EUROPEAN PARLIAMENT 2009 - 2014

Plenary sitting

A7-0307/2010

4.11.2010

***II
RECOMMENDATION FOR SECOND READING

on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
(11038/2010 – C7-0266/2010 – 2008/0142(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Françoise Grossetête

PR_COD_2am

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

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

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: **[...]**.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare
(11038/2010 – C7-0266/2010 – 2008/0142(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (11038/2010 – C7-0266/2010),

– having regard to the Commission proposal to 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 Commission Communication to Parliament and the Council entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

– having regard to Article 294(7) and Article 114 of the Treaty on the Functioning of the European Union,

– having regard to its position at first reading[1]

– having regard to the opinion of the European Economic and Social Committee,

– having regard to Rule 66 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A7-0307/2010),

1. Adopts its position at second reading hereinafter set out;

2. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C 184 E, 8.7.2010, p. 368.

Amendment 1

Council position
Recital 3 a (new)

Council common position	*Amendment*
	(3a). Within this general framework Member States themselves retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory. On no account may Member States dismantle their own health care due to its also being available in other Member States. Moreover, this Directive shall leave the choice of where to obtain healthcare to the patients and shall not have the result of creating policies that encourage patients in any way whatsoever to go to another Member State to obtain healthcare.

Amendment 2

Council position
Recital 5 a (new)

Council position	*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.

(General comment concerning all AMs: Since almost all AMs reflect the wording, mutatis mutandis, of the EP position of the first reading (see OJ 184 E, 8.7.2010, p. 368) references to the relevant recitals and provisions have been inserted under the AMs.)

(EP position recital 6)

Amendment 3

Council position
Recital 6

Council position	*Amendment*
(6) Some issues relating 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 already been addressed by the Court of Justice. ***As healthcare is 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 those issues in a specific Union legal instrument in order*** to achieve a more general and effective application of principles developed by the Court of Justice on a case-by-case basis.	(6) Some issues relating 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 already been addressed by the Court of Justice. ***This directive is intended*** to achieve a more general and ***also an*** effective application of principles developed by the Court of Justice on a case by case basis.
[1]OJ L 376, 27.12.2006, p. 36.	

Amendment 4

Council position
Recital 9

Council position	*Amendment*
(9) This Directive should apply to ***individual patients who decide to seek healthcare in a Member State other than the Member State of affiliation.*** As confirmed by the Court of Justice, neither ***its*** special nature nor the way in which it is organised or financed removes ***healthcare*** from the ambit of the fundamental principle of the freedom ***to provide services. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons relating to the quality and safety of the healthcare provided, where this can be justified by overriding reasons***	(9) This Directive should apply to ***all types of healthcare.*** As confirmed by the Court of Justice, neither ***the*** special nature ***of healthcare*** nor the way in which it is organised or financed removes ***it*** from the ambit of the fundamental principle of the freedom ***of movement***.

of general interest relating to public health. The Member State of affiliation may also take further measures on other grounds where this can be justified by such overriding reasons of general interest. Indeed, the Court of Justice has laid down that public health protection is among the overriding reasons of general interest that can justify restrictions to the freedom of movement envisaged in the Treaties.

Amendment 5

Council position
Recital 10

Council position	*Amendment*
(10) The concept of "overriding reasons of general interest" to which reference is made in certain provisions of this Directive has been developed by the Court of Justice in its case law in relation to Articles 49 and 56 of the Treaty and may continue to evolve. The Court of Justice has held on a number of occasions that it is possible for the risk of seriously undermining the financial balance of a social security system to constitute per se an overriding reason of general interest capable of justifying an obstacle to the freedom to provide services. The Court of Justice has likewise acknowledged that the objective of maintaining, on grounds of public health, a balanced medical and hospital service open to all may also fall within one of the derogations, on grounds of public health, provided for in Article 52 of the Treaty in so far as it contributes to the attainment of a high level of health protection. The Court of Justice has also held that such provision of the Treaty permits Member States to restrict the freedom to provide medical and hospital services in so far as the maintenance of treatment capacity or medical competence	***deleted***

on national territory is essential for public health.

Amendment 6

Council position
Recital 14 a (new)

Council position	*Amendment*
	(14a) As recognised by the Member States in the Council Conclusions of 1-2 June 2006, there is a set of operating principles that are shared by health systems throughout the EU. Those operating principles are necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving patient mobility as well as a high level of health protection. Notwithstanding those common values it is accepted that Member States take different decisions on ethical grounds as regards the availability of certain treatments and the specific access conditions. This Directive is without prejudice to ethical diversity.

(EP position recital 14)

Amendment 7

Council position
Recital 15

Council position	*Amendment*
(15) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the internet**.**	(15) This Directive should not affect Member States' rules concerning the sale of medicinal products and medical devices over the internet. ***Falsified medicines and medical devices are, however, a real and serious concern especially in the cross-border healthcare context.***

Amendment 8

Council position
Recital 16 a (new)

Council position	*Amendment*
	(16a) The transposition of this Directive and its application into national legislation should not result in patients being encouraged to receive treatment outside their Member State of affiliation when this is against their wishes. This would be particularly undesirable if the decision to encourage the patient to seek healthcare in another Member State were to be based on non-medical factors, such as the cost of treatment.

Justification

W przypadku udzielania opieki zdrowotnej, bardzo ważne jest by pacjenci mieli zapewnione jak najbardziej komfortowe warunki. Dlatego pożądane jest leczenie ich blisko miejsca zamieszkania, zorganizowane w sposób dobrze im znany, by porozumiewali się z pracownikami służby zdrowia w swoim ojczystym języku. Zasadniczo, wyjazdy do innego państwa członkowskiego, by się leczyć, są czymś wyjątkowym. Pacjenci decydują się na taki krok, gdy w ich kraju odpowiednio skuteczne leczenie jest niedostępne. Celem nowego motywu (16a) jest zapewnienie, że pacjenci nie będą „wypychani" ze swego państwa członkowskiego ubezpieczenia, co może się zdarzać, wziąwszy pod uwagę, że obecnie systemy opieki zdrowotnej w Unii Europejskiej usilnie dążą do równowagi finansowej. Istnieje zagrożenie, że niektórzy pracownicy służby zdrowia, świadczeniodawcy czy płatnicy mogliby, szukając oszczędności, próbować kierować pacjentów do innych państw członkowskich, zaniedbując przy tym ich potrzeby zdrowotne. Dyrektywa, której celem jest ochrona praw pacjentów, nie może stwarzać możliwości takiego postępowania. Proponowany motyw (16a) opisuje podobny problem, którego dotyczyła poprawka nr 12, wprowadzająca motyw (13a), przyjęta przez Parlament Europejski w kwietniu 2009 r. Ponieważ Rada jest przeciwna poprawce nr 12, ponieważ odczytuje ją jako sugerującą złą wolę państw członkowskich, konieczne jest skierowanie nowej poprawki, możliwej do przyjęcia przez Radę. Problem „wypychania" pacjentów z ich państw członkowskich jest zbyt istotny, by go całkiem pominąć.

Amendment 9

Council position
Recital 18

Council position	*Amendment*
(18) In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, ***the Member State of treatment*** should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on ***which healthcare providers are subject to these standards. Furthermore, healthcare providers should provide patients on request with information on specific aspects of the healthcare services they offer.*** To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.	(18) In order to enable patients to make an informed choice when they seek to receive healthcare in another Member State, ***Member States*** should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on ***the characteristics of healthcare provided by a specific healthcare provider. Such information should also be made available in formats accessible to persons with disabilities. Such information should be inter alia remotely accessible by electronic means.*** To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on those specific aspects, this Directive should not oblige healthcare providers to provide more extensive information to patients from other Member States. Nothing should prevent the Member State of treatment from also obliging other actors than the healthcare providers, such as insurance providers or public authorities, to provide the information on specific aspects of the healthcare services offered, if that would be more appropriate with regard to the organisation of its healthcare system.

(EP position recital 15)

Amendment 10

Council position
Recital 19

Council position	*Amendment*
(19) Members States should ensure that all patients are treated equitably on the basis	(19) ***Given that it is impossible to know in advance whether a given healthcare***

of their healthcare needs rather than on the basis of their Member State of affiliation. In doing so, Member States should respect the principles of free movement of ***persons*** within the internal market, non-discrimination, *inter alia* with regard to nationality ***and*** necessity and proportionality of any restrictions on free movement. However, nothing in this Directive should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients, for instance by increasing the waiting time for treatment of other patients. ***Inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 of the Treaty. However, this limitation should be without prejudice to Member States' obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.***

provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary for the requirements to ensure that healthcare is provided in accordance with common principles and clear quality and safety standards are applicable to all types 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 EU institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States should ***also*** 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 needs rather than on the basis of their Member State of affiliation. In doing so, Member States should respect the principles of free 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 should oblige healthcare providers to accept for planned treatment patients from other Member States or to prioritise them to the detriment of other patients ***with similar health needs***, for instance by increasing the waiting time for treatment of other patients.

