	5c. Patients with rare diseases shall not be subject to prior authorisation.

Justification

In a context of global scarcity of knowledge and expertise at national level, patients affected by rare diseases, both diagnosed and undiagnosed, should be recognised the right to choose where to purchase healthcare, without prior authorisation. They should also be recognised the right for their care, often expensive, to be fully paid directly by the country of origin to the country of provision of care (without having to pay up-front), even and especially when the

care they need does not exist in their country of affiliation, as this is often the reason for which they need to go abroad.

Amendment 50

Proposal for a directive – amending act
Article 9 – paragraph -1 a (new)

Text proposed by the Commission	*Amendment*
	-1a. Authorisation schemes shall be based on criteria which preclude the competent authorities from exercising their power of assessment in an arbitrary or discretionary manner.

Amendment 51

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

Text proposed by the Commission	*Amendment*
	3a. Where prior authorisation has been granted, the Member State of affiliation shall seek reimbursement for any further cost to be provided directly from the purchaser to the provider.

Justification

Member States should facilitate the direct payment of costs incurred between the insurer in the Member State of affiliation to the service provider in the Member State of treatment. This should be the case so that patients will not have to be burdened with upfront costs which might serve as a barrier to access to treatment.

Amendment 52

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

Text proposed by the Commission	*Amendment*
	5a. There will be a European Ombudsman who will treat patient complaints as regards prior authorisation,

the quality of treatment and payments.

Justification

Patients should be entitled to have their voices heard at EU level when they have complaints about important issues such as prior authorisation, the quality of treatment and payments.

Amendment 53

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

Text proposed by the Commission	*Amendment*
	5b. 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.

Justification

Member States should facilitate the reimbursement of costs between Member States in a manner that would allow as objective and impartial cost measurement as possible. This could form part of an efficient solution for achieving this objective.

Amendment 54

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 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

State.	State. ***Patients' organisations should be involved in cooperating with competent national authorities in the process of providing and disseminating information to patients.***

Justification

Patients organisations are a valuable resource in supporting national competent authorities involved in the process of providing and disseminating information directly to patients.

Amendment 55

Proposal for a directive
Article 10 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a There will be an independent counselling centre in every Member State to advice patients on the different treatments in the Member States. On the basis of the information the counselling centre provides, patients decide which treatment they prefer.

Amendment 56

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***These national contact points should be established in an efficient and transparent way. The information about their existence should be appropriately disseminated across Member States, so that patients have an easy access to the information.***

Amendment 57

Proposal for a directive
Article 12 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The national contact points for cross-border health care may also be incorporated into existing information centres in the Member States.

Justification

Recital 36 of the preamble clearly states that national contact points may be incorporated into existing structures in the Member States, and this should be clearly expressed in the provisions of the directive. This will make it possible to avoid placing additional administrative burdens on the Member States in connection with the implementation of the directive.

Amendment 58

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The national contact point in the Member State of affiliation shall, in close cooperation with other competent national authorities, and with national contact points in other Member States, in particular in the Member State of treatment, and with the Commission:	2. The national contact point in the Member State of affiliation shall, in close cooperation with other competent national authorities***, yet independently of same,*** and with national contact points in other Member States, in particular in the Member State of treatment ***with patients' organisations*** and with the Commission:

Justification

It is imperative to establish functional independence between the national contact points and other competent national authorities, such as national health services, as there may be an incentive for the latter to operate the former subject to its own, rather than patients', prerogatives.

Amendment 59

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 the guarantees of quality and safety, protection of personal data, ***the public or private status of the care provider, the reimbursement procedure and rates,*** procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Amendment 60

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

Text proposed by the Commission	*Amendment*
(d) facilitate the development of international out-of-court settlement scheme for disputes arising from cross-border healthcare;	(d) facilitate the development of international out-of-court settlement scheme, ***in cooperation with the Ombudsman,*** for disputes arising from cross-border healthcare;

Justification

The Ombudsman is an independent authority operating in every Member State, who principally investigates individual administrative practices or omissions or material actions by public service bodies which infringe the rights or prejudice the legitimate interests of natural or legal persons. In this specific instance, the Ombudsman could help towards the settlement of disputes.

Amendment 61

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

Text proposed by the Commission	*Amendment*
	(ea) Primary care providers shall inform patients of the availability and function of the national contact points in their

Member State of affiliation.

Justification

Primary care providers, such as family doctors/general practitioners, are in most cases the first point of contact between patient and health service. Therefore, in order to make patients aware of their rights to cross-border healthcare, primary care providers should be obliged to point patients in the direction of national contact points to give them the fullest information possible on their treatment options.

Amendment 62

Proposal for a Directive
Article 13 – paragraphs 2a, 2b and 2c (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that their various competent authorities cooperate in order to guarantee that the information made available to patients in accordance with the provisions of Article 10 is reliable.
	2b. Member States shall cooperate to ensure the medical follow-up and/or treatment of any complications resulting from healthcare provided abroad. The Member State of treatment shall ensure that the Member State of affiliation responsible for providing that follow-up and or treatment has the possibility of redress in the event of harm and shall provide access to the medical file.
	2c. There shall be an EU register of professional medical practitioners who have been struck off the medical register or are subject to restrictions or disciplinary procedures by the relevant authorities of any Member State in the EU.

Justification

The duty to cooperate should apply to the new provisions of Articles 5 and 10.

Amendment 63

Proposal for a directive
Article 14 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. If a medicinal product is authorised to be marketed on their territory in accordance with Article 6(1) of Directive 2001/83/EC, Member States shall ensure that prescriptions issued by an authorised person in another Member State for a named patient can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:	1. If a medicinal product is authorised to be marketed on their territory in accordance with Article 6(1) of Directive 2001/83/EC, Member States shall ensure that prescriptions issued ***for that medicinal product*** by an authorised person in another Member State for a named patient can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:

Justification

Artikel 6 der Richtlinie 2001/83/EG sieht vor, dass nur im jeweiligen Mitgliedstaat zugelassene Arzneimittel in den Verkehr gebracht werden dürfen. Diese nationalen Zulassungen machen auch heute noch den weit überwiegenden Marktanteil der Arzneimittel gegenüber zentralen europäischen Zulassungen auf der Grundlage der Verordnung (EG) 726/2004 aus. Auch bei an sich unzweifelhaft authentischen Verschreibungen können im konkreten Einzelfall legitime und begründete Zweifel an der Befugnis der verschreibenden Person zur Verschreibung des fraglichen Arzneimittels bestehen, z.B. bei einer möglichen Überschreitung berufsrechtlicher Grenzen der Approbation. Diesen möglichen Zweifeln wird durch die Änderung in Buchstabe b) Rechnung getragen.

Amendment 64

Proposal for a directive
Article 14 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription.	(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription ***or about the prescribing party's right to issue the prescription***.

Justification

Artikel 6 der Richtlinie 2001/83/EG sieht vor, dass nur im jeweiligen Mitgliedstaat zugelassene Arzneimittel in den Verkehr gebracht werden dürfen. Diese nationalen

Zulassungen machen auch heute noch den weit überwiegenden Marktanteil der Arzneimittel gegenüber zentralen europäischen Zulassungen auf der Grundlage der Verordnung (EG) 726/2004 aus. Auch bei an sich unzweifelhaft authentischen Verschreibungen können im konkreten Einzelfall legitime und begründete Zweifel an der Befugnis der verschreibenden Person zur Verschreibung des fraglichen Arzneimittels bestehen, z.B. bei einer möglichen Überschreitung berufsrechtlicher Grenzen der Approbation. Diesen möglichen Zweifeln wird durch die Änderung in Buchstabe b) Rechnung getragen.

Amendment 65

Proposal for a directive
Article 14 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. For facilitating the implementation of paragraph 1, the Commission shall ***adopt***:	2. For facilitating the implementation of paragraph 1, the Commission shall ***suggest***:

Justification

The listed measures are bound to have an effect on the activities of healthcare professionals and the protection of public health. Member States should be allowed to retain their competence in these fields.

Amendment 66

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

Text proposed by the Commission	*Amendment*
(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;	(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions. ***Data protection safeguards will be taken into account and incorporated from the initial stage of this development process;***

Justification

As recommended in the EDPS opinion, this is important in order to have a high level of data protection

Amendment 67

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

Text proposed by the Commission	*Amendment*
	(ba) measures to facilitate contact between the prescribing party and the dispensing party with a view to resolving uncertainties about prescription;

Justification

A system of European prescriptions recognition should permit direct contact between doctors and pharmacists. Such direct contact is an essential precondition for the resolution of uncertainties concerning treatment with medicines, and is already current practice in the Member States.

Amendment 68

Proposal for a directive
Article 14 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Article 14 shall also apply to prescriptions for the supply of medical devices authorised in accordance with the laws of the Member State concerned.

Amendment 69

Proposal for a directive
Article 15 – paragraph 3 – introductory part and point a

Text proposed by the Commission	*Amendment*
The Commission shall adopt:	The Commission shall adopt:
(a) a list of specific criteria and conditions that the European reference networks must	(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:	fulfil, including ***a list of rarer disease areas needing to be taken into account and*** 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:

Justification

As stated in the Explanatory Memorandum to the Commission proposal (point 8.3), the main objective of the European reference network is to 'provide healthcare to patients who have conditions requiring a particular concentration of resources or expertise, in order to provide affordable, high quality and cost-effective care.' The relevant article of the directive should reflect this.

Amendment 70

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

Text proposed by the Commission	*Amendment*
	(ba) measures to ensure the financial affordability and geographical accessibility of European reference networks.

Justification

If the provision of certain specialised care is to be organised at European level, guarantees must be provided that it remains accessible.

Amendment 71

Proposal for a directive
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16a
	Telemedicine
	Telemedicine practitioners who provide healthcare for patients in the EU shall be registered with the medical regulator of

the Member State from where the telemedicine treatment is provided.

Justification

Medical regulators in EU Member States must regulate all doctors who provide healthcare for patients in their Member States, irrespective of where the practitioner is providing such treatment.

Amendment 72

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

Justification

The proposed network must be operated according to good governance principles, as established in the Commission's White Paper on European Governance (2001), particularly with regard to openness, accountability, effectiveness and coherence. Cooperation on health technology assessments should be to foster transparent, objective, inclusive and timely procedures. The Commission should therefore only admit health technology assessment authorities which meet these standards. This amendment goes with an amendment to Recital 43.

