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Committee on the Environment, Public Health and Food Safety

2008/0142(COD)

5.10.2010

AMENDMENTS

96 - 227

Draft recommendation for second reading
Françoise Grossetête
(PE433.081v01-00)

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

Council common position
(11038/2010 – C6-0266/2010 – 2008/0142(COD))

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PE450.566v02-00

EN

United in diversity

EN

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Amendment 96
Kartika Tamara Liotard

Council position
Recital 1 a (new)

Council position

Amendment

(1a) Notwithstanding this Directive, Member States themselves retain responsibility for providing safe, high-quality, efficient and quantitatively sufficient health care to citizens within their territory. On no account may Member States dismantle health care because it is also available in other Member States. Moreover, this Directive must not have the result of encouraging patients in any way whatsoever to go to another Member State to obtain health care.

Or.nl

Justification

Health care unequivocally remains the responsibility of each Member State and there cannot and must not be any expectation that another Member State will provide it instead. This Directive must not encourage Member States to reassign this responsibility to the European Union or encourage insurance companies to buy care abroad on economic grounds.

Amendment 97
Karin Kadenbach

Council position
Recital 2

Council position

Amendment

(2) Article 114 of the Treaty is the appropriate legal basis since the majority of the provisions of this Directive ***aim to improve the functioning of the internal market and*** the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 of

(2) Article 114 of the Treaty is the appropriate legal basis since the majority of the provisions of this Directive ***have as their aim*** the free movement of goods, persons and services. Given that the conditions for recourse to Article 114 of the Treaty as a legal basis are fulfilled,

the Treaty as a legal basis are fulfilled, Union legislation has to rely on this legal basis even when public health protection is a decisive factor in the choices made. In this respect, Article 114(3) of the Treaty explicitly requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.

Union legislation has to rely on this legal basis even when public health protection is a decisive factor in the choices made. In this respect, Article 114(3) of the Treaty explicitly requires that, in achieving harmonisation, a high level of protection of human health is to be guaranteed taking account in particular of any new development based on scientific facts.

Or.de

Amendment 98
Kartika Tamara Liotard

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 market⁵ 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.

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⁵ OJ L 376, 27.12.2006, p. 36.

Or.en

Justification

Health care was excluded from the scope of Directive 2006/123/EC on services in the internal market for good reasons - it is not an issue for internal market regulation. There is no need to reintroduce the same issues (reimbursement of health care provided in another Member State,

definition of hospital care etc.) contained in the draft Directive on services in the internal market via the current separate proposal for a directive on cross-border health care. The application of the respective case law of the Court of Justice is the sole responsibility of the Member States. There is also no need for further action on this.

Amendment 99
Karin Kadenbach

Council position
Recital 6

Council position

(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.

¹*OJ L 376, 27.12.2006, p. 36.*

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. ***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.

Or.de

Amendment 100
Kartika Tamara Liotard, Sabine Wils

Council position
Recital 8

Council position

(8) This Directive aims to ***establish rules for facilitating*** access to safe and high-quality cross-border healthcare in the Union and to ensure ***patient mobility in***

Amendment

(8) This Directive aims to ***complement Regulation (EC) No 883/2004 with regard to the*** access to safe and high-quality cross-border healthcare in the Union and to

accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between Member States, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.

ensure the *application of patients' rights in the context of patient mobility*, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness.

Or. en

Justification

The directive should focus on ensuring clarity for European residents about their rights and entitlements in the context of cross-border health care in order to ensure legal certainty, especially as regards the application of patients' rights'. The regulation on the coordination of social security systems already provides a Community framework on patient mobility within the EU and the EEA. It should be complemented by this directive with a view to ensuring the application of patients' rights and improved information and transparency concerning the use of healthcare in another Member State.

Amendment 101 **Andres Perello Rodriguez**

Council position **Recital 9**

Council position

(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*

Amendment

(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*. However, the Member State of affiliation may choose to limit the reimbursement of cross-border healthcare for reasons of general interest relating to public health, *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*.

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.

Or.en

Justification

The reasons of “quality and safety of the healthcare provided” must be linked as a Prior Authorization criterion and not used as an argument to limit the reimbursement as, in fact, the Council is doing along the text. The consideration of the quality and safety criteria needs to be done at individual basis to guarantee every patient receives the best care. For a better interpretation of this recital it is more accurate to introduce an explicit reference to what the Court of Justice understands by “reasons of general interest relating to public health”. This concept 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, due to 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. In addition to this, 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. Moreover, 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 on national territory is essential for public health.