(EP position recital 15)

Amendment 11

Council position
Recital 19 a (new)

Council position	*Amendment*
	(19a) In any event, any measures taken by Member States with a view to ensuring that healthcare is provided in accordance with clear quality and safety standards should not constitute new obstacles to the free movement of patients and goods such as medicinal product and medical devices.

(EP position recital 19)

Amendment 12

Council position
Recital 20

Council position	*Amendment*
(20) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices.	(20) Systematic and continuous efforts should be made to ensure that quality and safety standards are improved in line with the Council Conclusions and taking into account advances in international medical science and generally recognised good medical practices ***as well as taking into account new health technology***.

(EP position recital 20)

Amendment 13

Council position
Recital 21

Council position	*Amendment*
(21) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border healthcare. Systems for addressing harm in the Member State of	(21) Ensuring clear common obligations in respect of the provision of mechanisms for responding to harm arising from healthcare***, including the provision of aftercare,*** is essential to prevent lack of confidence in those mechanisms being an obstacle to taking up cross-border

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 for the patient.	healthcare. Systems for addressing harm in the Member State 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 for the patient.

Amendment 14

Council position
Recital 23

Council position	*Amendment*
(23) 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 patients' 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 the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.	(23) 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 patients' health. Those personal data should be able to flow from one Member State to another, but at 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 the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. Those provisions should also apply in the context of cross-border healthcare covered by this Directive.

Amendment 15

Council position
Recital 27

Council position	*Amendment*
(27) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of ***services*** in accordance with the Treaty and with this Directive. Patients should enjoy a guarantee of assumption of the costs of ***that*** healthcare at least at the level as would be provided for the same ***healthcare***, had ***it*** been provided in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent any significant effect on the financing of the national healthcare systems.	(27) It is appropriate to require that also patients who seek healthcare in another Member State in other circumstances than those provided for in Regulation (EC) No 883/2004 should be able to benefit from the principles of free movement of ***patients and goods such as medicinal products and medical devices*** in accordance with the Treaty and with this Directive. Patients should enjoy a guarantee of assumption of the costs of healthcare ***and goods connected with healthcare provided in a Member State other than their Member State of affiliation*** at ***least at*** the level as would be provided for ***treatment which is*** the same ***or equally effective***, had ***they*** been provided ***or purchased*** in the Member State of affiliation. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevent 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. That may be the case in particular for any treatment provided through European reference networks.***

(EP position recital 27)

Amendment 16

Council position
Recital 29

Council position	*Amendment*
(29) Patients should not be deprived of the more beneficial rights guaranteed by the	(29) Patients should not be deprived of the more beneficial rights guaranteed by the

Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition. ***However, if a patient instead explicitly requests to seek treatment under the terms of this Directive, the benefits which apply to reimbursement should be limited to those which apply under this Directive.***	Union Regulations on the coordination of social security systems when the conditions are met. Therefore, any patient who requests an authorisation to receive treatment appropriate to his condition in another Member State should always be granted this authorisation under the conditions provided for in the Unions regulations when the treatment in question is among the benefits provided for by the legislation in the Member State where the patient resides and when the patient cannot be given such treatment within a time limit that is medically justifiable, taking account of his current state of health and the probable course of the condition.

Amendment 17

Council position
Recital 29 a (new)

Council position	*Amendment*
	(29a) The patient may choose which mechanism they prefer, but in any case, where the application of Regulation (EC) No 883/2004 is more beneficial for the patient, the patient should not be deprived of the rights guaranteed by that Regulation.

(EP position recital 29)

Amendment 18

Council position
Recital 30

Council position	*Amendment*
(30) Patients should, in any event, not derive a financial advantage from the	(30) Patients 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 the actual costs ***of healthcare received.***	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.***

(EP position recital 30)

Amendment 19

Council position
Recital 31

Council position	*Amendment*
(31) This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person. Equally, this Directive should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.	(31) This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person ***except in the case of rare diseases***. Equally, this Directive should not prevent the Member States from extending their benefits-in-kind scheme to healthcare provided in another Member State. This Directive should recognise that Member States are free to organise their healthcare and social security systems in such a way as to determine entitlement for treatment at a regional or local level.

Amendment 20

Council position
Recital 31 a (new)

Council position	*Amendment*
	(31a) 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.

(EP position recital 32)

Amendment 21

Council position
Recital 32

Council position	*Amendment*
(32) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care.	(32) This Directive should not provide either for the transfer of social security entitlements between Member States or other coordination of social security systems. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State should be to enable freedom to provide healthcare for patients and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently this Directive should fully respect the differences in national healthcare systems and the Member States' responsibilities for the organisation and delivery of health services and medical care. ***This Directive should also respect the different management systems and the specific approaches chosen by the Member States in integrating public and private provision of healthcare services.***

Justification

It is important to reinforce the references to the respect of the prominent role of Member States in the area of healthcare, also taking into account that Article 168(7) TFEU states that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

Amendment 22

Council position
Recital 34

Council position	*Amendment*
(34) 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 relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should 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 should be made as quickly as possible. This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation. ***Since conditions, criteria and formalities relating to entitlements to healthcare,***	(34) 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 relation to patients seeking healthcare in another Member State, provided that such conditions are necessary, proportionate to the aim, not discretionary or discriminatory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. It is thus appropriate to require that these general conditions, criteria and formalities should be applied in an objective, transparent and non-discriminatory way and should be known in advance, based primarily on medical considerations, and that they should 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 should be made as quickly as possible. This should be without prejudice to the rights of the Member States to lay down criteria or conditions for prior authorisation in the case of patients seeking healthcare in their Member State of affiliation.

such as determining the cost-effectiveness of a specific treatment, is a matter for the Member State of affiliation, such conditions, criteria and formalities cannot be required in the Member State of treatment as well, as this would constitute an obstacle to the free movement of goods, persons and services. However, the Member State of treatment may impose conditions, criteria and formalities relating to clinical circumstances, such as assessing the patient-safety risks involved in performing a specific procedure on a specific patient. Furthermore, these conditions, criteria and formalities may include a procedure that ensures that a person seeking healthcare in another Member State understands that the healthcare received will be subject to laws and regulations of the Member State of treatment, including standards on quality and safety and other standards required by that Member State, and that this person has been provided with all technical, professional and medical support required for making an informed choice of healthcare provider, so long as such a procedure is neither discriminatory nor an obstacle to the free movement of goods, persons or services.

Amendment 23

Council position
Recital 36

Council position	*Amendment*
(36) ***According to the constant case law of the Court of Justice, Member States may make the assumption of costs by the national system of hospital care provided in another Member State subject to prior authorisation. The Court of Justice has judged that this requirement is both necessary and reasonable, since the number of hospitals, their geographical***	(36) ***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***

distribution, the way in which they are organised and the facilities with which they are equipped, and even the nature of the medical services which they are able to offer, are all matters for which planning, generally designed to satisfy various needs, must be possible. The Court of Justice has found that such planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. In addition, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court of Justice, such wastage would be all the more damaging because it is generally recognised that the hospital care sector generates considerable costs and must satisfy increasing needs, while the financial resources made available for healthcare are not unlimited, whatever mode of funding is applied.

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 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 that 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 Member State concerned. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, this 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.

(EP position recital 38)

Amendment 24

Council position
Recital 36 a (new)

Council position	*Amendment*
	(36a) Rare diseases meet a prevalence threshold of not more than five affected persons per 10 thousand, in line with Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products*, and they are all serious, chronic and often life threatening. Patients affected by rare diseases face difficulties in their quest for a diagnosis and treatment to improve their quality of life and to increase their life expectancy;
	_____
	****OJ L18, 22.1.2000 p.1.***

Amendment 25

Council position
Recital 38

Council position	*Amendment*
(38) Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to	(38) Given that the Member States are responsible for laying down rules as regards the management, requirements, quality and safety standards and organisation and delivery of healthcare and that the planning necessities differ from one Member State to another, it should therefore be for the Member States to

decide whether there is a need to introduce a system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case law of the Court of Justice. The information concerning this healthcare should be made publicly available.

decide whether there is a need to introduce a system of prior authorisation, and if so, to identify the healthcare requiring prior authorisation in the context of their system in accordance with the criteria defined by this Directive and in the light of the case law of the Court of Justice. The information concerning this healthcare should be made publicly available ***in advance***.