Amendment 73

Proposal for a directive
Article 17 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The European Commission shall, in consultation with the European Parliament, set up an operational framework for the network which is based on the principles of good governance including transparency, objectiveness, fairness of procedures, and broad and full stakeholder participation of all relevant societal groups including healthcare professionals, patients, researchers and

industry.

Justification

The proposed network must be operated according to good governance principles, as established in the Commission's White Paper on European Governance (2001), particularly with regard to openness, accountability, effectiveness and coherence. Cooperation on health technology assessments should be to foster transparent, objective, inclusive and timely procedures. The Commission should therefore only admit health technology assessment authorities which meet these standards. This amendment goes with an amendment to Recital 43.

Amendment 74

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

Text proposed by the Commission	*Amendment*
	(aa) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets;
	(ab) develop transparent, objective, inclusive and timely procedures and methodologies which are balancing all objectives;
	(ac) ensure full participation of all relevant societal groups, in particular patients, medical community, research and industry;

Justification

The proposed network must be operated according to good governance principles, as established in the Commission's White Paper on European Governance (2001), particularly with regard to openness, accountability, effectiveness and coherence. Cooperation on health technology assessments should be to foster transparent, objective, inclusive and timely procedures. The Commission should therefore only admit health technology assessment authorities which meet these standards. This amendment goes with an amendment to Recital 43.

Amendment 75

Proposal for a directive
Article 17 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.	(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies ***and on their possible side-effects and impacts on society,*** and enable an effective exchange of this information between national authorities or bodies.

Justification

This article provides for cooperation among the bodies responsible for technology impact assessments in the healthcare sector. These bodies possess information not only on the effectiveness of technologies but also on their possible side-effects and the changes they may bring about in society. An exchange of information on these issues should therefore also take place.

Amendment 76

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.	3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1.***The Commission shall only allow authorities to join the network which fulfil the principles of good governance.***

Justification

The proposed network must be operated according to good governance principles, as established in the Commission's White Paper on European Governance (2001), particularly with regard to openness, accountability, effectiveness and coherence. Cooperation on health technology assessments should be to foster transparent, objective, inclusive and timely procedures. The Commission should therefore only admit health technology assessment authorities which meet these standards. This amendment goes with an amendment to Recital 43.

Amendment 77

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 and the management of this network ***according to the above objectives*** and specifying the nature and type of the information to be exchanged.

Justification

The proposed network must be operated according to good governance principles, as established in the Commission's White Paper on European Governance (2001), particularly with regard to openness, accountability, effectiveness and coherence. Cooperation on health technology assessments should be to foster transparent, objective, inclusive and timely procedures. The Commission should therefore only admit health technology assessment authorities which meet these standards. This amendment goes with an amendment to Recital 43.

Amendment 78

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect statistical ***and other additional*** data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.	1. Member States shall collect statistical data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data***, and specifically Article 8(4) of Directive 95/46/EC***.

Justification

Article 8(4) of Directive 95/46 lays down specific requirements relating to subsequent use of health data.

Amendment 79

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall transmit the data referred to in paragraph 1 to the Commission ***at least annually***, except for data that are already collected pursuant to Directive 2005/36/EC.	2. Member States shall, ***if necessary,*** transmit the data referred to in paragraph 1 to the Commission, except for data that are already collected pursuant to Directive 2005/36/EC. ***An assessment of the necessity of these transfers for legitimate purposes will be duly specified in advance.***

Justification

The obligation to transmit data to the Commission should be subject to an assessment of necessity rather than by definition on an annual basis.

Amendment 80

Proposal for a directive
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months.	2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 of that Decision. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 3 months. ***Where implementing measures relate to the processing of personal data the European Data Protection Supervisor shall be consulted.***

Justification

As recommended in the EDPS opinion, it is important the EDPS is consulted on these matters.

Amendment 81

Proposal for a Directive
Article 20

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 and submit it to the European Parliament and to the Council. ***That report shall pay particular attention to the effects of the application of this Directive on the mobility of patients and of all the actors in the Member States' health systems. If necessary, the Commission shall include with the report proposals for amending the legislation.***
To that end and without prejudice to Article 22, the Member States shall communicate to the Commission any measure they ***have introduced, modified or maintained with a view to implement the procedures laid down in Articles 8 and 9.***	To that end and without prejudice to Article 22, the Member States shall communicate to the Commission any measure they ***are applying*** to implement the ***Directive.***

Justification

Some of the aspects that should be covered in the report need to be specified. Furthermore, the report should be presented after three years.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 2.9.2008
Associated committee(s) - date announced in plenary	23.9.2008
Rapporteur Date appointed	Bernadette Vergnaud 10.9.2008
Discussed in committee	6.11.2008 22.1.2009 11.2.2009
Date adopted	9.3.2009
Result of final vote	+: 19 –: 16 0: 2
Members present for the final vote	Mogens Camre, Gabriela Creţu, Janelly Fourtou, Evelyne Gebhardt, Martí Grau i Segú, Ioan Lucian Hămbăşan, Malcolm Harbour, Pierre Jonckheer, Eija-Riitta Korhola, Kurt Lechner, Lasse Lehtinen, Catiuscia Marini, Nickolay Mladenov, Catherine Neris, Bill Newton Dunn, Zita Pleštinská, Karin Riis-Jørgensen, Zuzana Roithová, Heide Rühle, Leopold Józef Rutowicz, Christel Schaldemose, Andreas Schwab, Eva-Britt Svensson, Jacques Toubon, Bernadette Vergnaud
Substitute(s) present for the final vote	Emmanouil Angelakas, Wolfgang Bulfon, Colm Burke, Jan Cremers, Magor Imre Csibi, Brigitte Fouré, Benoît Hamon, Othmar Karas, José Ribeiro e Castro, Olle Schmidt, Søren Bo Søndergaard, Anja Weisgerber, Stefano Zappalà
Substitute(s) under Rule 178(2) present for the final vote	Alfredo Antoniozzi, Thijs Berman, Christofer Fjellner, Jim Higgins, Maria Grazia Pagano

10.3.2009

OPINION OF THE COMMITTEE ON ECONOMIC AND MONETARY AFFAIRS

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Harald Ettl

SHORT JUSTIFICATION

The rapporteur welcomes the Commission's proposal for a directive on the application of patients' rights in cross-border healthcare, as the proposal seeks to increase transparency and legal certainty for patients. The growing quality of the services available at medical treatment institutions and better patient information suggest that patient mobility will increase. The advantages which can be derived for health policy from better-networked treatment institutions in Europe should be pursued with greater intensity. At the same time, it must be ensured that the proposal for a directive neither results in one-sided imposition of costs on Member States nor damages health care or the health services available within a country if disproportionate numbers of patients seek health services.

Health services were excluded from the scope of the Services Directive because these services are of overriding importance and should be recognised by separate European legislation. This being so, the European Parliament called on the Commission in an own-initiative report in May 2008 to propose a new European regulatory framework for cross-border health care. In July 2008, as part of the social package, the Commission published the proposal for a directive now under consideration, which is intended particularly to codify the case law of the Court of Justice of the EU concerning cross-border health care.

The rapporteur supports the Commission's proposal to facilitate cross-border patient mobility and to clarify patients' rights by means of secondary legislation. It ought to be possible at least to make full use of all synergies available in the field of medicine. This requires economic, insurance-related and organisational measures, for example relating to Member States' bed capacity and financial capacity. To avoid capacity problems in providing services to a Member State's own population on account of the numbers of patients coming from other Member States, patients should be afforded access to European establishments with due

consideration for the capacities of each Member State and its financial resources.

Pursuant to Article 35 of the Charter of Fundamental Rights of the European Union and Article 152(1) of the EC Treaty, Member States must ensure a high level of health protection. At present the health services on offer vary substantially between Member States. This situation should be further developed and preserved with high standards of quality. Health is an overriding concern and should be supported by treaty policy, quality assurance and ombudsman's rules. The possibility of cross-border health care must not encourage individual Member States to cease to develop their health institutions, nor should it provide an incentive for them to promote treatment abroad.

The rapporteur endorses the approach of allowing Member States, if the financial balance of their health system and/or a Member State's capacity to provide hospital services is seriously undermined, to introduce a requirement to obtain prior authorisation of reimbursements of costs. In this context it is important to point out that Member States must have the option of charging the full cost of a service to the systems from which patients come. In some Member States, hospital treatment is funded partly from social insurance contributions and partly from tax revenue. If patients from abroad were charged only the social insurance rate, those Member States whose inadequate capacity may provide the inducement for patients to seek treatment in another Member State would derive an unjustified financial advantage from tax-payers in the country of treatment.

AMENDMENTS

The Committee on Economic and Monetary Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 95(3) of the Treaty explicitly requires that***, *in achieving harmonisation,*** a high level of protection of human health should be guaranteed taking account in particular of any new	(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are fulfilled, the Community legislature shall rely on this legal basis even when public health protection is a decisive factor in the choices made; in this respect Article 95(3) of the Treaty explicitly requires that a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific

development based on scientific facts. facts.

Justification

The aim of this directive should be to clarify patients' rights and not to harmonise the organisation of health care. This is a matter for which Member States bear sole responsibility.

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. They are also part of the wider framework of services of general interest. ***They enjoy a special status among services of general interest on account of their priority objectives of ensuring patient safety and protecting public health.***

Justification

Although the directive under consideration creates a separate set of rules for health services, which were excluded from the Services Directive, the subject of health is treated in a manner similar to that which it was intended to adopt previously under the Services Directive. It must be made clear that health services are an overriding concern, taking precedence over other services.

Amendment 3

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	(15) Research suggests that ***physical*** 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. 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.	essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. 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.

Amendment 4

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. ***The Member State of affiliation should also reimburse other related costs, such as costs of therapeutic treatment.***

Justification

Although the directive under consideration creates a separate set of rules for health services, which were excluded from the Services Directive, the subject of health is treated in a manner similar to that which it was intended to adopt previously under the Services Directive. It must be made clear that health services are an overriding concern, taking precedence over other services.

Amendment 5

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.	This Directive shall apply to ***cross-border*** provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private. ***This Directive shall apply to statutory, private and combined sickness insurance schemes.***

Justification

'Cross-border' should be inserted, because otherwise the provision will be incompatible with Article 152 of the EC Treaty (complementary action by the Community).

