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Committee on Industry, Research and Energy

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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

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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 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 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***, 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	(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.	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***	(b) 'cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person;

healthcare provider resides, is registered or is established;

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	MEMBER ***STATES*** RESPONSIBLE FOR COMPLIANCE WITH COMMON PRINCIPLES FOR HEALTHCARE

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	***deleted***

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.

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***	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.

1408/71 are met.

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 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 ***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, 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.	***deleted***

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 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***,*** management ***and 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