Amendment 26

Council position
Recital 39

Council position	*Amendment*
(39) ***The criteria attached to the grant of prior authorisation should be justified in the light of the overriding reasons of general interest capable of justifying obstacles to the free movement of healthcare.*** The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all and the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation system. Conversely, the refusal to grant prior authorisation ***may not*** be based ***solely*** on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, ***without carrying out an objective medical***	(39) The Court of Justice has identified several potential considerations: the risk of seriously undermining the financial balance of a social security system, the objective of maintaining on grounds of public health a balanced medical and hospital service open to all and the objective of maintaining treatment capacity or medical competence on national territory, essential for the public health, and even the survival of the population. It is also important to take into consideration the general principle of ensuring the safety of the patient, in a sector well known for information asymmetry, when managing a prior authorisation system. Conversely, the refusal to grant prior authorisation ***cannot*** be based on the ground that there are waiting lists on national territory intended to enable the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities. ***Prior authorisation may be refused only if the patient is not entitled to the treatment in question, or on the basis of a clinical evaluation, or on the basis of exposure of the general public to a substantial safety hazard. The decision should be based on an objective*** assessment of the patient's

assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed.

medical condition, the history and probable course of his illness, the degree of pain he is in and/or the nature of his disability at the time when the request for authorisation was made or renewed. ***In the event of refusal, an appeal procedure should be available.***

Amendment 27

Council position
Recital 41

Council position	*Amendment*
(41) In any event, if a Member State decides to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State 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 ***healthcare*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in ***Regulation (EEC) No 1408/71 or*** Regulation (EC) No 883/2004 are fulfilled, the authorisation should be granted and the benefits provided in accordance with ***those Regulations unless otherwise requested by the patient***. This should apply in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that event, Articles 7 and 8 of this Directive should not apply. This is in line with the case law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were subsequently held to be unfounded, are entitled to have the cost of the treatment	(41) In any event, if a Member State decides to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member State 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 Regulation (EC) No 883/2004 are fulfilled, the authorisation should be granted and the benefits provided in accordance with ***that Regulation***. This should apply in particular in instances where the authorisation is granted after an administrative or judicial review of the request and the person concerned has received the treatment in another Member State. In that event, Articles 7 and 8 of this Directive should not apply. This is in line with the case law of the Court of Justice which has specified that patients who were refused prior authorisation on grounds that were subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member

obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Amendment 28

Council position
Recital 42

Council position	*Amendment*
(42) 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 should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment.	(42) 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 should also apply to the actual reimbursement of costs of healthcare incurred in another Member State after the patient has received treatment. ***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.***

(EP position recital 42)

Amendment 29

Council position
Recital 43

Council position	*Amendment*
(43) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for	(43) Appropriate information on all essential aspects of cross-border healthcare is necessary in order to enable patients to exercise their rights on cross-border healthcare in practice. For cross-border healthcare, one of the mechanisms for

providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may***, but does not have to,*** be provided in any other language.

providing such information is to establish national contact points within each Member State. Information that has to be provided compulsorily to patients should be specified. However, the national contact points may provide more information voluntarily and also with the support of the Commission. Information should be provided by national contact points to patients in any of the official languages of the Member State in which the contact points are situated. Information may be provided in any other language. ***All that information should be inter alia remotely accessible by electronic means. Since questions about aspects of cross-border healthcare will also require liaison between authorities in different Member States, those contact points should also constitute a network through which such questions can be most efficiently addressed. Those 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 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.***

(EP position recital 43)

Amendment 30

Council position
Recital 43 a (new)

Council position	*Amendment*
	(43a) It is essential for the patient to know in advance which rules are to be applicable. An equivalent level of clarity is needed for cross-border telemedicine healthcare. 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 this Directive, given that in accordance with Article 168(1) of the Treaty the organisation and delivery of health services and medical care is the responsibility of Member States. This will help the patient to make 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.

(EP position recital 44)

Amendment 31

Council position
Recital 44

Council position	*Amendment*
(44) The Member States should decide on the form and number of their national contact points. Such national contact points may also be 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. The Commission should work together	(44) The Member States should decide on the form and number of their national contact points. Such national contact points may also be 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. ***National contact points should be established in an independent, efficient and transparent way. Independent patient organisations, sickness funds and healthcare providers***

with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Union level. 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.

should be encompassed by the national contact points. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare. 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 Union level. 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.

Amendment 32

Council position
Recital 48

Council position	*Amendment*
(48) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation. This Directive should therefore give incentives to Member States to ***facilitate*** the continued development of European reference networks. ***European reference networks are based on the voluntary participation of their members, but the Commission should develop criteria and conditions that the networks should be required to fulfil in order to receive***	(48) The Commission should support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States. European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, ***especially for rare diseases.*** This Directive should therefore give incentives to Member States to ***reinforce*** the continued development of European reference networks.

support from the Commission.

Amendment 33

Council position
Recital 49

Council position	*Amendment*
(49) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary ***for Member States to aim at interoperability of ICT systems. The deployment of health ICT systems, however, is entirely a national competence. This Directive therefore should recognise the importance of the work on interoperability and respect the division of competences by providing for the Commission and Member States to work together on developing measures which are not legally binding but provide additional tools that are available to Member States to facilitate greater interoperability.***	(49) Technological developments in cross-border provision of healthcare through the use of ICTs may result in the exercise of supervisory responsibilities by Member States being unclear, and can thus hinder the free movement of healthcare and give rise to possible additional risks to health protection. Widely different and incompatible formats and standards are used for provision of healthcare using ICTs throughout the Union, creating both obstacles to this mode of cross-border healthcare provision and possible risks to health protection. It is therefore necessary ***to adopt specific measures for achieving the interoperability of information and communication technology systems in the healthcare field and for supporting patient access to e-health applications, applicable whenever Member States decide to introduce them. Those measures should specify, in particular, the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality, accessible and efficient provision of cross-border health services***.

Amendment 34

Council position
Recital 49 a (new)

Council position	*Amendment*
	(49a) 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 Court of Justice and Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts.

[1] OJ L 144, 4.6.1997, p. 19.

Amendment 35

Council position
Recital 49 b (new)

Council position	*Amendment*
	(49b) Routine statistics as well as complementary data on cross-border healthcare are required for efficient monitoring, planning and management of healthcare in general and cross-border healthcare in particular, and their production should be integrated as far as possible within existing data collection systems to enable appropriate monitoring and planning to take account of cross-border care.

(EP position recital 52)

Amendment 36

Council position
Recital 50

Council position	*Amendment*
(50) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States.	(50) 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 avoid duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. ***Such cooperation requires sustained structures involving all the relevant authorities of the Member States, building on existing pilot projects. This Directive should therefore provide a basis for continued Union support for such cooperation.***	Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoid duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. ***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 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.***

(EP position recital 53)

Amendment 37

Council position
Article 1 – paragraph 1

Council common position	*Amendment*
1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.	1. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare ***and aims at complementing the existing framework on the coordination of social security systems, Regulation EC (No) 883/2004, with a view to application of patients' rights***. ***This Directive establishes a***

	general framework for patients' rights regarding cross-border mobility. In the application of this Directive, Member States shall take into account the principle of equity.

Justification

In order to strengthen patients' rights in cross-border mobility, the already existing framework of the coordination of social security systems - Regulation 883/2004 - should be used and complemented.

Amendment 38

Council position
Article 1 – paragraph 2

Council position	*Amendment*
2. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.	2. This Directive shall apply to the provision of ***cross-border*** healthcare to patients, regardless of how it is organised, delivered and financed.

Amendment 39

Council position
Article 1 – paragraph 3 – point b

Council position	*Amendment*
(b) ***allocation of and access to organs for the purpose of organ transplants;***	(b) ***organ transplantation;***

Justification

The full process of organ transplantation is totally dependent on organ availability in every country member. Inclusion of organ transplantation in the scope of this directive would mean great movements of patients from low to high donor rate countries and potential conflicts among patients with life threaten diseases waiting for a transplant.

Amendment 40

Council position
Article 1 – paragraph 3 – point c a (new)

Council position	*Amendment*
	(ca) sales of medicinal products and medical devices over the Internet.