Amendment 102 **Marianne Thyssen**

Council position **Recital 11**

Council position

(11) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which

Amendment

(11) It is clear that the obligation to reimburse costs of cross-border healthcare should be limited to healthcare to which

the insured person is entitled according to the legislation of the Member State of affiliation.

the insured person is entitled according to the legislation of the Member State of affiliation, ***except where the care relates to rare, life-threatening diseases.***

Or.nl

Justification

In the case of rare, life-threatening conditions, increases in scale may benefit patients. Certain treatments will not be available in all Member States, precisely because of the low incidence of the condition and/or possibly the expense of the treatment. If patients cannot find the treatment in the Member State where they have social insurance, even though the treatment has been validated by international medical science, they must be entitled to reimbursement of the cost of the treatment.

Amendment 103
Andres Perello Rodriguez

Council position
Recital 13

Council position

(13) Given their specificity, ***access to and the allocation of organs for the purpose of organ transplants*** should fall outside the scope of this Directive.

Amendment

(13) Given their specificity, organ ***transplantation*** should fall outside the scope of this Directive.

Or.en

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 104
Elżbieta Katarzyna Łukacijewska, Jolanta Emilia Hibner, Bogusław Sonik

Council position
Recital 16 a (new)

(16a) The transposition of this Directive 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.

Or.pl

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 105
Milan Cabrnoch

Council position
Recital 18

Council position

(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.

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. ***Such information should be remotely accessible in electronic form.*** 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.

Or.en

Amendment 106

Bernadette Vergnaud, Gilles Pargneaux

Council position

Recital 18

Council position

(18) In order to enable patients to make an informed choice when they seek to receive

Amendment

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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.

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. ***All such information should also be made available in formats accessible to persons with disabilities.***

Or.fr

Amendment 107
Paolo Bartolozzi

Council position
Recital 19

Council position

(19) Member States should ensure 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 persons

Amendment

(19) Member States should ensure 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 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.

within the internal market, non-discrimination, 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.

Or.it

Justification

This amendment is necessary to ensure the provision is consistent with Article 4(3) of the Council position, which states that 'the principle of non-discrimination with regard to nationality shall be applied to patients from other Member States'.

Amendment 108 **Marianne Thyssen**

Council position **Recital 19**

Council position

(19) *Members* States should ensure 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

Amendment

(19) *Member* States should ensure 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 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 systems⁶.

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 systems⁶.

Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States as for domestic patients unless there are urgent public-interest reasons to the contrary.

Or.nl

Justification

As healthcare in some Member States is organised in such a way that prices charged to patients do not always fully cover the costs, and care is therefore financed, for example, from tax revenue, Member States must have the power to charge other EU patients a price which covers costs, in the interests of the financial equilibrium of the healthcare system. This price should be based on objective, non-discriminatory parameters.

Amendment 109
Antonyia Parvanova

Council position
Recital 19 a (new)

Council position

Amendment

(19a) It is also important to put in place measures to ensure that women have equitable access to public health schemes and care that are specific to them, particularly gynaecological and reproductive healthcare.

Or.en

Amendment 110
Dagmar Roth-Behrendt

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 taking into account advances in international medical science and generally recognised good medical practices ***as well as taking into account new health technology.***

Or.en

Justification

Ist reading - AM 14

Amendment 111
Antonyia Parvanova

Council position
Recital 21

Council position

(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 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

(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 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.

Or.en

Amendment 112
Karin Kadenbach

Council position
Recital 23

Council position

(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

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. 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.

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.

Or.de

Amendment 113
Kartika Tamara Liotard

Council position
Recital 25

Council position

(25) In accordance with the principles established by the Court of Justice, and without endangering the financial balance of Member States' healthcare and social security systems, greater legal certainty as regards the reimbursement of healthcare costs should be provided for patients and for health professionals, healthcare providers and social security institutions.

Amendment

deleted

Or.en

Justification

Applying and implementing the case law of the European Court of Justice is the sole responsibility of the Member States, many of which have already done this. There is no need to address these issues by a separate directive on cross-border health care.