Amendment 6

Proposal for a directive
Article 3 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) Regulations on coordination of social security schemes, in particular ***Article 22*** of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.	(f) Regulations on coordination of social security schemes, in particular ***Articles 19, 20, 22 and 25*** of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and ***Articles 17, 18, 19, 20, 27 and 28 of*** Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

Amendment 7

Proposal for a directive
Article 3 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) Directive 2002/83/EC of the

European Parliament and of the Council of 5 November 2002 concerning life assurance[1]:

[1] OJ L 345, 19.12.2002, p. 1.

Amendment 8

Proposal for a directive
Article 3 – paragraph 1 – point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance[1]; ***[1] OJ L 228, 16.8.1973, p. 3.***

Amendment 9

Proposal for a directive
Article 3 – paragraph 1 – point g c (new)

Text proposed by the Commission	*Amendment*
	(gc) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance (third non-life insurance Directive)[1]. ***[1] OJ L 228, 11.8.1992, p. 1.***

Amendment 10

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation	***Until the date of entry into force of Regulation (EC) No 883/2004,*** when the circumstances under which an authorisation to go to another Member

(EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. ***Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply.*** However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Justification

The sentence which is to be deleted establishes an 'opt-in' from Regulation No 1408/71/EC to this directive: the consequences and administrative practicality of this are unclear, and it is undesirable to undermine Regulation No 1408.

Amendment 11

Proposal for a directive
Article 3 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

From the date of entry into force of Regulation (EC) No 883/2004,

when the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 20 of Regulation (EC) No 883/2004 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 20 of Council Regulation (EC) No 883/2004 shall not apply. However, whenever the conditions

for granting an authorisation set out in Article 20(2) of Regulation (EC) No 883/2004 are fulfilled, the authorisation shall always be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Amendment 12

Proposal for a directive
Article 4 – point g – point ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) an insured person as defined in the policy conditions of the relevant private sickness insurance schemes;

Amendment 13

Proposal for a directive
Article 5 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Pursuant to Article 152 of the Treaty, the Member State of treatment is fully responsible for the organisation of the health care system and for the medical care provided.

Justification

The 'recipient side' is not addressed; hence the reference to the EC Treaty here.

Amendment 14

Proposal for a directive
Article 5 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. In accordance with Article 12(2)(da), the authorities of the Member State of treatment shall be responsible for constant monitoring on the basis of the data obtained there. The authorities shall,

	if appropriate, on the basis of the results of that monitoring, take prompt measures to ensure public health and preserve the financial balance of the social security system.

Justification

As the data are collected anyway, it should be possible to put them to immediate use to help Member States to plan their national health policies - to 'act instead of reacting'.

Amendment 15

Proposal for a directive
Article 5 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In view of the major importance, particularly to patients, of safeguarding the quality and safety of cross-border care, the organisations involved in drawing up norms and guidelines as referred to in paragraphs 1 and 3 shall at least include patients' organisations, and, in particular, those with a cross-border remit.

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	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***. The competent institution*** of the Member State of affiliation shall reimburse the ***effective*** costs ***of the***

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.	***treatment*** to the insured person. ***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, if they are not available in the 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.

Justification

Clarification that it is not the Member State but the social insurance institution(s) concerned that should reimburse the costs. Clarification that not only the costs to be covered by the statutory social security system but also those to be covered by the State-financed health systems are to be reimbursed.

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 competent institution of*** 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.

Justification

Clarification that it is not the Member State but the social insurance institution(s) concerned that should reimburse the costs.

Amendment 18

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by ***the*** statutory ***social security*** system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.	4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by ***the*** statutory ***health*** system ***concerned*** for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

Justification

Clarification that not only the costs to be covered by the statutory social security system but also those to be covered by the State-financed health systems or mixed systems are to be reimbursed.

Amendment 19

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).	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). ***In drawing up that list, the Commission shall take account of the special position of European reference networks as referred to in Article 15.***

Amendment 20

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 apply without prejudice to Article 3(2) and*** shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

Amendment 21

Proposal for a directive
Article 8 a (new)

Text proposed by the Commission	*Amendment*
	Article 8a
	Rejection of hospital and specialised care
	8a. A Member State of treatment may permit an individual healthcare provider to refuse hospital or specialised care to patients in another Member State who seek treatment in that Member State if that would be detrimental to other patients with similar health needs, for example because of increased waiting time for treatment.

Justification

Inclusion of the last clause of Recital 12. This vital clause from the recitals is lacking in the body of the text of the directive: in the interests of legal certainty and greater clarity, it would be preferable to include this clause here. The aim of providing health care for patients as close as possible to their place of residence or work must not be made impossible on account of unlimited access for patients from other Member States.

Amendment 22

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State of affiliation shall	1. The Member State of affiliation shall

ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. ***In any event***, an insured person shall *always* be granted the authorisation pursuant to Regulations on coordination of social security referred to in *Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2* of Regulation 1408/71 *are met*.

ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. ***Until the date of entry into force of Regulation (EC) No 883/2004***, an insured person shall be granted the authorisation pursuant to *the* regulations on *the* coordination of social security referred to in *Article 3(1)(f) of this Directive, in accordance with Article 22(1)(c) and Article 22(2)* of Regulation 1408/71. ***From the date of entry into force of Regulation (EC) No 883/2004, an insured person shall be granted the authorisation on the basis of the regulations concerning the coordination of social security schemes as referred to in Article 3(1)(f) in accordance with Article 20 of Regulation (EC) No 883/2004.***

Amendment 23

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
10. 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 State.	10. 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 State. ***In regard to information relating to cross-border care, a clear distinction shall be made between the rights which patients have under this Directive and rights arising from regulations on the***

coordination of social security schemes as referred to in Article 3(1)(f).

Amendment 24

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that patients' organisations, health insurance funds and care providers are involved in the work of those national contact points.***

Amendment 25

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

Text proposed by the Commission	*Amendment*
	(da) register all activities in the Member State of treatment pursuant to Articles 6, 7, 8, 9 and 15 and notify the competent authorities of the Member State of treatment thereof, with healthcare providers supplying the necessary information as soon as they receive it.

Justification

To ensure that the procedure runs as smoothly as possible.

Amendment 26

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.	1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive ***and shall***

	conclude agreements in this regard.

Amendment 27

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies**,** cross-border healthcare provided on a temporary or ad hoc basis ***and other forms of cross-border cooperation***.	2. Member States shall facilitate cooperation in cross-border healthcare provision at ***national,*** regional and local level as well as through information and communication technologies ***and*** cross-border healthcare provided on a temporary or ad hoc basis***, and shall conclude agreements in this regard***.

Amendment 28

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article 15 a
	Border regions
	In order, in future, to establish as effective as possible a health care policy, the Commission shall designate border regions as trial areas where innovative initiatives relating to cross-border care can be thoroughly tested, analysed and assessed.

Amendment 29

Proposal for a directive
Article 20 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall be responsible for collecting the requisite information with a view to charting cross-border flows of patients and practitioners in order to be able to remedy any adverse effects

promptly and further encourage positive effects. The Commission shall include that information in the report referred to in paragraph 1.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ECON 2.9.2008
Rapporteur Date appointed	Harald Ettl 22.10.2008
Discussed in committee	11.12.2008 20.1.2009
Date adopted	9.3.2009
Result of final vote	+: 24 –: 0 0: 7
Members present for the final vote	Zsolt László Becsey, Pervenche Berès, Sharon Bowles, Udo Bullmann, Jonathan Evans, Elisa Ferreira, José Manuel García-Margallo y Marfil, Jean-Paul Gauzès, Donata Gottardi, Benoît Hamon, Gunnar Hökmark, Sophia in 't Veld, Othmar Karas, Wolf Klinz, Kurt Joachim Lauk, Hans-Peter Martin, Gay Mitchell, Sirpa Pietikäinen, John Purvis, Bernhard Rapkay, Eoin Ryan, Antolín Sánchez Presedo, Olle Schmidt, Peter Skinner, Margarita Starkevičiūtė, Ivo Strejček, Ieke van den Burg, Cornelis Visser
Substitute(s) present for the final vote	Harald Ettl, Margaritis Schinas, Eva-Riitta Siitonen

17.2.2009

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Françoise Grossetête

SHORT JUSTIFICATION

1) Background

It is important to clearly distinguish the scope of this proposal for a directive, in order to avoid any confusion or amalgam of ideas. The proposal is aimed solely at patient mobility. It does not relate to the mobility of healthcare professionals. The idea is not, therefore, to apply the 'Services Directive' to the field of health.

Generally speaking, patients want to access quality healthcare as close to where they live as possible and as quickly as possible. In some cases, however, the best healthcare is to be found in another Member State. Patients may thus travel elsewhere to obtain better quality, quicker or cheaper healthcare services.

Before accessing those healthcare services, there is a need for information enabling them to find out whether the various services are of good quality, available and suitable; it is also important for the applicable administrative procedure to be clear. Then, when patients actually decide to travel abroad for treatment, it is essential to guarantee that their safety and well-being are adequately safeguarded.

The current situation is characterised by the growing interdependence of health systems and health policies across the European Union.

That situation has developed owing to a host of factors, including an increase in the movement of patients and professionals within the EU (facilitated by the rulings of the European Court of Justice), the expectations that are shared by people across the Union and the dissemination of new medical technologies and techniques based on information technologies.

2) Weakness of the current system to the detriment of patients

There is, however, much legal uncertainty in this area. The Court of Justice has developed case law which is in part contradictory and which is not, moreover, applied in a uniform manner in all the Member States.

There is therefore a need to clarify the case law of the Court of Justice of the European Communities with regard to some of those rulings:

– any non-hospital care to which citizens are entitled in their own Member State, they may also seek in any other Member State without prior authorisation, and be reimbursed up to the level of reimbursement provided by their own system. As regards hospital care, the prior authorisation of the patient's own system is required. That authorisation must be given to the patient if their system cannot provide them with care within a medically acceptable time limit considering their condition. In this case too, the person concerned will be reimbursed up to at least the level of reimbursement provided by their own system;

– confirmation that matters relating to the organisation of health care social security are a national competence;

– maintenance of the need for prior authorisation for hospital care, which is the most burdensome and costly, and consequently of the Member State's regulatory and planning powers.

The directive does not aim to harmonise Member States' health or social security systems, but rather to strengthen legal certainty for patients and improve the current situations in the Member States.