Justification

In the interests of legal certainty, this insertion serves to include in the legislative text of the Directive the shared view of the Council and Parliament that sales of medicinal products and medical devices over the Internet should be excluded from the scope of the Directive.

Amendment 41

Council position
Article 4 – paragraph 1

Council position	*Amendment*
1. Cross-border healthcare ***shall be*** provided in accordance with the legislation of the Member State of treatment ***and*** with standards and guidelines on quality ***and safety laid down*** by ***that*** Member State.	***1. The Member States of treatment shall be responsible for the organisation and the delivery of cross-border healthcare, 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 compliance with existing Union legislation on safety standards, and that:*** (a) cross-border healthcare ***is*** provided in accordance with the legislation of the Member State of treatment***;*** (b) ***cross-border healthcare is provided in accordance with*** standards and guidelines on quality ***defined*** by ***the*** Member State ***of*** treatment; ***(c) cross-border healthcare shall not lead to patients being encouraged against their will to receive treatment outside of their Member State of affiliation.***

Amendment 42

Council position
Article 4 – paragraph 2 – points a - f

Council common position	*Amendment*
(a) patients receive upon request relevant information on the standards and guidelines referred to in paragraph 1, including provisions on supervision and assessment of healthcare providers, and information on which healthcare providers are subject to these standards and guidelines;	(a) patients receive ***from the national contact point*** upon request relevant information on the standards and guidelines referred to in ***point (b) of*** paragraph 1***,*** including provisions on supervision and assessment of healthcare providers, and information on which healthcare providers are subject to these standards and guidelines ***and clear information on costs in accordance with Article 7(6), on accessibility for persons with disabilities as well as on the healthcare provider's authorisation or registration status and number, and any restrictions on their practice;***
(b) healthcare providers provide ***individual patients with*** relevant information ***on*** the availability, ***quality and safety of the healthcare they provide in the Member State of treatment,*** clear invoices and clear information on prices, as well as on the healthcare providers' ***authorisation or registration status, their*** insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;	(b) healthcare providers provide ***all*** relevant information ***to enable patients to make an informed choice, including on treatment options,*** on the availability***,*** clear invoices and clear information on prices, as well as on the healthcare providers' insurance cover or other means of personal or collective protection with regard to professional liability. To the extent that healthcare providers already provide patients resident in the Member State of treatment with relevant information on these subjects, this Directive does not oblige healthcare providers to provide more extensive information to patients from other Member States;
	(ba) the information referred to in points (a) and (b) is inter alia remotely accessible by electronic means and that such information is also made available in formats accessible to persons with disabilities.
(c) there are complaints procedures and	(c) there are ***transparent*** complaints

mechanisms for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;	procedures and mechanisms ***in place*** for patients***, in order*** to ***seek*** remedies ***and compensation*** in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;
(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;	(d) systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided on its territory;
(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;	(e) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;
(f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	(f) patients who have received treatment are entitled to a written or electronic medical record of such treatment, ***and of any medical advice for the continuity of their care,*** and access to at least a copy of this record in conformity with and subject to national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC, ***without prejudice to the exceptions applicable in the Member States***.

Amendment 43

Council position
Article 4 – paragraph 3 – subparagraph 2

Council position	*Amendment*
This shall be without prejudice to the possibility for the Member State of treatment, ***where it is justified by overriding reasons of general interest,*** to adopt measures regarding access to	This shall be without prejudice to the possibility for the Member State of treatment to adopt measures regarding access to treatment aimed at fulfilling its fundamental responsibility to ensure

treatment aimed at fulfilling its fundamental responsibility to ensure sufficient and permanent access to healthcare within its territory. Such measures shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination.	sufficient and permanent access to healthcare within its territory. Such measures shall be ***justified and*** limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination ***or an obstacle to the free movement of patients or goods such as medicinal products and medical devices, and shall be made publicly available in advance.***

Amendment 44

Council position
Article 4 – paragraph 3 – subparagraph 2 a (new)

Council position	*Amendment*
	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;

(EP position Article 5(1h))

Justification

1st reading - AM 59 + AM 140

Amendment 45

Council position
Article 4 – paragraph 4 – subparagraph 1

Council common position	*Amendment*
4. Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for	4. ***The Member State of treatment*** shall ensure that the healthcare providers on ***its*** territory apply the same scale of fees for healthcare for patients from other Member

domestic patients in a comparable situation***, or that they charge a price calculated according to objective, non discriminatory criteria if there is no comparable price for domestic patients***.	States, as for domestic patients in a comparable situation***, whatever the socio-economic position of the patient.***

Amendment 46

Council position
Article 4 – paragraph 5

Council position	*Amendment*
5. This Directive shall not affect laws and regulations in Member States on the use of languages***, nor shall it imply any obligation to*** deliver information in other languages than those which are official languages in the Member State concerned.	5. This Directive shall not affect laws and regulations in Member States on the use of languages***. The Member State of treatment may*** deliver information in other languages than those which are official languages in the Member State concerned.

Amendment 47

Council position
Article 4 – paragraph 5 a (new)

Council position	*Amendment*
	5a. 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.

Amendment 48

Council position
Article 5 – point b- c

Council common position	*Amendment*
(b) there are mechanisms in place to	(b) there are ***easily accessible*** mechanisms

provide patients on request with information on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patients considers that their rights have not been respected;	in place to provide patients on request with information, ***inter alia remotely accessible by electronic means,*** on their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards procedures for accessing and determining those entitlements, conditions for reimbursement of costs and systems of appeal and redress if the patients considers that their rights have not been respected ***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 patient 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 Regulation (EC) No 883/2004.
	(ba) in the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, it guarantees to provide healthcare equivalent to that received on its territory;
(c) patients who seek to receive or do receive cross-border healthcare have access to at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	(c) patients who seek to receive or do receive cross-border healthcare have access to at least a copy of their medical records, in conformity with, and subject to, national measures implementing Union 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, or a right of remote access to, those records. Data shall be transmitted only with the express written consent of the patient or the patient's relatives.***

Amendment 49

Council position
Article 6 – paragraph 1

Council position	*Amendment*
1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission.	1. Each Member State shall designate one or more national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States shall ensure that independent patient organisations, sickness funds and healthcare providers are encompassed by national contact points. The national contact points shall be established in an independent, 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.***

(EP position Article 14(1))

Justification

am 97 of first reading

Amendment 50

Council position
Article 6 – paragraph 2

Council common position	*Amendment*
2. National contact points shall cooperate with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.	2. National contact points shall ***facilitate the exchange of information referred to in paragraph 3 and*** cooperate ***closely*** with each other and with the Commission. National contact points shall provide patients on request with contact details of national contact points in other Member States.

Amendment 51

Council position
Article 6 – paragraph 3

Council common position	*Amendment*
3. National contact points in the Member State of treatment shall provide patients with information concerning healthcare providers, including on request information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State.	3. National contact points in the Member State of treatment shall ***support patients in protecting their rights by providing them*** with information***, inter alia remotely accessible by electronic means,*** concerning healthcare providers, including on request information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), ***and information on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities***, as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State***, as well as the options available to settle any dispute, and to identify the appropriate out-of-court settlement scheme for the specific case, including in the event of harm arising from cross-border healthcare.***

Amendment 52

Council position
Article 6 – paragraph 4

Council position	*Amendment*
4. National contact points in the Member State of affiliation shall provide patients with the information referred to in Article 5(b).	4. National contact points in the Member State of affiliation shall provide patients ***and healthcare professionals*** with the information referred to in Article 5(b).

Amendment 53

Council position
Article 6 – paragraph 5

Council position	*Amendment*
5. The information referred to in this Article shall be easily accessible, ***including by electronic means.***	5. The information referred to in this Article shall be ***in formats*** easily accessible ***for people with disabilities.***

(EP position Article 14(6))

Justification

1st reading - AM 99

Amendment 54

Council position
Article 7 – paragraph 1

Council common position	*Amendment*
1. Subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits to which the insured person is entitled in the Member State of affiliation.	1. Subject to the provisions of Articles 8 and 9, the Member State of affiliation shall ensure the costs incurred by an insured person who receives cross-border healthcare are reimbursed, if the healthcare in question is among the benefits ***provided for by legislation, administrative regulations, or guidelines or codes of conduct of the medical professions,*** to which the insured person is entitled in the Member State of affiliation ***or is equally effective to healthcare that is among those benefits***. ***Member States may choose to only reimburse such methods of treatment that are sufficiently tried and tested by international medical science.***. ***Without prejudice to 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***

on its territory. If the Member State of affiliation refuses to reimburse this treatment, that Member State shall 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.