Amendment 114
Kartika Tamara Liotard, Sabine Wils

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.

deleted

Or.en

Justification

To apply and implement the case law of European Court of Justice is the sole responsibility of the Member States and has already been coped with by quite a number of them. There is no need to address these issues by a separate directive on cross-border health care. The framework on patient mobility established by Regulation 1408/71/EC and Regulation 883/2004 is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured person's Member State of affiliation, and it is more beneficial for patients than the reimbursement mechanism as proposed by the Council, which entails upfront payments from the patients own pocket.

Amendment 115

Dagmar Roth-Behrendt

Council position

Recital 27

Council position

Amendment

(27) It is appropriate to require that also patients who seek healthcare in another

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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.

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.*

Or.en

(EP position recital 27)

Amendment 116
Marianne Thyssen

Council position
Recital 31

Council position

(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

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.

among the benefits provided for by the legislation of the Member State of affiliation of the insured person, ***except in the case of rare, life-threatening 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.

Or.nl

Justification

In the case of rare, life-threatening conditions, increases in scale may benefit patients. Certain treatments will not be available in all Member States, precisely because of the low incidence of the condition and/or possibly the expense of the treatment. If patients cannot find the treatment in the Member State where they have social insurance, even though the treatment has been validated by international medical science, they must be entitled to reimbursement of the cost of the treatment.

Amendment 117 **Licia Ronzulli**

Council position **Recital 31 a (new)**

Council position

Amendment

(31 a) The patient should be reimbursed if he needs to undergo a form of medical treatment which is recognised by international medical science, in the event that different types of treatment are available but cannot be carried out in the patient's Member State of affiliation.

Or.it

Amendment 118

Kartika Tamara Liotard, Sabine Wils

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.

deleted

Or.en

Justification

To apply and implement the case law of European Court Justice is the sole responsibility of the Member States and has already been coped with by quite a number of them. There is no need to address these issues by a separate directive on cross-border health care. The framework on patient mobility established by Regulation 1408/71/EC and Regulation 883/2004 is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured person's Member State of affiliation, and it is more beneficial for patients than the reimbursement mechanism as proposed by the Council, which entails upfront payments from the patients own pocket.

Amendment 119

Alojz Peterle

Council position

Recital 32

Council position

(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.

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.

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.

Or.en

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 120
Bogusław Sonik

Council position
Recital 39

Council position

(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 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.

Amendment

(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 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 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.

Or.pl

Amendment 121
Andres Perello Rodriguez

Council position
Recital 39

Council position

(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** 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.

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 **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 or the individual patient to a substantial safety hazard. The decision should be based on*** an objective 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. ***In the event of refusal, an appeal procedure should be available.***

Or.en

Justification

A reference to “or the individual patient to” has been introduced into the amendment. The reason behind this is that a possibility to protect a patient, through the refusal of the Prior Autorotation, should be reflected, whenever there are well based concerns about the risk for that single person to be expose to a danger for his/her health due to, i.e., reasons of non-fulfilment by the healthcare provider of the minimum quality standards.

Amendment 122 **Milan Cabrnoch**

Council position **Recital 43**

Council position

(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.

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 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. ***All that information should be remotely accessible in electronic form.***

Or.en

Amendment 123 **Kartika Tamara Liotard, Sabine Wils**

Council position **Recital 44**

Council position

(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 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

(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, ***including the potential risks involved***. 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.

Or.en

Amendment 124
Karin Kadenbach

Council position
Recital 44

Council position

(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

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 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.

main aspects of cross-border healthcare, ***including the potential risks involved***. 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.

Or.en

Amendment 125
Antonyia Parvanova

Council position
Recital 44

Council position

(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 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

(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 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. ***The national contact points should be able to provide***

patients with relevant information on cross-border healthcare, and to advise and assist them. This should not include legal advice.