One must nevertheless ask whether the directive awards enough attention to the real-life cases that handicap our citizens in their daily lives. Faced with such complexities, those primarily concerned sometimes voluntarily relinquish their rights. Everything possible must be done to inform patients, especially with regard to the European reference networks described in Article 15 of the directive, on procedures.

3) Need to act

By providing a framework for, and codifying, the case law of the Court of Justice, the directive will lend greater coherence and increased clarity to the actual rights of patients. Patient mobility must not, under any circumstances, result in 'dumping' between healthcare systems, or undermine the safety of healthcare.

Legal certainty should be ensured, and support provided for cooperation between national healthcare systems, in the interest of the patient. In order to achieve this, it is important to improve the provisions on the guarantee of patients' access to information and the credibility of sources of information on the provision of healthcare, pharmaceutical products and medical treatment.

The European Commission has also proposed that a network of national authorities or bodies responsible for health technology assessment (HTA) be set up, with a view to an optimum

harnessing of new technologies, in order to ensure the provision of safe, effective and high-quality healthcare. While this idea is worthy of support, the practical arrangements for that network could be amplified.

Similarly, it would seem vital to facilitate greater cooperation between emergency medical services in order to improve their coordination. This need is all the more apparent in cross-border areas.

Beyond the issue of cross-border healthcare itself, this initiative should make it possible to pinpoint the challenges and necessary reforms in the field of healthcare.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Title

Text proposed by the Commission	*Amendment*
Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights ***in cross-border*** healthcare	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights ***to access to safe, high-quality and effective*** healthcare***, under equitable conditions***

Justification

It is proposed that the proposal for a directive should not focus chiefly on patient mobility but on the three fundamental strands around which the Commission has structured its proposal: common principles in all EU health systems, European cooperation on healthcare and a specific framework for cross-border healthcare.

Amendment 2

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does not apply to assistance and support for families or individuals who are, over an extended period of time, in ***a*** particular ***state of*** need. ***It*** does not apply, for example, to residential homes or housing, or assistance provided to elderly people or children by social workers or volunteer carers or professionals other than health professionals.	(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does not apply to assistance and support for families or individuals who are, over an extended period of time, in particular need ***of nursing, support or care in so far as this involves specific expert treatment or help provided by a social security system. This covers above all such long-term care services as are considered necessary in order to provide the person in need of care with as full and independent a life as possible. This Directive*** does not apply, for example, to residential homes or housing, or assistance provided to elderly people or children by social workers or volunteer carers or professionals other than health professionals.

Justification

This amendment serves to clarify the fact that services in the area of social assistance or care, rehabilitation with a view to resuming work and long-term care are excluded from the scope of this directive.

Amendment 3

Proposal for a directive
Recital 25

Text proposed by the Commission	*Amendment*
(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such	(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such

a treatment is not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions.	a treatment is not among the benefits provided for by the legislation of the patient's Member State of affiliation***, or to modify the conditions for that entitlement, if they are provided for by the legislation of the Member State of affiliation***. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions.

Justification

Competency as regards the organisation of health services rests with the Member States in accordance with Article 152 of the EC Treaty.

Amendment 4

Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product ***is not authorised for marketing*** in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.	(27) This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing ***or healthcare services*** in the Member State where healthcare is provided, even if the medicinal product ***or healthcare services are not available*** in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State.

Justification

It is essential that a patient in a Member State other than that of residence can benefit from healthcare services and medicines even where they are not available in the Member State of affiliation.

Amendment 5

Proposal for a directive
Recital 43

Text proposed by the Commission	*Amendment*
(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***Cooperation in*** the evaluation of ***new*** health technologies ***can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This will also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant authorities of all the Member States, building on existing pilot projects.***	(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***However,*** the evaluation of health technologies ***and the potential restriction of access to new technologies owing to administrative decisions pose a number of basic social questions which call for the involvement of an extensive group of stakeholders and the introduction of a viable model of governance. Consequently, any cooperation should include not only the competent authorities in all the Member States, but also all the stakeholders, including healthcare professionals, patients' representatives and industry. Moreover, that cooperation should be based on viable principles of good governance such as the transparency, openness, objectivity and impartiality of procedures. The Commission should ensure that only health technology assessment bodies which adhere to those principles are allowed to join that network.***

Justification

The exchange of information between health technology assessment bodies presupposes and requires the implementation of principles of good practice (such as good governance, transparency and stakeholder participation) in the assessments conducted by the Member States. Health technology assessments must therefore fulfil the criteria of openness and objectivity and must be based on dialogue and involvement of all stakeholders, including patients and industry.

Amendment 6

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) In particular, power should be conferred on the ***Commission*** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive***; a list of specific criteria and conditions that European reference networks must fulfil; the procedure for establishing European reference networks***. ***Since those measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC***.	(45) In particular, power should be conferred on the ***Member States' competent authorities*** to adopt the following measures: a list of treatments, other than those requiring overnight accommodation, to be subject to the same regime as hospital care; accompanying measures to exclude specific categories of medicinal products or substances from the recognition of prescriptions issued in another Member State provided for in this Directive.

Amendment 7

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare.	This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare***, while ensuring that EU citizens have fair access to this care and respecting national competences as regards the organisation and provision of healthcare***.

Amendment 8

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare ***regardless of how it is organised, delivered and financed or whether it is public or private***.	This Directive shall apply to provision of healthcare***, defined in Article 4, which is not guaranteed by Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems***[1]
	_____
	[1] OJ L 166, 30.4.2004, p. 1.

Justification

Any overlapping of the directive and regulations would make it possible to establish two parallel systems for cross-border healthcare: under the regulations on the coordination of social security and under this new directive, which would give rise to legal uncertainty. The borderline between the scope of Regulation 883/2004 and this directive should be well defined.

Amendment 9

Proposal for a directive
Article 2 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	This Directive shall not apply to services mainly geared to long-term care. These include in particular services provided over an extended period that are designed to assist people with the general organisation of their day-to-day lives.

Justification

This amendment serves to clarify the fact that services in the area of social assistance or care, rehabilitation with a view to resuming work and long-term care are excluded from the scope of this directive.

Amendment 10

Proposal for a directive
Article 4 – point a

Text proposed by the Commission	*Amendment*
a) "healthcare" means a health service provided ***by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private***;	a) "healthcare" means a health service provided ***to patients to assess, maintain or restore their state of health***. ***For the purpose of Articles 6 to 11, "healthcare" means treatments that are among the healthcare benefits provided for by the legislation of the Member State of affiliation***;

Amendment 11

Proposal for a directive
Article 4 – point b

Text proposed by the Commission	*Amendment*
(b) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person ***or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established***;	(b) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person;

Justification

As in the case of recital 10, the concept of cross-border care would include both patient mobility in the narrower sense and the mobility of health services which can be provided remotely; the reference in this article to healthcare providers is not considered appropriate.

Amendment 12

Proposal for a directive
Article 4 – point g

Text proposed by the Commission	*Amendment*
(g) 'insured person' means	(g) 'insured person' means a person who is insured ***in accordance with the definition in*** Article 1(c) of Regulation (EC) 883/2004;

(i) until the date of application of Regulation (EC) No 883/2004: a person who is insured in accordance with the provisions of Articles 1, 2 and 4 of Regulation (EC) No 1408/71,

(ii) as from the date of application of Regulation (EC) No 883/2004: a person who is ***an*** insured ***person within the meaning of*** Article 1(c) of Regulation (EC) No 883/2004;

Justification

Regulation (EC) No 883/2004 comes into force on 1 January 2009.

Amendment 13

Proposal for a directive
Chapter II – title

Text proposed by the Commission	*Amendment*
MEMBER ***STATE AUTHORITIES*** RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE	MEMBER ***STATES*** RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE

Justification

If used, the term 'authorities' would need to be defined.

Amendment 14

Proposal for a directive
Article 5 – title

Text proposed by the Commission	*Amendment*
Responsibilities ***of authorities*** of the Member State of treatment	Responsibilities of the Member State of treatment

Justification

To be consistent with the amendment to the title of Chapter II.

Amendment 15

Proposal for a directive
Article 5 – paragraph 1 – introductory part

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. ***Where healthcare is dispensed in a Member State other than that in which the patient is affiliated, treatment shall take place in accordance with the legislation of the Member State where the treatment is dispensed. Healthcare shall be provided in accordance with the quality and safety standards and guidelines defined by the Member State in which the treatment takes place. That Member State must ensure that:***

Justification

This rewording reinforces the principle that the organisation and provision of healthcare falls within the national competence of the Member States. The principles of universality, quality, equity and solidarity of healthcare should be included in Article 1 on the objectives of the directive.

Amendment 16

Proposal for a directive
Article 5 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
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) mechanisms are in place for ensuring that healthcare providers ***and emergency medical services*** are able to meet such standards, taking into account ***developments in*** international medical science and generally recognised good medical practices;

Justification

It is important for quality standards to also cover emergency medical services.

Amendment 17

Proposal for a directive
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
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) the application of such standards by healthcare providers ***and emergency medical services*** 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;

Justification

It is important for quality standards to also cover emergency medical services.

Amendment 18

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.	***deleted***

Justification

It is preferable to delete this paragraph, given that the way in which the guidelines have been developed by the Commission interferes directly with exclusive national competencies in the area of the organisation and provision of healthcare.

Amendment 19

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 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. ***Patients shall be entitled to reimbursement for methods of treatment, even where those methods are not reimbursed in their own Member State, provided that this is the case in the host Member State and that the method is recognised by international medical science;***

Justification

Member States must have the right to design their own social security systems. However, the method of treatment used is often a question of practice within the medical profession based on its training and specialisation. This should not be a guiding principle in determining reimbursement, which should be dependent on the results achieved for the patient. This does not affect the level of reimbursement but simply gives patients greater freedom of choice, which is particularly important for patients with new or rarer diseases.

Amendment 20

Proposal for a directive
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) A national of a Member State may be affiliated to a health insurance scheme of a Member State other than that of residence, by paying contributions to that scheme.

Justification

Supporting the interests of citizens who are in a Member State other than that of residence means allowing them access to a health scheme of a Member State other than that of residence.

Amendment 21

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 ***in respect of the*** same ***medical condition*** in the Member State of affiliation, without exceeding the actual costs of healthcare received.