Without prejudice to Regulation (EC) No 883/2004, on the basis of a prior objective clinical examination subject to Article 9(3), patients affected or suspected to be affected by rare diseases shall have the right to access healthcare in another Member State and to receive reimbursement even if the diagnosis or treatment in question is not among the benefits provided for by legislation, administrative regulations, or guidelines or codes of conduct of the medical professions, of the Member State of affiliation. Such treatment shall be subject to prior authorisation.

Justification

As diagnosis of rare diseases is the first difficulty met by patients, a clinical examination would enable to determine also the suspicion of rare diseases and then should open the possibility for such cases to have access to cross border healthcare and reimbursement even if the treatment methods are not among the benefits provided by the Member State of affiliation.

Amendment 55

Council position
Article 7 – paragraph 1 a (new)

Council position	*Amendment*
	1 a. Any costs incurred by the insured person over and above the level reimbursed by the Member State of affiliation shall be borne solely by the insured person, unless the Member State of affiliation decides also to reimburse the insured person for the costs incurred in

excess of that level.

Justification

The limits applying to the reimbursement of insured persons by the Member State of affiliation are clearly indicated in paragraph 4 of this Article. However, in accordance with the aim – expressed in Articles 5 and 6 – of providing patients with clear information, it would be well to clarify that, if the costs incurred by the insured person exceed the level reimbursed by the Member State of affiliation, the difference in cost must be borne by the insured person. Naturally, this provision must not preclude the Member State of affiliation from reimbursing the insured person in full, or to a greater extent.

Amendment 56

Council position
Article 7 – paragraph 4

Council position	*Amendment*
4. The costs of cross-border healthcare shall be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed by the Member State of affiliation, had this healthcare been provided in its territory without exceeding the actual costs of healthcare received.	4. The costs of cross-border healthcare shall be reimbursed ***or paid directly*** 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 by the Member State of affiliation, had this healthcare been provided in its territory 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.*** ***The extra costs which persons with disabilities might incur when receiving cross-border healthcare 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.***

Justification

am 68 of first reading

Amendment 57

Council position
Article 7 – paragraph 6

Council position	*Amendment*
6. For the purposes of ***paragraph 4***, Member States shall have a mechanism for calculation of costs of cross-border healthcare ***that are to be reimbursed to the insured person by the Member State of affiliation***. This mechanism shall be based on objective, non-discriminatory criteria known in advance. ***The mechanism shall be*** applied at the relevant administrative level ***in cases where the Member State of affiliation has a decentralised healthcare system***.	6. For the purposes of ***this Article,*** Member States shall have a ***transparent*** mechanism for the calculation of costs of cross-border healthcare. This mechanism shall be based on objective, non-discriminatory criteria known in advance. The mechanism shall be based on objective, non-discriminatory criteria known in advance ***and*** applied at the relevant ***(local, regional or national)*** administrative level.

Amendment 58

Council position
Article 7 – paragraph 7

Council position	*Amendment*
7. The Member State of affiliation may impose on an insured person seeking ***reimbursement of the costs of*** cross-border healthcare, including healthcare ***received*** through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare. However, no	7. The Member State of affiliation may impose on an insured person seeking cross-border healthcare, including healthcare through means of telemedicine, the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, national or regional level, ***for receiving healthcare and reimbursement of healthcare costs*** as it would impose if that healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation, such as the general practitioner or primary care practitioner with whom the patient is registered, if this is necessary for determining the individual patient's entitlement to healthcare.

conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an ***unjustified*** obstacle to the free movement of goods, ***persons or services***.	However, no conditions, criteria of eligibility and regulatory and administrative formalities imposed according to this paragraph may be discriminatory or constitute an obstacle to the free movement of ***patientsor*** goods, ***such as medicinal products and medical devices, and such conditions, criteria and formalities shall be made publicly available in advance***.

Amendment 59

Council position
Article 7 – paragraph 9

Council position	*Amendment*
9. The Member State of affiliation may limit the application of the rules on reimbursement for cross-border healthcare according to this Article:	***deleted***
a) based on overriding reasons of general interest such as the risk of seriously undermining the financial balance of a social security system, or the objective of maintaining a balanced hospital service open to all, and	
b) to providers that are affiliated to a system of professional liability insurance, a guarantee or a similar arrangement as established by the Member State of treatment according to Article 4(2)(d).	

Amendment 60

Council position
Article 7 – paragraph 10

Council position	*Amendment*
10. The decision to limit the application of this Article pursuant to paragraph 9(a) and (b) shall be restricted to what is necessary and proportionate and may not	***deleted***

constitute a means of arbitrary discrimination or an unjustified obstacle to the free movement of goods, persons or services. Member States shall notify the Commission of any decisions to limit reimbursement on the grounds stated in paragraph 9(a).

Amendment 61

Council position
Article 7 a (new)

Council common position	*Amendment*
	Article 7a
	Prior notification
	Member States may offer patients a voluntary system of prior notification whereby, in return for such notification , the patient shallreceive a written confirmation of the maximum amount that will be paid. On presentation of that written confirmation by the patient at the hospital of treatment, reimbursement shall be made directly to that hospital by the Member State of affiliation.

Justification

When this voluntary system is applied, the reimbursement shall then be done directly by the competent authority of the Member State of affiliation to the hospital of treatement.

Amendment 62

Council position
Article 8 – paragraph 1

Council position	*Amendment*
1. The Member State of affiliation may make the reimbursement of costs of cross-border healthcare subject to prior authorisation, in accordance with this Article and Article 9.	***deleted***

Amendment 63

Council position
Article 8 – paragraph 2

Council position	*Amendment*
2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:	2. Healthcare that may be subject to prior authorisation ***shall be set out in a list, by the Member State of affiliation, to be transmitted to the Commission. It*** shall be limited to healthcare which:
(a) is made subject to planning in so far as it involves overnight hospital accommodation of the patient in question for at least one night;	(a) is made subject to planning in so far as it involves overnight hospital accommodation of the patient in question for at least one night;
(b) is made subject to planning in so far as it requires the use of highly specialised and costintensive medical infrastructure or medical equipment or	(b) is made subject to planning in so far as it requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment or
(c) involves treatments presenting a particular risk for the patient or the population ***or which could raise serious and specific concerns relating to the quality or safety of the care with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union***;	(c) involves treatments presenting a particular risk for the patient or the population;

Amendment 64

Council position
Article 8 – paragraph 2 a (new)

Council position	*Amendment*
	2a. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of cross-border healthcare where the following conditions are met:
	(a) had the healthcare been provided on its territory, it would have been assumed by the Member State's social security

	system; and
	(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
	(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.

(EP position Article 8(2))

Justification

1st reading - AM 76

Amendment 65

Council position
Article 8 – paragraph 3

Council position	*Amendment*
3. The system of prior authorisation***, including the criteria for refusing prior authorisation to patients,*** shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination.	3. The system of prior authorisation ***shall apply without prejudice to Regulation (EC) No 883/2004 and*** shall be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination ***or an obstacle to the free movement of patients or goods, such as medicinal products and medical devices***. ***Member States shall notify the Commission of any decisions to limit reimbursement on justified grounds as stated in this Article.***

Justification

1st reading - AM 77

Amendment 66

Council position
Article 8 – paragraph 4

Council position	*Amendment*
4. ***When a patient applies*** for prior authorisation, the Member State of affiliation shall ***check*** whether the conditions of Regulation (EC) No 883/2004 are met.Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation ***unless the patient requests otherwise***.	4. ***With regard to any request*** for prior authorisation ***made by an insured person with a view to receiving cross-border healthcare***, the Member State of affiliation shall ***ascertain*** whether the conditions laid down in Regulation (EC) No 883/2004 are met. Where those conditions are met, the prior authorisation shall be granted pursuant to that Regulation.