Or.en

Amendment 126
Paolo Bartolozzi

Council position
Recital 47

Council position

(47) Where medicinal products are authorised within a Member State and have been prescribed in a Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States *should* not affect any professional or ethical duty that would require pharmacists to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on

Amendment

(47) Where medicinal products are authorised within a Member State and have been prescribed in a Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. The removal of regulatory and administrative barriers to such recognition should be without prejudice to the need for appropriate agreement of the patient's treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. The recognition of prescriptions from other Member States *must* not affect any professional or ethical duty that would require pharmacists to refuse to dispense the prescription. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products among the benefits covered by the social security system of affiliation. It should further be noted that the reimbursement of medicinal products is not affected by the rules on mutual recognition

mutual recognition of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

of prescriptions, but covered by the general rules on reimbursement of cross-border healthcare in Chapter III of this Directive. The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. Nothing should prevent Member States from having further elements in their prescriptions, as long as this does not prevent prescriptions from other Member States that contain the common list of elements from being recognised. The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed.

Or.it

Justification

The wording used in the Council position – 'should not' – does not seem to be strong enough to ensure full compliance with the important principle entrenched in this provision.

Amendment 127

Andres Perello Rodriguez

Council position

Recital 48

Council position

(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

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 support from the Commission.

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. 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 support from the Commission.

Or.en

Justification

The reference networks exist mainly because the rare diseases. Due to the particular specificity of these diseases, extra incentives need to be provided to continue the works in those areas and encourage the centres to participate in the networks. However, in order to ensure/guarantee the competence of the references networks, they should fulfil with certain common criteria along Europe; criteria that should be set up by the Commission, since it is also the one providing the support to the references network.

Amendment 128 **Milan Cabrnoch**

Council position **Recital 49**

Council position

(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

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.

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 *should do so* by *empowering* the Commission to *adopt implementing* measures *in order to allow the sufficiently rapid establishment and updating of responsibilities and standards in that area to reflect constant progress in the relevant technologies and techniques* and to facilitate greater interoperability.

Or.en

Amendment 129
Antonyia Parvanova

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.

Or.en

Amendment 130
Licia Ronzulli

Council position
Recital 49 a (new)

Council position

Amendment

(49 a) Routine statistics on healthcare should be compiled on a regular basis and integrated so far as possible within existing data collection systems in order to enable data to be consulted rapidly and ensure the overall situation as regards cross-border care can be monitored effectively.

Or.it

Amendment 131
Bernadette Vergnaud, Gilles Pargneaux

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. 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.***

(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. ***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. Moreover, this cooperation should be based on viable principles of good governance such as transparency, openness, objectivity and the impartiality of procedures.

Or.fr

Amendment 132
Milan Cabrnoch

Council position
Recital 50

Council position

(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.

Amendment

(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, ***but also all the stakeholders concerned, including health professionals and representatives of patients and industry*** building on existing pilot projects. This Directive should therefore provide a basis for continued Union support for such cooperation.

Or.en

Amendment 133

Kartika Tamara Liotard, Sabine Wils, Bairbre de Brún

Council position

Article 1 – paragraph 1

Council position

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.

Amendment

1. This Directive **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 in the context of** access to safe, high-quality and **efficient** cross-border healthcare, in full respect of national competencies in organising and delivering healthcare. **This Directive establishes a general framework for patients' rights regarding cross-border mobility.**

Or.en

Justification

In order to strengthen patients' rights in cross-border mobility, the already existing framework of the coordination of social security systems - Regulation 1408/71/EC and Regulation 883/2004 - should be used and complemented.

Amendment 134

Antonya Parvanova

Council position

Article 1 – paragraph 1

Council position

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.

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.

In the application of this Directive, Member States shall take into account the

principles of good quality care and equity.

Or.en

Amendment 135
Kartika Tamara Liotard

Council position
Article 1 – paragraph 1 a (new)

Council position

Amendment

1a. 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.

Or.en

Justification

Health care unequivocally remains the responsibility of each Member State and there cannot and must not be any expectation that another Member State will provide it instead. This Directive must not encourage Member States to reassign this responsibility to the European Union or encourage insurance companies to buy care abroad on economic grounds.

Amendment 136
Kartika Tamara Liotard

Council position
Article 1 – paragraph 2

Council position

2. This Directive shall apply to the provision of healthcare to patients, regardless of how it is organised, delivered and financed.

Amendment

2. This Directive shall apply to the provision of healthcare to patients ***and care of the elderly***, regardless of how it is organised, delivered and financed.