Justification

Member States must have the right to design their own social security systems. However, the method of treatment used is often a question of practice within the medical profession based on its training and specialisation. This should not be a guiding principle in determining reimbursement, which should be dependent on the results achieved for the patient. This does not affect the level of reimbursement but simply gives patients greater freedom of choice, which is particularly important for patients with new or rarer diseases.

Amendment 22

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC. ***Data shall be transmitted only with the express consent in writing of the patient or the patient's relatives.***

Justification

It is essential to ensure that data may only be transmitted with the explicit consent in writing of the patient or the patient's relatives.

Amendment 23

Proposal for a directive
Article 6 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The necessary measures shall be taken to enable EU citizens who suffer accidents or other medical emergencies in other Member States to receive high-quality emergency medical care.

Justification

Collaboration should not be restricted to accidents, but should also apply to other medical emergencies.

Amendment 24

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 ***the costs of*** healthcare provided in another Member State in accordance with this Directive, hospital care ***and specialised care*** shall mean, ***as defined in the legislation of the Member State of affiliation,*** healthcare that requires use of specialised and cost-intensive infrastructure or equipment***,*** or healthcare involving treatments presenting a particular risk for the patient or the population.
a) healthcare ***which requires overnight accommodation of the patient in question for at least one night.***	
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:	
- 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.	

Amendment 25

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).***	2. This list shall be set up and may be regularly updated by ***each Member State of affiliation or by the competent authorities of that Member State, depending on its specific organisational arrangements.***

Amendment 26

Proposal for a directive
Article 8 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) the purpose of the system is to address ***the consequent outflow of patients*** due to the implementation of the present Article and to prevent it from ***seriously*** undermining, or being likely to ***seriously*** undermine:	(b) the purpose of the system is to address ***significant patient flow*** due to the implementation of the present Article and to prevent it from undermining, or being likely to undermine:
(i) the financial balance of the Member State's social security system; and/or	(i) the financial balance of the Member State's social security system; and/or
(ii) the planning and rationalisation carried out in the ***hospital*** sector to avoid ***hospital*** overcapacity, imbalance in the supply of ***hospital care*** and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.	(ii) the planning and rationalisation carried out in the ***healthcare*** sector to avoid overcapacity, imbalance in the supply of ***healthcare*** and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment 27

Proposal for a directive
Article 8 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) The competent authorities of the Member State of affiliation shall establish criteria to identify when the financial balance of the Member States social security system, or the planning and rationalisation carried out in its healthcare sector, is undermined or is likely to be undermined.

Amendment 28

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, and shall not constitute a means of arbitrary discrimination.

Justification

To be consistent with the amendment to Article 8(3).

Amendment 29

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 ***of affiliation*** shall make publicly available ***the list of hospitals and specialised healthcare services and*** all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3.

Amendment 30

Proposal for a directive
Article 8 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The system of prior authorisation should not apply in cases of acute illnesses and emergencies where prompt action is essential. In addition, the requirement for prior authorisation shall be waived in the event of transfer from one hospital to another hospital in a different Member State.

Justification

Pre-authorisation is not feasible in acute cases. Emergencies must be treated separately, since pre-authorisation cannot be obtained in these cases. Likewise, in the case of hospitalised patients it is not usually possible to wait for the costs to be assumed.

Amendment 31

Proposal for a directive
Article 8 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5b. In the event of any requests for authorisation by an insured person to receive healthcare in another Member State, the Member State of affiliation shall ascertain whether the conditions laid down by Regulation (EC) No 883/2004 have been met and, if so, shall grant the prior authorisation in accordance with that Regulation.

Justification

The proposal for a directive is at odds with the existing rules on coordination of social security schemes. If the directive were to overlap with existing regulations, this would allow two parallel systems for cross-border healthcare to be established. In fact a dual system is being created because the proposal not only fails to identify the areas not covered in the regulation, but focuses essentially on those areas which it does already cover.

Amendment 32

Proposal for a directive
Article 8 – paragraph 5 c (new)

Text proposed by the Commission	*Amendment*
	5c. In any event, the Member State may refuse to grant prior authorisation if the same treatment can be provided within its territory within a medically justifiable timeframe, taking into account the current state of health of the patient concerned and the probable development of his or her illness.

Justification

It is proposed that the national health authority should be responsible (via prior authorisation) for ensuring that citizens are provided with healthcare by health professionals and at health centres with adequate quality and safety standards.

Amendment 33

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article ***8(3)***, ***reimbursement*** of costs of healthcare incurred in another Member State ***and other conditions and formalities referred to in Article 6(3)***, are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. ***In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.***	1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article ***8***, ***and assumption*** of costs of healthcare incurred in another Member State, are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved.

Justification

In the interests of legal clarity as regards the directive and the regulation.

Amendment 34

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and	2. Any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and

impartially within time limits set out and made public in advance by the Member States.	impartially within ***maximum*** time limits set out and made public in advance by the Member States. ***In dealing with such requests, account shall be taken of the urgency of the case and of individual circumstances.***

Justification

It is essential that the current situation should be maintained whereby it is public sector health professionals (particularly those involved in primary care who act as gate-keepers for the system) who decide on the need to provide healthcare to patients in other Member States, so as to avoid situations where healthcare is provided unnecessarily.

Prior authorisation may be seen by citizens as a restriction on their rights to cross-border mobility, although in reality it represents a guarantee for citizens who travel to undergo treatment.

Amendment 35

Proposal for a directive
Article 9 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:	***deleted***
(a) the specific medical condition,	
(b) the patient's degree of pain,	
(c) the nature of the patient's disability, and	
(d) the patient's ability to carry out a professional activity.	

Justification

To be consistent with the amendment to Article 9(2).

Amendment 36

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

Text proposed by the Commission	*Amendment*
	da) facilitate access by patients to the European reference networks referred to in Article 15.

Justification

Participation in European reference networks is subject to the conditions indicated in Article 15 of the Directive. These could hinder the participation of some Member States, which would be detrimental to patients from those Member States suffering from illnesses treated by these centres of reference.

Amendment 37

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.	2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation. ***This shall apply especially to cases of emergency medical care, with a view in particular to the smooth functioning of ambulance and rescue services.***

Justification

In the case of accidents and other medical emergencies in particular, cross-border cooperation, especially in the area of rescue services, should function smoothly so that delays do not occur as a result of bureaucratic obstacles.

Amendment 38

Proposal for a directive
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	fa) to implement instruments which enable the best possible use to be made of healthcare resources in the event of serious accidents, particularly in cross-border areas.

Justification

The European reference networks must cater for serious accidents requiring emergency medical care.

Amendment 39

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

Text proposed by the Commission	*Amendment*
	ix a) maintain appropriate and effective relations with technology providers;

Justification

The centres of reference are intended to speed up the dissemination of innovative medical technologies, but the text says nothing concerning relations with technology providers, who are an important source of innovation.

Amendment 40

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), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field,	***deleted***

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.

Justification

Political management of healthcare is not a question of interfering in how operations should be conducted, for example. It should be a question of establishing guidelines, conducting efficiency assessments, providing guidance on financial matters and monitoring that quality is satisfactory and in keeping with the level to which health policy aspires. The Member States have organised their healthcare in a safe and reliable manner. Healthcare, including the evaluation of new products and methods, should continue to be managed at national level, otherwise there is a risk that more bureaucracy will ensue.

Amendment 41

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

Justification

The assessments must apply to all health technologies, including existing technologies. This can help ensure effective allocation of resources from the Member States' health systems. In some cases, the funding for existing technologies could be reallocated to new technologies.

Amendment 42

Proposal for a directive
Article 17 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall establish, in agreement with the European Parliament, an operational framework for the network referred to in paragraph 1, based on principles of good governance, including procedural transparency, objectivity and impartiality, and on the participation of stakeholders from all the social groups concerned, including doctors, patients and industry.

Justification

The network must be open to stakeholder participation, so as to ensure that interinstitutional cooperation between the national authorities or bodies responsible for technology assessment results in a decision-making process that is balanced, informed and transparent.

Amendment 43

Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The objective of the health technology assessment network shall be:	2. The objective of the health technology assessment network shall be:
(a) ***to support cooperation between national authorities or bodies;***	(a) ***to find long-term ways of striking a balance between the objectives of public health and access to medicines, rewarding innovation and management of healthcare budgets;***
	(aa) to develop transparent procedures and methodologies with which to pursue these three objectives;
	(ab) to ensure that all the parties concerned, particularly patients, the medical community and industry, participate in addressing choices which can affect public health, innovation and

	competitiveness in Europe in the medium and long term;
(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies**.**	(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies***;***.
	(ba) to consider the nature and type of information that could be exchanged.

Amendment 44

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.	3. Member States shall***, with due regard for the assessment of the relative effectiveness of health technologies,*** designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.

Justification

The Commission must ensure that the principles of good governance are endorsed by the network. In this way everyone involved in health technology assessment will be able to support the decisions taken.

Amendment 45

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	4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment***,*** management ***and***

network ***and specifying the nature and type of the information to be exchanged***.	***transparency*** of this network.

Justification

The network must operate transparently in order to ensure that credible decisions are taken following the exchange of information. The network must decide what type of information is to be exchanged. All the participants in the network must be involved in that discussion, which must be one of network's key activities.

Amendment 46

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

Text proposed by the Commission	*Amendment*
	4a. The network referred to in paragraph 1 shall consult, and ensure the active involvement of, the representatives of industry, patient groups and the medical community.

Justification

The network must be open to stakeholder participation, so as to ensure that interinstitutional cooperation between the national authorities or bodies responsible for technology assessment results in a decision-making process that is balanced, informed and transparent.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 2.9.2008
Drafts(wo)man Date appointed	Françoise Grossetête 25.9.2008
Discussed in committee	5.11.2008 2.12.2008 20.1.2009
Date adopted	17.2.2009
Result of final vote	+: 25 –: 9 0: 1
Members present for the final vote	Jorgo Chatzimarkakis, Giles Chichester, Dragoş Florin David, Pilar del Castillo Vera, Den Dover, Lena Ek, Nicole Fontaine, Adam Gierek, Norbert Glante, Fiona Hall, David Hammerstein, Rebecca Harms, Erna Hennicot-Schoepges, Mary Honeyball, Werner Langen, Pia Elda Locatelli, Angelika Niebler, Reino Paasilinna, Atanas Paparizov, Miloslav Ransdorf, Paul Rübig, Patrizia Toia, Nikolaos Vakalis, Alejo Vidal-Quadras, Dominique Vlasto
Substitute(s) present for the final vote	Alexander Alvaro, Ivo Belet, Zdzisław Kazimierz Chmielewski, Neena Gill, Robert Goebbels, Françoise Grossetête, Gunnar Hökmark, Pierre Pribetich, John Purvis, Silvia-Adriana Ţicău

13.2.2009

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur: Diana Wallis

SHORT JUSTIFICATION

The rapporteur welcomes the increased legal certainty produced by the judgments of the Court of Justice on patients' right to receive health care in a Member State other than their own. She emphasises that this is a matter of direct importance to the daily lives and welfare of many EU citizens, particularly in view of the increasingly ageing profile of the population.