(EP position Article 8(8))

Amendment 67

Council position
Article 8 – paragraph 5

Council position	*Amendment*
5. ***The*** Member State of affiliation may refuse to grant prior authorisation for ***reasons including, but not limited to,*** the following:	5. ***Without prejudice to paragraph 3, the*** Member State of affiliation may refuse to grant prior authorisation ***only*** for the following ***reasons***:
(a) if the patient is not entitled to the healthcare in question, in accordance with Article 7;	(a) if the patient is not entitled to the healthcare in question, in accordance with Article 7;
(b) if this healthcare can be provided on its territory within a time-limit which is medically justifiable, taking into account the current state of health and the probable course of the illness of the person concerned;	
(c) if the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border	(c) if the patient will, according to a clinical evaluation, be exposed with reasonable certainty to a patient-safety risk that cannot be regarded as acceptable, taking into account the potential benefit for the patient of the sought cross-border

healthcare;	healthcare;
(d) if the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;	(d) if the general public will be exposed with reasonable certainty to a substantial safety hazard as a result of the cross-border healthcare in question;

Amendment 68

Council position
Article 8 – paragraph 5 – point e

Council position	*Amendment*
(e) if ***this*** healthcare is to ***be provided by healthcare providers that raise serious and specific concerns relating to*** the ***respect of standards and guidelines on quality of*** care ***and patient safety***, ***including provisions on supervision, whether these*** standards and guidelines ***are*** laid down by laws and regulations or through accreditation systems established by the Member State of treatment.	(e) if ***the*** healthcare ***provider in question*** is ***not authorised, registered, licensed, certified or accredited,*** to ***provide or perform*** the care ***or treatment for which the authorisation has been sought***, ***according to the*** standards and guidelines laid down by laws and regulations or through accreditation systems established by the Member State of treatment.

Justification

The reasons to reject an application for Prior Authorisation cannot be left open. This is the reason why they need to be specifically limited. The cases raised in the Council's compromise are reasonable, but they must limited just to those cases.

Amendment 69

Council position
Article 8 – paragraph 5 a (new)

Council position	*Amendment*
.	***5a. 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 public and available in advance of an application so that the application can be made in a fair***

and transparent way.

(EP position Article 8(5))

Justification

am 79 of first reading

Amendment 70

Council position
Article 8 – paragraph 6

Council position	*Amendment*
6. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive as well as all relevant information on the system of prior authorisation.	6. The Member State of affiliation shall make publicly available which healthcare is subject to prior authorisation for the purposes of this Directive as well as all relevant information on the system of prior authorisation ***including appeal procedures in the event of a refusal to give authorisation***.

(EP position Article 8(7))

Justification

am 81 of first reading

Amendment 71

Council position
Article 8 – paragraph 6 a (new)

Council position	*Amendment*
	6a. 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, inter alia by electronic means, where appropriate.

Justification

The right to apply for prior authorisation should be granted electronically for patients not staying in the Member State of affiliation in the time of application.

Amendment 72

Council position
Article 9 – paragraph 1 a (new)

Council common position	*Amendment*
.	***1a. Member States shall organise, in all cases where and when appropriate, transfer of funds of corresponding costs of cross border healthcare directly between the competent institutions.***

Justification

This would enable patients receiving cross border healthcare under the provisions of this directive to benefit, when and where possible, of the same system than the one set in the regulation 2004/883/2004. When and where it is concretely feasible, depending on national healthcare invoice system ('forfait' or not, ...etc), this will avoid to patients to pay up front and to wait for being reimbursed. This will not create an extra charge for MS because it will be based on the same practices that the ones already set and used in the regulation.

Amendment 73

Council position
Article 9 – paragraph 1 b (new)

Council common position	*Amendment*
	(1b). In the other cases, the Member State of affiliation shall ensure that patients will receive reimbursement without undue delay.

Justification

When and where not possible to organise the direct transfer of funds corresponding to the costs of cross border healthcare between the competent Institutions, and when prior authorisation has been granted, Member State of affiliation shall guarantee patients to receive reimbursement without undue delay. Taking into account that care submitted to prior authorisation are in general the more expensive ones, this is a crucial provision for patients especially for ones who have less financial means.

Amendment 74

Council position
Article 9 – paragraph 2 a (new)

Council position	*Amendment*
	2a. Member States shall, when setting out the time limits within which requests for cross-border healthcare must be dealt with and, when considering these requests, take into account:
	(a) the specific medical condition,
	(b) individual circumstances,
	(c) the patient's degree of pain,
	(d) the nature of the patient's disability, and
	(e) the patient's ability to carry out a professional activity.

(EP position Article 9(4))

Justification

1st reading - AM 87

Amendment 75Council position
Article 9 – paragraph 3

Council common position	*Amendment*
3. Member States shall ensure that administrative decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are subject to administrative review and are capable of being challenged in judicial proceedings, which include provision for interim measures.	3. Member States shall ensure that ***any*** administrative ***or medical*** decisions regarding the use of cross-border healthcare and reimbursement of costs of healthcare incurred in another Member State are subject, ***on a case-by-case basis,*** to ***an appeal procedure, to an additional medical opinion or an*** administrative review and are capable of being challenged in judicial proceedings, which include provision for interim measures.

Amendment 76

Council position
Article 10 – paragraph 1

Council position	*Amendment*
1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including the exchange of information about standards and guidelines on quality and safety, including provisions on supervision, in order to facilitate the implementation of Article 7(9), and including mutual assistance to clarify the content of invoices.	1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive, including the exchange of information***, especially between their national contact points in accordance with Articles 4, 5 and 6 and*** about standards and guidelines on quality and safety, including provisions on supervision, in order to facilitate the implementation of Article 7(9), and including mutual assistance to clarify the content of invoices.

Amendment 77

Council position
Article 10 – paragraph 2

Council position	*Amendment*
2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level.	2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level ***as well as through information and communication technologies and other forms of cross-border cooperation.***

(EP position Article 15(2))

Amendment 78

Council position
Article 10 – paragraph 2 a (new)

Council position	*Amendment*
	2a. The Commission shall encourage Member States, particularly neighbouring countries, to conclude agreements among themselves and to develop joint action

programmes.
The Commission shall also encourage the Member States to cooperate to create areas in which patients will have improved access to health care, particularly in cross-border areas.

Amendment 79

Council position
Article 10 – paragraph 2 b (new)

Council position	*Amendment*
	2b. Member States shall guarantee that registers in which health professionals are listed are available to relevant authorities of other Member States.

(EP position Article 15(4))

Justification

am 100 of first reading

Amendment 80

Council position
Article 10 – paragraph 2c (new)

Council position	*Amendment*
	2c. Member States shall immediately and proactively exchange information about disciplinary and criminal findings against health professionals where they impact upon their registration or their right to provide services.

(EP position Article 15(5))

Justification

am 100 of first reading

Amendment 81

Council position
Article 11 – paragraph 1 – subparagraph 1 – introductory part

Council position	*Amendment*
If a medicinal product is authorised to be marketed on their territory, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:	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 such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:

Amendment 82

Council position
Article 11 – paragraph 1 – subparagraphs 2 and 3

Council position	*Amendment*
The recognition of prescriptions shall not affect national rules governing dispensing***, if those rules are compatible with Union law, and shall not affect rules governing*** generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive.	The recognition of such prescription shall not affect national rules governing ***prescribing and*** dispensing***, including*** generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of ***cross-border prescriptions of*** medicinal products is covered by Chapter III of this Directive.
This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.	This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.
	The recognition of prescriptions shall not affect 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.

(EP position Article 16(1) points (i),(ii) and (iii))

Justification

1st reading - AM 101

Amendment 83

Council position
Article 11 – paragraph 2

Council position	*Amendment*
2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:	2. In order to facilitate implementation of paragraph 1, the Commission shall adopt ***no later than***….****:***
(a) ***no later than*** ….* measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing ***a non-exhaustive list of elements to be included in the prescriptions***;	(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 a member of a regulated health profession who is legally entitled to do so through developing ***single EU cross-border prescription template and supporting interoperability of*** prescriptions;
(b) guidelines supporting the Member States in developing the interoperability of ePrescriptions;	(b) guidelines supporting the Member States in developing the interoperability of ePrescriptions;
(c) ***no later than*** ….* measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross-border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, *inter alia*, using the International Non-proprietary Name and the dosage of medicinal products;	(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross-border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, *inter alia*, using the International Non-proprietary Name and the dosage of medicinal products;
(d) ***no later than*** …* measures to facilitate the comprehensibility of the information to patients concerning the prescription, and the instructions included therein, on the use of the medicinal products or medical	(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription, and the instructions included therein, on the use of the medicinal products or medical devices***, including clarity as to different***

devices.	***names used for the same medicinal product or medical device****;*

(EP position Article 16(2) points (a) and (b))

Justification

am 101 of first reading

Amendment 84

Council position
Article 11 – paragraph 2 – point d a (new)

Council position	*Amendment*
	(da)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 patients' data.

(EP position Article 16(2)(d))

Justification

am 101 of first reading

Amendment 85

Council position
Article 11 – paragraph 3

Council position	*Amendment*
3. The measures and guidelines referred to in points (a) to ***(d)*** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 15(2).	3. The measures referred to in points (a) to ***(da)*** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 15(2).