Or.nl

Amendment 137

Andres Perello Rodriguez

Council position

Article 1 – paragraph 3 – point b

Council position

(b) allocation of and access to organs for the purpose of organ transplants;

Amendment

(b) organ transplantation;

Or.en

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 138

Thomas Ulmer, Horst Schnellhardt

Council position

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

Council position

Amendment

(ca) sales of medicinal products and medical devices over the Internet.

Or.de

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 139

Andres Perello Rodriguez

Council position

Article 2 – paragraph 1 – point q a (new)

Council position

Amendment

(qa) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (*)

(*) OJ L 207, 6.8.2010 , p. 14.

Or.en

Justification

This Directive has been published in the official journal after 1st reading by the parliament

Amendment 140

Thomas Ulmer, Anja Weisgerber

Council position

Article 3 – paragraph 1 – point a

Council position

Amendment

(a) "healthcare" means health services provided ***by health professionals*** to patients ***to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;***

(a) "healthcare" means health services provided to patients ***by health professionals belonging to the regulated health professions if these activities are performed in a Member State where the services are provided by members of a regulated health profession under the appropriate professional title;***

Justification

For the purpose of defining health services it is not enough to refer to services provided to patients 'to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'. What matters for the purpose of defining a health service is the medical or health treatment. Only members of certain health professions are qualified to provide these. They demonstrate that they are qualified by using the appropriate professional title.

Amendment 141
Horst Schnellhardt

Council position
Article 3 – paragraph 1 – point a

Council position

(a) "healthcare" means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;

Amendment

(a) "healthcare" means health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices ***if these activities are performed in a Member State where the services are provided by members of the health professions under the appropriate professional title;***

Justification

What matters for the purpose of defining a health service is the medical or health treatment, which only members of the health professions are qualified to provide. They demonstrate that they are qualified by using the appropriate professional title.

Amendment 142
Karin Kadenbach

Council position
Article 4 – paragraph 1 – introductory part

Council position

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.

Amendment

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.

Or.en

Amendment 143

Elżbieta Katarzyna Łukacijewska, Bogusław Sonik, Jolanta Emilia Hibner

Council position

Article 4 – paragraph 2 – point a

Council position

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;***

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;

Or.pl

Justification

Wykreślony fragment tekstu sugeruje, że w Unii Europejskiej mogą działać świadczeniodawcy, którzy nie spełniają wymagań co do jakości i bezpieczeństwa, określonych przez państwa członkowskie, w których są zarejestrowani. Nawet tylko sugerowanie takiej możliwości może być szkodliwe i poważnie nadszarpnąć opinię obywateli Unii Europejskiej na temat jakości i bezpieczeństwa europejskiej opieki zdrowotnej. Byłoby to bez wątpienia wbrew celowi dyrektywy o prawach pacjentów, którym jest ułatwienie dostępu „do bezpiecznej transgranicznej opieki zdrowotnej o wysokiej jakości” – art. 1 ust. 1.

Amendment 144

Dagmar Roth-Behrendt

Council position

Article 4 – paragraph 2 – point a

Council position

(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;

Amendment

(a) patients receive ***from the national contact point*** upon request relevant information, ***inter alia via electronic means***, 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;

Or.en

Amendment 145

Kartika Tamara Liotard, Sabine Wils, Bairbre de Brún

Council position

Article 4 – paragraph 2 – point a

Council position

(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

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, ***as well as information on the***

guidelines;

potential risks of cross-border healthcare;

Or.en

Justification

There need to be safeguards in the Directive in order to be sure that patients are not coerced into choosing cross-border because there is no alternative. Patients need to be provided with balanced information concerning the possible disadvantages of cross-border treatment, not only the advantages.

Amendment 146
Karin Kadenbach

Council position
Article 4 – paragraph 2 – point a

Council position

(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;

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 *as well as information on the potential risks involved in cross-border healthcare.*

Or.en

Amendment 147
Milan Cabrnoch

Council position
Article 4 – paragraph 2 – point b a (new)

Council position

(ba) the information referred to in points (a) and (b) is remotely accessible in electronic form and that such information is also made available in formats accessible to persons with disabilities.