The rapporteur confirms the choice of legal basis and finds that the proposal for a directive complies with the principle of subsidiarity. This should serve to protect national health systems and allay concerns about the impact of the proposed directive on their future funding.

The rapporteur further notes the importance of the interaction of the directive with Regulation No 1408/71[1] and the complementary role which it will play thereto. Indeed, it is important to note that the proposal does not seek to replace the existing framework for cross-border healthcare set forth in that regulation. In fact, Regulation No 1408/71 organises the coordination of the national social security schemes, whilst the provisions regarding entitlements set out in the proposed directive and the provisions of Regulation No 1408/71 constitute alternative mechanisms for the assumption of medical costs incurred in other Member States. As a result, the patient has a choice: an insured person either benefits from the mechanism of that regulation or may opt for the system of the proposed directive.

The proposed directive will give EU citizens the right to seek non-hospital care in another Member State without their having to obtain prior authorisation from their national health schemes. Patients will need to pay for the care first and then seek reimbursement from their national systems. Under the proposal, the reimbursement will cover the costs of the care

[1] Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, OJ L 148, 5.6.1974, p. 35.

which would have been paid for by the national social security system had the care been provided on the national territory.

In view of the fact that the directive raises certain issues of private international law (claims may arise in both tort and contract in the course of the provision of medical care), the rapporteur has been at pains to underscore that the Community rules on jurisdiction and applicable law apply. There is no incompatibility with either the Rome I[1] or the Rome II[2] Regulation.

Having said that, your rapporteur would point to one aspect of "unfinished business" in that Parliament is awaiting a study promised by the Commission on damages in personal injury cases. With this aspect in mind, she has considered it appropriate to include in the proposed directive a recital on damages taken from the Rome II Regulation.

Lastly, as regards jurisdiction and the application of the Brussels I Regulation[3], the rapporteur considers that where the conditions set forth in the Court's judgment in the *Odenbreit*[4] case are satisfied, an injured party in a medical negligence case should be able to bring an action directly against his or her insurer in the Member State where the injured party is domiciled.

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Title

Text proposed by the Commission	*Amendment*
Proposal for a directive of the European Parliament and of the Council on the application of patients' rights ***in cross-border*** healthcare	Proposal for a directive of the European Parliament and of the Council on the application of patients' rights ***to access to safe, high-quality and effective*** healthcare***, under equitable conditions***

[1] Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), OJ L 177, 4.7.2008, p. 6.
[2] Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II), OJ L 199, 31.7.2007, p. 40.
[3] Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 12, 16.01.2001, p. 1.
[4] Case C-463/06 *FBTO Schadeverzekering* v. *Odenbreit* [2007] ECR I-11321.

Justification

El marco específico para la asistencia sanitaria afecta sólo a una minoría de pacientes, mientras que la mejora de la calidad y seguridad de la asistencia, así como la cooperación entre EEMM son cuestiones que redundarán en beneficio de la generalidad de los ciudadanos y se considera que deberían constituir el núcleo principal de la propuesta.

Se propone que la asistencia sanitaria transfronteriza no sea presentada como un ideal en la propuesta de directiva, sino como una segunda opción a considerar si no es posible la asistencia sanitaria en el lugar de residencia del ciudadano. Debe quedar claro que el objetivo es que el ciudadano pueda acceder a una asistencia sanitaria segura y de la mayor calidad lo más cerca posible de su lugar de residencia.

Amendment 2

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Notwithstanding the foregoing, in the case of claims based on contractual or non-contractual liability, the applicable law should be determined in accordance with the provisions of Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)[1] and Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)[2]. Jurisdiction should be determined in accordance with the provisions of Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters[3], it being understood that, where the conditions are satisfied, injured parties may bring an action directly against their insurer in the Member State in which they are domiciled.
	[1]OJ L 177, 4.7.2008, p. 6. ***[2]OJ L 199, 31.7.2007, p. 40.*** ***[3]OJ L 12, 16.1.2001, p. 1.***

Amendment 3

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive establishes a general framework for ***the provision of*** safe, high quality and efficient ***cross-border*** healthcare.	This Directive establishes a general framework for ***access by EU citizens to*** safe, high quality and efficient healthcare ***under equitable conditions, and establishes mechanisms for cooperation between Member States in the field of health, respecting national competences as regards the organisation and provision of healthcare***.

Justification

Se propone que el objetivo de la propuesta no se centre en abordar la movilidad de los pacientes, sino que su núcleo fundamental sean los otros 2 ejes en los que la Comisión Europea dice estructurar la propuesta: principios comunes a todos los sistemas sanitarios de la UE y cooperación europea en el ámbito de la salud.

La actual propuesta, centrada en la movilidad de pacientes, podría considerarse beneficiosa por un determinado perfil de ciudadanos (con alto poder adquisitivo, informados, con conocimiento de idiomas), pero se trata de una minoría de ciudadanos.

No obstante, la propuesta descuida las necesidades de la mayoría de los ciudadanos (perfil: sin recursos suficientes para adelantar el coste de la atención sanitaria prestada en otro EM, sin conocimientos suficientes de idiomas, sin suficiente información para poder desplazarse a otros EEMM) y genera inequidades.

Se propone que la propuesta no se centre en abordar la movilidad de pacientes (que sólo afecta a una minoría), sino en mejorar la calidad y seguridad de la asistencia, así como en la cooperación entre EEMM, aspectos que redundarán en beneficio de la generalidad de los ciudadanos.

Amendment 4

Proposal for a directive
Article 5 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) systems of professional liability insurance or a guarantee or similar arrangement, ***which are equivalent or***	(e) ***sufficient and effective*** systems of professional liability insurance or a guarantee or similar arrangement, which

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;	are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;

Justification

The concern is that the wording deleted might legitimise the provision of discretionary indemnity schemes.

Amendment 5

Proposal for a directive
Article 11 – title

Text proposed by the Commission	*Amendment*
Applicable rules to healthcare provided in another Member State	***Rules applicable*** to healthcare provided in another Member State ***and the law applicable to any claims arising on the basis of contractual or non-contractual liability***

Justification

It is necessary to distinguish in this provision between the rules applicable to the provision of healthcare services and the law applicable to any claims which might arise out of the provision of those services.

Amendment 6

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. 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 service is provided ***according to*** the legislation of the Member State of treatment ***in accordance*** with *Art.*5.	1. 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 service is provided ***in accordance with*** the legislation of the Member State of treatment ***and*** with *Article* 5.

Amendment 7

Proposal for a directive
Article 11 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. In so far as the provision of healthcare in a Member State other than that in which the patient is an insured person gives rise to claims based on contractual or non-contractual liability, the applicable law shall be determined in accordance with the provisions of Regulation (EC) No 593/2008 and Regulation (EC) No 864/2007. Jurisdiction shall be determined in accordance with the provisions of Regulation (EC) No 44/2001, it being understood that, where the conditions are satisfied, injured parties may bring an action directly against their insurer in the Member State in which they are domiciled.

Amendment 8

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

Text proposed by the Commission	*Amendment*
	(da) provide information and assistance to patients as injured parties where they bring an action directly against their insurer in the Member State in which they are domiciled.

Amendment 9

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

Text proposed by the Commission	*Amendment*
	2a. The national contact point in the Member State of affiliation shall provide,

	to patients so requesting, contact data for national contact points in other Member States.

Justification

Como se ha indicado en relación con el 10, este art. impone a los Estados miembros obligación de informar sobre datos en poder de otros EEMM, lo que supone una sobrecarga excesiva para los primeros. Además, para que la información fuera útil para los ciudadanos, se requeriría de una actualización continua, lo cual parece inviable. Entendemos que bastaría con que cada Estado miembro se responsabilizase de facilitar información en relación con la asistencia sanitaria prestada en su propio territorio y, en todo caso, facilitara información relativa a los datos de contacto de los puntos nacionales de contacto de otros Estados miembros.

Amendment 10

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.	1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive***, in cooperation with the regional and local authorities when they are responsible for the healthcare system***.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	JURI 2.9.2008
Drafts(wo)man Date appointed	Diana Wallis 22.9.2008
Discussed in committee	20.1.2009
Date adopted	12.2.2009
Result of final vote	+: 14 –: 7 0: 3
Members present for the final vote	Alin Lucian Antochi, Marek Aleksander Czarnecki, Bert Doorn, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Neena Gill, Klaus-Heiner Lehne, Alain Lipietz, Manuel Medina Ortega, Aloyzas Sakalas, Francesco Enrico Speroni, Diana Wallis, Rainer Wieland, Jaroslav Zvěřina, Tadeusz Zwiefka
Substitute(s) present for the final vote	Sharon Bowles, Mogens Camre, Jean-Paul Gauzès, Kurt Lechner, Arlene McCarthy, Georgios Papastamkos, Jacques Toubon
Substitute(s) under Rule 178(2) present for the final vote	Michael Cashman, Helga Trüpel

11.2.2009

OPINION OF THE COMMITTEE ON WOMEN'S RIGHTS AND GENDER EQUALITY

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur: Anna Záborská

SHORT JUSTIFICATION

Respecting the complementary nature of women and men, applying the equity principle

When the European legislator addresses the rights of patients, there is a need to apply the principle of equity. Men and women complement one another. There is no denying that women's medical needs differ from those of men; so the long-standing fundamental values that are common to the EU's healthcare systems, as the Council adopted them in June 2006, namely universality, access to good quality care, equity and solidarity, should also incorporate the principle of *equity in health*, which means calling for men and women to be treated equally where they have common needs, while at the same time addressing their differences in an equitable manner.

The rapporteur insists on the need to safeguard *access to public health systems* in the cross-border context. This naturally means providing gynaecological and obstetric care for maternal and neonatal health, as defined by the World Health Organisation at its 56th World Health Assembly in Alma-Ata (Resolution A56/21)[1].