Amendment 86

Council position
Article 11 – paragraph 5 – subparagraph 1 a(new)

Council position	*Amendment*
	However, where a prescription is issued in the Member State of treatment for medicinal products or medical devices 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 have the same therapeutic effect.

(EP position Article 9(3))

Amendment 87

Council position
Article 12 – paragraph 1

Council position	*Amendment*
1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States. ***The networks shall be based on the voluntary participation of their members, which shall participate and contribute to the networks' activities in accordance with the legislation of the Member State where the members are established.***	1. The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States***, 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 to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria.***

(EP position Article 17(1))

Justification

1st reading - AM 102

Amendment 88

Council position
Article 12 – paragraph 2

Council position	*Amendment*
2. The ***aim*** of European reference networks shall be ***to help***:	2. The ***objective*** of European reference networks shall be:
(a) realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;	(a) ***to help*** realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;
	(aa) to contribute to the pooling of knowledge regarding sickness prevention and the treatment of major commonly occurring disorders;
(b***)*** facilitate improvements in diagnosis and the delivery of high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise;	(b) ***to help promote access and*** facilitate improvements in diagnosis and the delivery of high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise;
(c) maximise cost-effective use of resources;	(c) ***to*** maximise cost-effective use of resources;
(d) reinforce research, epidemiological surveillance like registries and provide training for health professionals;	(d) ***to*** reinforce research, epidemiological surveillance like registries and provide training for health professionals;
(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice within and outside the networks;	(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice ***and to foster developments of the diagnosis and treatment of rare diseases,*** within and outside the networks;
	(ea) to provide quality and safety benchmarks and to help develop and spread best practice within and outside the network;
(f) Member States that have an insufficient	(f) ***to help*** Member States that have an

number of patients with a particular medical condition or ***that lack*** technology or expertise to provide highly specialised services.	insufficient number of patients with a particular medical condition or ***lacking*** technology or expertise to provide ***a full range of*** highly specialised services ***of the highest quality***;
	(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.

(EP position Article 17(2))

Justification

1st reading - AM 103+104

Amendment 89

Council position
Article 12 – paragraph 3

Council position	*Amendment*
3. ***Member States are encouraged*** to facilitate the development of the European reference networks:	3. ***In order*** to facilitate the development of the European reference networks***, the Commission, in collaboration with the Member States, shall***:
(a) ***by identifying*** appropriate healthcare providers and centres of expertise throughout their national territory;	(a) ***identify*** appropriate healthcare providers and centres of expertise throughout their national territory***;***
(b) ***by fostering*** the participation of healthcare providers and centres of expertise in the European reference networks.	(b) ***foster*** the participation of healthcare providers and centres of expertise in the European reference networks.

Amendment 90

Council position
Article 12 – paragraph 4

Council position	*Amendment*
4. For the purposes of paragraph 1, the Commission shall:	4. For the purposes of paragraph 1, the Commission***, in collaboration with***

relevant experts and stakeholders, shall:

(a) ***develop and publish*** criteria and conditions that the European reference networks ***should*** fulfil in order to receive support from the Commission

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

(i) have appropriate capacities to diagnose, to follow-up and manage patients with evidence of good outcomes so far as applicable;

(ii) have sufficient capacity and activity to provide relevant services and maintain the quality of the services provided;

(iii) have capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control;

(iv) can demonstrate a multi-disciplinary approach;

(v) provide a high level of expertise and experience documented through publications, grants or honorific positions, teaching and training activities;

(vi) provide a strong contribution to research;

(vii) are involved in epidemiological surveillance, such as registries;

(viii) have close links and collaboration with other expert centres and networks at national and international level and capacity to network;

(ix) have close links and collaboration with patients associations where such associations exist;

(x) have appropriate and effective relationships with technology providers.

(b) develop and publish ***criteria for***

(b) develop, ***adopt*** and publish ***the procedures for establishing*** and evaluating

evaluating European reference networks;	European reference networks;
(c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and the evaluation of them.	(c) facilitate the exchange of information and expertise in relation to the establishment of European reference networks and the evaluation of them.
	c a) part-finance the establishment of the said networks.

(EP position Article 17(3))

Justification

1st reading - AM 106 and 107 The Commission should help finance the establishment of the networks in question.

Amendment 91

Council position
Article 12 – paragraph 5

Council position	*Amendment*
5. The criteria and conditions referred to in paragraph 4 shall be adopted in accordance with the regulatory procedure referred to in Article 15(2).	***5. The Commission shall adopt, by means of delegated acts in accordance with Article 16 and subject to the conditions of Article 17 and 18, the measures referred to in paragraph 4.***

Amendment 92

Council position
Article 12 – paragraph 6

Council position	*Amendment*
6. Measures adopted pursuant to this Article shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.	***deleted***

Amendment 93

Council position
Article 13 – paragraph 1

Council position	*Amendment*
1. The Commission shall ***support the Member States towards delivering sustainable economic and social benefits of European e-health systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and quality healthcare.***	1. The Commission shall***, in accordance with the procedure referred to in Article 15(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 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, accessible and efficient provision of cross-border health services.*** ***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 health professionals similar to those in use for non-electronic healthcare provision.***

(EP position Article 19)

Justification

1st reading - AM 110

Amendment 94

Council position
Article 13 – paragraph 2 – point a – point i

Council position	*Amendment*
(i) a non-exhaustive list of data that are to be included in ***patients' summaries*** and that can be shared between health professionals to enable continuity of care and patient safety across borders, and	(i) a non-exhaustive list of data that are to be included in ***Electronic Health Records*** and that can be shared between health professionals to enable continuity of care and patient safety across borders, and

Amendment 95

Council position
Article 13 – paragraph 2 – point b

Council position	*Amendment*
(b) ***support the Member States in developing common*** identification and authentication measures to ***facilitate*** transferability of data in cross-border healthcare.	(b) ***adopt*** identification and authentication measures to ***ensure*** transferability of data in cross-border healthcare ***while guaranteeing a high level of security and the protection of personal data***. ***These measures shall be adopted in accordance with the regulatory procedure referred to in Article 15(2).***

Amendment 96

Council position
Article 13 – paragraph 2 – subparagraph 1 a (new)

Council position	*Amendment*
	Work on the measures referred to in points (a) and (b) shall start no later than two years after entry into force the Directive.

Amendment 97

Council position
Article 14 – paragraph 1

Council position	*Amendment*
1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States ***within*** a ***voluntary*** network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The members of the network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established.	1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States ***For this purpose, the Commission shall, in consultation with the European Parliament, facilitate the establishment of*** a network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The members of the network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established. ***That network shall be based on the principles of good governance including transparency, objectivity, independence of expertise, fairness of procedures, and broad stakeholder participation from all relevant groups, including - but not limited to - health professionals, patients' representatives, social partners, scientists and industry, whilst respecting Member States' competence in the area of health technology assessment. Names of experts and individuals participating to the network's activities should be publicly available, together with their declaration of interest.***

Amendment 98

Council position
Article 14 – paragraph 2

Council position	*Amendment*
2. The objectives of the ***Union support referred to in paragraph 1*** shall be to:	2. The objectives of the ***health technology assessment network*** shall be to:

(a) support ***Member States in their*** cooperation ***through the*** national authorities or bodies ***referred to in paragraph 1; and***	(a) support cooperation ***between*** national authorities or bodies;
	(aa) find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets;
(b) support ***Member States in the*** provision of objective, reliable, timely, transparent and transferable ***scientific*** information on the ***short- and long-term effectiveness*** of health technologies and enable an effective exchange of this information between the national authorities or bodies.	(b) support Member States in the provision of objective, reliable, timely, transparent***, comparable*** and transferable scientific information on the ***relative efficacy as well as on the*** short- and long-term effectiveness ***when applicable,*** of health technologies, and to enable an effective exchange of this information between the national authorities or bodies.
	(ba) analyse the nature and type of information that can be exchanged.
	(bb) avoid duplications of assessments made by the European regulatory bodies, particularly in so far as these bodies take decisions with regards to safety, efficacy, quality and eligible patient populations;

(EP position Article 20(2))

Amendment 99

Council position
Article 14 – paragraph 3 a (new)

Council position	*Amendment*
	3a. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission the names and contact details of those authorities or bodies.

(EP position Article 20(3))

Justification

am 135 of first reading

Amendment 100

Council position
Article 14 – paragraph 3 b (new)

Council position	*Amendment*
	3b. The Commission shall, in accordance with the regulatory procedure referred to in Article 15(2), adopt the necessary measures for the establishment, management and transparent functioning of that network.