Amendment 148
Dagmar Roth-Behrendt

Council position
Article 4 – paragraph 2 – point c

Council position

(c) there are complaints procedures and 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;

Amendment

(c) there are complaints procedures and mechanisms *in place* for patients, *in order to guarantee remedies and compensation* in accordance with the legislation of the Member State of treatment if they suffer harm arising from the healthcare they receive;

Or.en

Amendment 149
Kartika Tamara Liotard, Sabine Wils

Council position
Article 4 – paragraph 2 – point c

Council position

(c) there are complaints procedures and 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;

Amendment

(c) there are *transparent* complaints procedures and mechanisms for patients to seek remedies, *which are free of charge and* in accordance with the legislation of the Member State of treatment if they *become aware of or* suffer harm arising from the healthcare they receive;

Or.en

Justification

Patients should be able to claim remedy or compensation in the case of harm and have a guarantee that this process is free and transparent; making reference to mechanisms in place for this purpose is crucial to achieving this goal.

Amendment 150

Thomas Ulmer, Horst Schnellhardt

Council position

Article 4 – paragraph 2 – point f

Council position

(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.

Amendment

(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, ***without prejudice to the exceptions applicable in the Member States.***

Or.de

Justification

Particularly in the case of inheritance – but also in the case of treatment of certain illnesses and with reference to personal notes made by doctors – it is not possible for legislation to require the issuing of copies. Germany has settled case law on this subject.

Amendment 151

Kartika Tamara Liotard, Sabine Wils

Council position

Article 4 – paragraph 2 – point f a (new)

Council position

Amendment

(fa) healthcare providers do not deny healthcare to any patient, whether they be a citizen of the same or of another Member State, on account of the socio-economic position of the patient;

Or.en

Justification

Each Member State retains responsibility for the provision of health care irrespective of the

socio-economic position of the patient.

Amendment 152

Dagmar Roth-Behrendt

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;

Or.en

(EP position Article 5(1h))

Justification

1st reading - AM 59 + AM 140

Amendment 153

Marianne Thyssen

Council position

Article 4 – paragraph 4 – subparagraph 1

Council position

Amendment

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

Member States shall ensure that the healthcare providers on their territory apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable situation. ***If, however, no comparable situation exists or there is no comparable price for domestic patients it may be***

comparable price for domestic patients.

necessary and proportionate in the light of urgent public-interest grounds to apply a different price. Member States may decide to do so on condition that the scale of fees is calculated according to objective, non-discriminatory criteria.

Or.nl

Justification

As healthcare in some Member States is organised in such a way that prices charged to patients do not always fully cover the costs, and care is therefore financed, for example, from tax revenue, Member States must have the power to charge other EU patients a price which covers costs, in the interests of the financial equilibrium of the healthcare system. This price should be based on objective, non-discriminatory parameters.

Amendment 154 **Karin Kadenbach**

Council position **Article 4 – paragraph 4 – subparagraph 1**

Council position

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

Amendment

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 States, as for 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. ***At all events, health service providers shall be permitted to charge such costs of examination and treatment as the health service of the Member State of treatment covers for domestic patients receiving comparable treatment.***

Or.de

Amendment 155
Milan Cabrnoch

Council position
Article 5 – paragraph 1 – point b

Council position

(b) there are mechanisms in place to 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;

Amendment

(b) there are mechanisms in place to provide patients on request with information, ***which should be remotely accessible in electronic form***, 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;

Or.en

Amendment 156
Dagmar Roth-Behrendt

Council position
Article 5 – paragraph 1 – point b

Council position

(b) there are mechanisms in place to 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;

Amendment

(b) there are ***easily accessible*** mechanisms in place to provide patients on request with information, ***inter alia via 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.***

That information shall be published in a format accessible to persons with disabilities. Member States shall consult stakeholders, including patients' organisations, to ensure information is clear and accessible. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from Regulation (EC) No 883/2004.

Or.en

Justification

1st reading - AM 60 + AM 93

Amendment 157
Milan Cabrnoch

Council position
Article 5 – paragraph 1 – point c

Council position

(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.

Amendment

(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.***

Or.en

Amendment 158
Dagmar Roth-Behrendt

Council position
Article 5 – paragraph 1 – point c

Council position

(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.

Amendment

(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. ***Data shall be transmitted only with the express written consent of the patient or the patient's relatives.***

Or.en

(EP position Art 6(6))

Justification

1st reading - AM 71

Amendment 159
Antonyia Parvanova

Council position
Article 6 – paragraph 2

Council position

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.

Amendment

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.