The rapporteur draws attention to concern in the Committee on Women's Rights on the issue of *treatment of cancer* of the breast, which is today the main cause of death in the EU in women aged 35 to 55. Prevention, mammography screening and the treatment of breast or cervical cancer should be included in the procedures for reimbursement of cross-border healthcare. Similar requirements are needed for men, who should also benefit from preventive measures, screening and the treatment of lung, prostate, pancreatic or testicular cancer. We can save the lives of many women/mothers and men/fathers unknowingly affected by cancer

[1] International Conference on Primary Health Care, Alma-Ata; twenty-fifth anniversary; report by the Secretariat, Agenda item 14.7 of 24 April 2003.

if the legislator does not obstruct greater cross-border cooperation in this area, and if the Member States commit themselves to determined cooperation.

The procedures for the *reimbursement* of treatment and healthcare costs reveal differences between the sexes. Insurance companies, mutual societies and health funds should put a stop to any form of discrimination, including covert discrimination, when they are for instance based on risk factors associated with hereditary or genetic disorders. They should also stop calculating sickness insurance costs and insurance premiums as a function of the sex and type of work subject to indexation. In calculating costs and premiums the relevant mechanisms should cease all discrimination based on the type of work indexed. Many women do not work in the formalised employment market but rather invest their lives in other activities such as leading self-help networks for solidarity between the generations, looking after and bringing up children or caring for the elderly. The rapporteur therefore draws attention to the need to calculate costs and premiums rather in terms of the life-cycle, particularly in the case of women.

To *avoid discrimination between patients on the grounds of wealth or nationality,* I would suggest drawing on the experience of the European Directorate for the Quality of Medicines and HealthCare, a Council of Europe institution located in Strasbourg which works to improve the circulation of medicinal information between its members whilst also improving medicinal quality.

The implementation of *cross-border healthcare services* represents a huge opportunity for interregional cooperation. In practice this will take place in different ways, depending on the geographical configuration of the old Member States (EU-15) compared with the new Member States (EU-12) and some combinations of new and older Member States, particularly in the central Europe. Social and economic regional development is often variable, with the result that the organisation of public health is variable too. The situation is particularly evident at the crossroads between an old and a new Member State. As a result the Member States should do their utmost to foresee the economic and organisational effects forced upon healthcare professionals, healthcare providers and sickness insurance schemes. The needs of patients who benefit from cross-border healthcare services must be reconciled with those of healthcare staff, who are facing a new perception of healthcare services in economic terms. For health and the services concerned cannot be regarded purely in economic terms and subjected to the rules of competition. That view also explains the need to base this Directive not on Article 95 of the Treaty dealing with the operation of the free market, but on Article 152 relating to public health. It is for the Member States to take responsibility for safeguarding the continuity of the national public health service and access on equal conditions to that service, and to make the good health of all their citizens a priority. The Member States will continue to hold their national health card.

AMENDMENTS

The Committee on Women's Rights and Gender Equality calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Citation 1

Text proposed by the Commission	*Amendment*
– Having regard to the Treaty establishing the European Community, and in particular ***Article 95*** thereof,	– Having regard to the Treaty establishing the European Community, and in particular ***Article 152*** thereof,

Justification

A European directive on the application of patients' healthcare rights must be based on Article 152 of the EC Treaty, as it sets out the Community's policies and activities in the field of public health.

Amendment 2

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Although there are advantages for patients in cross-border healthcare, this Directive is not intended to promote cross-border healthcare as an aim in itself.

Justification

All patients are entitled to receive safe high quality healthcare in their own Member States. The majority of people wish to be treated as close to home as possible. Besides that, it is essential that Member States ensure that systems established to provide for and facilitate cross-border healthcare should not be disproportionate in scale and cost to the level of cross-border activity and should not have wider, unintended, consequences for national health systems as a whole.

Amendment 3

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) This directive aims to ***establish a general framework for provision of safe,***	(8) This directive aims to ***provide rules for the reimbursement of the costs of***

high quality and efficient cross-border healthcare in the Community and to ensure patients mobility and freedom to provide healthcare and high level of protection of health, whilst fully respecting the responsibilities of the Member States ***for*** the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

healthcare received in another Member State for patients who choose to go to another Member State for the purpose of receiving healthcare there and to enable cooperation between Member States in relation to health technology assessment, centres of reference and e-health, whilst fully respecting national competence in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control. It fully respects the responsibilities of the Member States ***in the field of healthcare according to the Treaty including*** the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

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 use of healthcare in a Member State other than the Member State of residence by patients who choose to travel to another Member State for the purpose of receiving healthcare there.***
– 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;	
– 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).

Amendment 5

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) Moreover, patients from other Member States should enjoy equal treatment with the nationals of the Member State of treatment and, according to the general principles of equity and non discrimination, as recognized in *Article 21* of the Charter they should in no way be discriminated upon on the basis of their sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation. Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds, such as in case of specific measures for women or for certain ages groups (e.g. free of charge vaccination for children or elderly people). Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, it has to be implemented and applied with due respect for the rights to equality before the law and the principle of non-discrimination in accordance with the general principles of law, as enshrined in Articles 20 and 21 of the Charter. This Directive applies without prejudice to	(13) Moreover, patients from other Member States should enjoy equal treatment with the nationals of the Member State of treatment and, according to the general principles of equity and non discrimination, as recognized in *Article 21* of the Charter they should in no way be discriminated upon on the basis of their sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation. ***There is therefore a need to require the fundamental values common to the European Union's health systems as adopted by the Council in June 2006, including universality, access to good quality care, equity and solidarity, to be an essential component of social protection in Europe.*** Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds, such as in case of specific measures for women or for certain ages groups (e.g. free of charge vaccination for children or elderly people). Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the

Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, and other Directives giving effect to Article 13 of the EC Treaty. In the light of this, the Directive provides that patients shall enjoy equal treatment with the nationals of the Member State of treatment, including the benefit from the protection against discrimination provided for according to Community law as well as from the legislation of the Member State of treatment.	European Union, it has to be implemented and applied with due respect for the rights to equality before the law and the principle of non-discrimination in accordance with the general principles of law, as enshrined in Articles 20 and 21 of the Charter. This Directive applies without prejudice to Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, and other Directives giving effect to Article 13 of the *Treaty*. In the light of this, the Directive provides that patients shall enjoy equal treatment with the nationals of the Member State of treatment, including the benefit from the protection against discrimination provided for according to Community law as well as from the legislation of the Member State of treatment.

Amendment 6

Proposal for a directive
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) It is important to underline the need to put in place specific measures to ensure that women have equitable access to public health schemes. This applies both to access to care which is intended for women and men and to access to gynaecological and obstetric health care, including the protection of mothers and infants, in accordance with the definition of primary health care established by the World Health Organisation at its 56th World Health Assembly on 24 April 2003[1]. Every Member State should respect women's rights to sexual and reproductive health.

[1] *International Conference on Primary Health Care, Alma-Ata; twenty-fifth anniversary; report by the Secretariat (A56/21).*

Amendment 7

Proposal for a directive
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) It is also important to underline the need to put in place measures to ensure that women have equitable access to public health schemes and care that is specific to them, particularly gynaecological and reproductive healthcare.

Amendment 8

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	(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.	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 ***and for any treatment which is conditional upon the availability of inpatient hospital care in the Member State of affiliation within the medically indicated time limit***.

Justification

The prices of health care services in countries which joined the EU before 2004 differ from those in countries which have joined more recently, in many cases enormously, to the detriment of the latter. In order to prevent patients from being divided between those who are poor and unsuitable for treatment and those who are affluent and privileged, so that the principle of equal access becomes an empty phrase, it is essential to create equal opportunities for all patients who require inpatient hospital treatment. A proposal is also essential on creating equal opportunities for women and men (pay differentials in the EU being 15% and in some countries as much as 25%). As far as the legal aspect is concerned, the amendment can draw support from the judgment of the Court of Justice of the EU in Case C-372/04 (Watts), point 147, which does not exclude the requirement to adjust Member States' social insurance systems, and from Article 35 of the EU Charter of Fundamental Rights and the principle underlying this Directive that equal access should be guaranteed, which otherwise would be pure rhetoric.

Amendment 9

Proposal for a directive
Recital 28

Text proposed by the Commission	*Amendment*
(28) Member States ***may*** maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare ***and*** reimbursement of healthcare costs, such as the requirement to consult a general practitioner before consulting a specialist or before receiving hospital care, also in	(28) Member States ***should*** maintain general conditions, criteria for eligibility and regulatory and administrative formalities for receipt of healthcare***,*** reimbursement of healthcare costs ***and follow-up treatment provided by the healthcare professional in the Member State of affiliation***, such as the requirement

relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. It is thus appropriate to require that these general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, that they are based primarily on medical considerations and that they do not impose any additional burden on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.	to consult a general practitioner before consulting a specialist or before receiving hospital care, also in relation to patients seeking healthcare in another Member State provided that such conditions are necessary, proportionate to the aim and are not discretionary and discriminatory. It is thus appropriate to require that these general conditions and formalities are being applied in an objective, transparent and non-discriminatory way and are known in advance, that they are based primarily on medical considerations and that they do not impose any additional burden ***either on the healthcare professional in the Member State of affiliation or*** on patients seeking healthcare in another Member State in comparison with patients being treated in their Member State of affiliation, and that decisions are made as quickly as possible. This is without prejudice to the rights of the Member States to provide for criteria or conditions of prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.

Justification

We need to ensure that the cost of treatment following an operation undergone in a different Member State does not result in additional costs being charged to the healthcare professionals in the patient's Member State of affiliation, particularly in the case of emergency operations.