(EP position Article 20(4))

Amendment 101

Council position
Article 14 – paragraph 3 c (new)

Council position	*Amendment*
	3c. The Commission shall only allow such authorities to join the network which fulfil the principles of good governance as defined in paragraph 1.

(EP position Article 20(5))

Justification

am 135 of first reading

Amendment 102

Council position
Article 14 – paragraph 6

Council position	*Amendment*
6. Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.	***deleted***

Amendment 103

Council position
Article 15 – paragraph 1

Council position	*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 that process, the Commission shall ensure the consultation of experts from the relevant patient and professional groups, as well as the social partners, in an appropriate manner, especially in the context of the implementation of this Directive***

Amendment 104

Council position
Article 16 – paragraph 1

Council position	*Amendment*
The powers to adopt delegated acts referred to in Article 11(5) shall be	The powers to adopt delegated acts referred to in Article 11(5) ***and Article***

conferred on the Commission for a period of five years from ...*. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 17.

12(5) shall be conferred on the Commission for a period of five years from ...*. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 17.

Amendment 105

Council position
Article 19 a (new)

Council common position	*Amendment*
	Article 19a
	Data collection
	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 Union law for the production of statistics and on the protection of personal data, and specifically Article 8(4) of Directive 95/46/EC.
	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.
	3. Without prejudice to the measures adopted for the implementation of the Community Statistical Programme as well as to those adopted for the implementation of Regulation (EC) No 1338/2008, the Commission shall, in accordance with the regulatory procedure referred to in Article 15(2), adopt

measures for the implementation of this Article.

4. In accordance with Article 4, 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 paragraph 1.

5. The Commission shall, in accordance with the regulatory procedure referred to in Article 15(2), adopt:

(a) measures necessary for the management of the network of national contact points provided for in Article 6, the nature and type of data to be collected and exchanged within this network;

(b) guidelines on information to patients provided for in Articles 5 and 6.

6. The Commission shall, in accordance with the regulatory procedure referred to in Article 15(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.

(EP position Article 21 and Article 5(2), 5(3) and 5(4))

Justification

1st reading - AM 59 and 140

Amendment 106

Council position
Article 20 – paragraph 1

Council position	*Amendment*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by….** They shall forthwith inform the Commission thereof.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by….** They shall forthwith inform the Commission thereof.

Member States shall communicate the text of those provisions and a correlation table between those provisions and this Directive.

** OJ: ***3 years*** from the date of entry into force of this Directive.

** OJ: ***1 year*** from the date of entry into force of this Directive.

EXPLANATORY STATEMENT

Context

Today, there is too much uncertainty surrounding the issues of access to care, reimbursements and responsibility for clinical follow-up in relation to cross-border healthcare.

This directive is intended to allow all patients – and not only the best informed or richest – to enjoy a series of healthcare rights which have already been recognised by the Court of Justice of the European Union. The Member States will retain full responsibility for organising and managing social security systems. The proposal concerns patients and their mobility within the EU, not the free movement of service providers.

The aim is absolutely not to encourage cross-border healthcare as such, but to ensure its availability, safety and quality when it is of use or necessary. We need better information and more clarity regarding the legal rules applicable to travel to a Member State other than the Member State of affiliation for the purpose of receiving healthcare. The current situation is unsatisfactory, since two different sets of legal rules apply: Regulation No 883/2004 on the coordination of social security systems and the rules established over the years by the case law of the Court of Justice.

The directive is intended to offer patients a choice which is based on their needs, not their means, and which is informed, not made under duress.

First reading in Parliament

On 23 April 2009, Parliament adopted, at first reading, the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.

Parliament sought to codify the case law of the Court of Justice on cross-border healthcare in this directive. For example, the directive aims to give patients the possibility of receiving the necessary healthcare faster. Patient mobility allows national waiting lists to be sidestepped legitimately, since it enables patients to benefit from available medical capacity in other Member States. Furthermore, medical progress means that healthcare cannot be provided locally for all diseases and must be provided across borders in some cases.

The directive establishes the following principles: patients may receive all the non-hospital healthcare to which they are entitled in their own Member State in another Member State without prior approval and be reimbursed up to the ceiling established by their own healthcare system. Patients may receive all the hospital healthcare to which they are entitled in their own Member State in another Member State and be reimbursed up to the ceiling established by their own healthcare system. The proposal includes a specific safeguard clause for cases where an unpredictable rise in the volume of cross-border healthcare threatens to create serious difficulties. In accordance with the Court of Justice's case law, the directive allows a Member State to require prior authorisation for hospital care if this is necessary in order to

protect its healthcare system.

Information is also a key issue, and each Member State will be obliged to maintain national contact points to inform patients about the availability of healthcare, administrative procedures, complaints and appeals and so on.

At first reading, Parliament came out clearly in favour of a directive which would provide certainty for patients, not wishing to leave it up to the courts to decide on a case-by-case basis.

Finally, Parliament wished to strengthen healthcare cooperation between Member States by means of a number of measures, including the development of 'e-health' and the mutual recognition of prescriptions.

Second reading in Parliament

In June 2010, a political agreement was reached in the Council.

The Council did not, however, take Parliament's amendments on board.

Whilst taking into account the outcome of the negotiations in the Council, the draft recommendation for second reading seeks to remain as close as possible to the position which Parliament adopted at first reading by a large majority.

This recommendation for second reading is in keeping with the Council's desire to combat medical tourism. The Court of Justice has approved the principle of prior authorisation for hospital care, which is explicitly based on the need to plan and rationalise healthcare in order to avoid overcapacity, imbalances and logistical waste, maintain universal medical and hospital services and keep indispensible skills in each Member State.

Nevertheless, it is important to note that the case law concerned not the authorisation procedure in itself, but the manner in which it has been abused to deny patients the right to travel to receive healthcare or to hinder the use of that right. The objective, therefore, is to introduce a simplified prior authorisation system for patients which will nevertheless ensure that healthcare managers are given advance warning of any exceptional costs.

The 'quality and safety of healthcare' criteria proposed by the Council are too vague to be assessed adequately.

Parliament's proposal also aims to strengthen patients' rights, particularly by ensuring the provision of information and cooperation between Member States. The Member State of affiliation must ensure that its nationals have access to information.

As regards 'e-health', the Council's position only makes general statements. The recommendation for second reading seeks to go beyond these statements by taking proper account of the potential of 'e-health', which should be supervised. Without affecting medical confidentiality, by facilitating the exchange and sharing of documents and data, information and communication technologies play an important role in healthcare coordination.

It would be regrettable if the EU legislator were to be caught unawares by future developments and the legal consequences were once again settled by the Court of Justice.

PROCEDURE

Title	Patients' rights in cross-border healthcare
References	11038/2/2010 – C7-0266/2010 – 2008/0142(COD)
Date of Parliament's first reading – P number	23.4.2009 T6-0286/2009
Commission proposal	COM(2008)0414 - C6-0257/2008
Receipt of Council position at first reading announced in plenary	23.9.2010
Committee responsible Date announced in plenary	ENVI 23.9.2010
Rapporteur(s) Date appointed	Françoise Grossetête 21.7.2009
Previous rapporteur(s)	John Bowis
Discussed in committee	28.9.2010
Date adopted	27.10.2010
Result of final vote	+: 47 –: 2 0: 1
Members present for the final vote	Elena Oana Antonescu, Kriton Arsenis, Pilar Ayuso, Sergio Berlato, Milan Cabrnoch, Martin Callanan, Nessa Childers, Chris Davies, Jill Evans, Elisabetta Gardini, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Christa Klaß, Corinne Lepage, Peter Liese, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Antonyia Parvanova, Andres Perello Rodriguez, Sirpa Pietikäinen, Mario Pirillo, Pavel Poc, Frédérique Ries, Oreste Rossi, Dagmar Roth-Behrendt, Theodoros Skylakakis, Catherine Soullie, Glenis Willmott, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	János Áder, Margrete Auken, Christofer Fjellner, Matthias Groote, Philippe Juvin, Jiří Maštálka, Bill Newton Dunn, Alojz Peterle, Alojz Peterle, Marianne Thyssen, Thomas Ulmer, Vladimir Urutchev, Kathleen Van Brempt, Anja Weisgerber, Anna Záborská, Elżbieta Katarzyna Łukacijewska
Substitute(s) under Rule 187(2) present for the final vote	Josefa Andrés Barea, Birgit Sippel, Jan Zahradil
Date tabled	5.11.2010