Amendment 10

Proposal for a directive
Recital 29

Text proposed by the Commission	*Amendment*
(29) Any healthcare which is not regarded as hospital care according to the provisions of this Directive should be considered as non-hospital care. In the light of the case-law of the Court of Justice on the free movement of services, it is appropriate not to set a requirement of prior authorisation	(29) Any healthcare which is not regarded as hospital care according to the provisions of this Directive should be considered as non-hospital care. In the light of the case-law of the Court of Justice on the free movement of services, it is appropriate not to set a requirement of prior authorisation

for reimbursement by the statutory social security system of a Member State of affiliation for non-hospital care provided in another Member State. In so far as the reimbursement of such care remains within the limits of the cover guaranteed by the sickness insurance scheme of the Member State of affiliation, the absence of a prior authorisation requirement will not undermine the financial equilibrium of social security systems.	for reimbursement by the statutory social security system of a Member State of affiliation for non-hospital care provided in another Member State. ***However, the Member State of affiliation should take steps to make prior arrangements determining the procedure for and reimbursement of follow-up treatment by healthcare professionals in the Member State of affiliation, particularly in the case of emergency operations.*** In so far as the reimbursement of such care remains within the limits of the cover guaranteed by the sickness insurance scheme of the Member State of affiliation, the absence of a prior authorisation requirement will not undermine the financial equilibrium of social security systems.

Amendment 11

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
This Directive ***establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare.***	This Directive ***provides rules for reimbursement of the costs of healthcare received in another Member State for patients who choose to go to another Member State for the purpose of receiving healthcare there and enables cooperation between Member States in relation to health technology assessment, centres of reference and e-health, whilst fully respecting national competence in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control.***

Justification

The different objectives that this directive covers are better specified by the aim stated this way. It is important to point to the responsibilities of Member States and the principles that should be taken into account by healthcare policy already in the aim of this directive.

Amendment 12

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
This Directive shall apply to provision of healthcare ***regardless of how it is organised, delivered and financed or whether it is public or private***.	This Directive shall apply to provision of healthcare ***within the meaning of Article 4***.

Amendment 13

Proposal for a directive
Article 4 – point b

Text proposed by the Commission	*Amendment*
(b) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person ***or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established***;	(b) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person;

Amendment 14

Proposal for a directive
Article 5 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) insurance companies, mutual societies and healthcare funds put an end to any form of discrimination, including covert discrimination, based on risk factors associated with genetic or hereditary disorders and cease to calculate sickness insurance costs and insurance premiums as a function of the sex and type of work, and that the mechanisms applicable to the calculation

of costs and premiums end any discrimination, particularly against women.

Amendment 15

Proposal for a directive
Article 5 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) there is equity in health, which means that men and women shall be treated equally where they have common needs, while at the same time addressing their differences in an equitable manner.

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	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 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

the healthcare that is paid for regardless of where it is provided.	regardless of where it is provided.

Justification

Equal access to care abroad can be compromised by the need for a patient to pay for the care first from his own pocket before being able to seek reimbursement. Member States of affiliation and treatment could set up swift reimbursement schemes between them (at least for economically disadvantaged patients, if not for all). By specifying that the costs will be reimbursed to the insured person, this possibility is excluded.

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. ***If a patient requires immediate inpatient hospital treatment but it is not guaranteed to him or her in the Member State of affiliation within the medically indicated time limit, the Member State of affiliation shall pay the whole of the actual charge for the health care.***

Justification

The prices of health care services in countries which joined the EU before 2004 differ from those in countries which have joined more recently, in many cases enormously, to the detriment of the latter. In order to prevent patients from being divided between those who are poor and unsuitable for treatment and those who are affluent and privileged, so that the principle of equal access becomes an empty phrase, it is essential to create equal opportunities for all patients who require inpatient hospital treatment. A proposal is also essential on creating equal opportunities for women and men (pay differentials in the EU being 15% and in some countries as much as 25%). As far as the legal aspect is concerned, the amendment can draw support from the judgment of the Court of Justice of the EU in Case C-372/04 (Watts), point 147, which does not exclude the requirement to adjust Member

States' social insurance systems, and from Article 35 of the EU Charter of Fundamental Rights and the principle underlying this Directive that equal access should be guaranteed, which otherwise would be pure rhetoric.

Amendment 18

Proposal for a directive
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or similar healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons.	3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if the same or similar healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons, ***goods and services, on condition that it has first ensured universal access to healthcare for its own citizens, with particular reference to women and children***.

Justification

The influx of substantial numbers of patients from old Member States into healthcare facilities in new Member States is giving rise to discrimination between patients in some facilities. This situation is made all the worse by the fact that it is women and children who are suffering.

Amendment 19

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***to*** the insured person by the statutory social security system for	4. Member States shall have a mechanism for calculation of costs that are to be reimbursed ***on behalf of*** the insured person by the statutory social security system for

healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.	healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed according to this mechanism shall be not less than what would have been assumed had the same or similar healthcare been provided in the territory of the Member State of affiliation.

Justification

Equal access to care abroad can be compromised by the need for a patient to pay for the care first from his own pocket before being able to seek reimbursement. Member States of affiliation and treatment could set up swift reimbursement schemes between them (at least for economically disadvantaged patients, if not for all). By specifying that the costs will be reimbursed to the insured person, this possibility is excluded.

Amendment 20

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' ***and 'specialised care'*** shall mean ***healthcare, as defined in the legislation in force in the Member State of affiliation, in cases where care requires overnight accommodation of the patient in question for at least one night or the use of highly specialised and cost-intensive medical infrastructure or medical equipment or where the treatment involves a particular risk for the patient or the population***.
(a) healthcare which requires overnight accommodation of the patient in question for at least one night.	
(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:	

– 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.

Amendment 21

Proposal for a directive
Article 8 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Prior authorisation shall in any case be granted when the patient is in need of medical treatment normally provided for by the social security system of the Member State of affiliation and the treatment cannot be provided in the Member State of residence, within a time limit which is medically justifiable, as established by Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004.

Justification

It is important to point out here the limits of the reach of this article resulting from the application of Regulations 1408/71 and 883/2004.

Amendment 22

Proposal for a directive
Article 8 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Member State of treatment may take appropriate measures to address the inflow of patients and to prevent it from undermining, or being likely to undermine, the planning and rationalisation carried out in the hospital

sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the Member State concerned. The Member State of treatment shall refrain from discriminating with regard to nationality and shall ensure that the measures restricting free movement shall be limited to what is necessary and proportionate. The Member State of treatment shall notify these measures to the Commission.

Justification

Article 5 of this directive establishes the responsibilities of Member States of treatment in the case of cross border healthcare. Whereas the means of controlling patient flows by the Member State of affiliation is covered elsewhere (in Article 8), this directive remains silent on the possibilities of Member States of treatment to control large inflows of patients that may affect their healthcare system and the possibilities to carry out their responsibilities in the field of healthcare.

Amendment 23

Proposal for a directive
Article 9 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the urgency of the treatment or of the medical procedure in question,

Justification

Although many medical conditions may not be painful, they might require urgent treatment or intervention through specific medical procedures.

Amendment 24

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
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 State.	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, the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State***, the conditions authorising follow-up treatment by healthcare professionals in the Member State of affiliation, and reimbursement***. ***In information about cross-border care, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from regulations on the coordination of social security schemes as referred to in Article 3(1)(f).***

Amendment 25

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 ***and healthcare professionals*** in particular on ***the patients'*** 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;

Justification

Health professionals are the patients' first point of contact and need information about patient's rights in order both to observe all the rights and to guide the patients to get the help they need.

Amendment 26

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

Text proposed by the Commission	*Amendment*
(b) help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;	(b) ***provide information on what to do in cases of redress and harm***, help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;

Justification

Information on what to do in cases of redress and harm from the Member State of treatment must be available at the national contact points.

Amendment 27

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.	2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and ***communication between healthcare providers abroad and continued healthcare providers at home***, as well as through information and communication technologies, cross-border healthcare

	provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Justification

Continuity of care is vital to patient safety. Medical teams from the patients' country of origin should cooperate closely with the medical and specialists teams of the country of treatment to ensure continuity of care.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	FEMM 2.9.2008
Drafts(wo)man Date appointed	Anna Záborská 17.9.2008
Discussed in committee	20.1.2009 10.2.2009
Date adopted	10.2.2009
Result of final vote	+: 26 –: 3 0: 1
Members present for the final vote	Edit Bauer, Emine Bozkurt, Hiltrud Breyer, Edite Estrela, Ilda Figueiredo, Věra Flasarová, Claire Gibault, Lissy Gröner, Anneli Jäätteenmäki, Rodi Kratsa-Tsagaropoulou, Urszula Krupa, Roselyne Lefrançois, Pia Elda Locatelli, Astrid Lulling, Siiri Oviir, Doris Pack, Zita Pleštinská, Anni Podimata, Christa Prets, Karin Resetarits, Teresa Riera Madurell, Eva-Riitta Siitonen, Eva-Britt Svensson, Britta Thomsen, Corien Wortmann-Kool, Anna Záborská
Substitute(s) present for the final vote	Gabriela Creţu, Donata Gottardi, Elisabeth Jeggle, Maria Petre

PROCEDURE

Title	Patients' rights in cross-border healthcare			
References	COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)			
Date submitted to Parliament	2.7.2008			
Committee responsible Date announced in plenary	ENVI 2.9.2008			
Committee(s) asked for opinion(s) Date announced in plenary	ECON 2.9.2008	EMPL 2.9.2008	ITRE 2.9.2008	IMCO 2.9.2008
	JURI 2.9.2008	FEMM 2.9.2008		
Associated committee(s) Date announced in plenary	EMPL 23.9.2008	IMCO 23.9.2008		
Rapporteur(s) Date appointed	John Bowis 28.8.2008			
Legal basis disputed Date of JURI opinion	JURI 12.2.2009			
Discussed in committee	1.12.2008	10.2.2009		
Date adopted	31.3.2009			
Result of final vote	+: –: 0:	31 3 20		
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Maria Berger, Johannes Blokland, John Bowis, Frieda Brepoels, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Edite Estrela, Anne Ferreira, Alessandro Foglietta, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Gyula Hegyi, Marie Anne Isler Béguin, Dan Jørgensen, Christa Klaß, Urszula Krupa, Peter Liese, Jules Maaten, Marios Matsakis, Linda McAvan, Péter Olajos, Miroslav Ouzký, Vittorio Prodi, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Bogusław Sonik, María Sornosa Martínez, Evangelia Tzampazi, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Glenis Willmott			
Substitute(s) present for the final vote	Iles Braghetto, Nicodim Bulzesc, Philip Bushill-Matthews, Christofer Fjellner, Milan Gaľa, Johannes Lebech, Miroslav Mikolášik, Bart Staes			
Substitute(s) under Rule 178(2) present for the final vote	Christopher Heaton-Harris, Ria Oomen-Ruijten, Struan Stevenson, Søren Bo Søndergaard			