Or.en

Amendment 160
Dagmar Roth-Behrendt

Council position
Article 6 – paragraph 3

Council position

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.

Amendment

3. National contact points in the Member State of treatment shall provide patients with information, ***inter alia via 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 help to identify the appropriate out-of-court settlement scheme for the specific case.***

Or.en

(EP position Article 14(4))

Justification

1st reading - AM 99

Amendment 161
Milan Cabrnoch

Council position
Article 6 – paragraph 3

Council position

3. National contact points in the Member State of treatment shall provide patients with information concerning healthcare

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.

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. ***Such information should be remotely accessible in electronic form.***

Or.en

Amendment 162
Antonyia Parvanova

Council position
Article 6 – paragraph 3

Council position

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.

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. ***The national contact point shall inform patients about their rights and help them to seek appropriate redress in the event of harm arising from healthcare received in another Member State.***

Or.en

Amendment 163
Dagmar Roth-Behrendt

Council position
Article 6 – paragraph 4 – subparagraph 1 a (new)

Council position

Amendment

The national contact point shall help patients to protect their rights and seek appropriate redress in the event of harm arising from healthcare received in another Member State.

Or.en

(EP position Art 12.3)

Justification

1st reading - AM 99

Amendment 164
Dagmar Roth-Behrendt

Council position
Article 7 – paragraph 1

Council 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 the legislation, administrative regulations and guidelines*** to which the insured person is entitled in the Member State of affiliation.

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 a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall

have to give a medical justification for its decision. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Without prejudice to Regulation (EC) No 883/2004, patients affected by rare diseases shall have the right to access healthcare in another Member State and to receive reimbursement for methods of treatment that are sufficiently tried and tested by international medical science even if the treatment in question is not among the benefits provided for by the legislation, administrative regulations and guidelines of the Member State of affiliation. Such treatment shall be subject to prior authorisation.

Or.en

(EP position Article 6(2) and 6(3))

Justification

1st reading - AM 66

Amendment 165
Sirpa Pietikäinen

Council position
Article 7 – paragraph 1

Council position

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.

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 ***provided for by the legislation, administrative regulations, guidelines and codes of conduct of the medical professions***, to which the insured person is entitled in the Member State of affiliation.

Amendment 166
Marianne Thyssen

Council position
Article 7 – paragraph 1

Council position

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.

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.

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 in its territory. If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Patients with rare, life-threatening diseases, the treatment for which has been validated by international medical science, should have the right to access healthcare in another Member State and to receive reimbursement.

Or.nl

Justification

In the case of rare, life-threatening conditions, increases in scale may benefit patients. Certain treatments will not be available in all Member States, precisely because of the low

incidence of the condition and/or possibly the expense of the treatment. If patients cannot find the treatment in the Member State where they have social insurance, even though the treatment has been validated by international medical science, they must be entitled to reimbursement of the cost of the treatment.

Amendment 167

Bernadette Vergnaud, Gilles Pargneaux

Council position

Article 7 – paragraph 1 – subparagraph 1 a (new)

Council position

Amendment

After obtaining authorisation on the basis of an objective clinical examination, which procedure should be subject to appeal in the event of authorisation being refused, patients affected by rare diseases shall have the right to access healthcare in another Member State and to receive reimbursement, even if the treatment in question is not among the benefits provided for by the legislation, administrative regulations, guidelines and codes of conduct of the medical professions of the Member State of affiliation. However, the Member State of affiliation may require the treatment to be recognised by the European reference networks or, failing that, by international medical science.

Or.fr

Justification

Even if patients suffering from rare diseases are more likely than other patients to require treatment which is not available in their Member State of affiliation, care should be taken to ensure that their potential vulnerability does not place them at the mercy of potentially dangerous 'miracle' treatments.

Amendment 168
Christofer Fjellner

Council position
Article 7 – paragraph 1

Council position

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.

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 ***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.***

Or.en

Amendment 169
Elisabetta Gardini, Oreste Rossi

Council position
Article 7 – paragraph 1

Council position

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.

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, ***within the bounds set by the provisions of paragraphs 3, 4 and 7 of this Article.***

Or.it

Amendment 170
Elisabetta Gardini, Oreste Rossi

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.

Or.it

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 171
Licia Ronzulli

Council position
Article 7 – paragraph 5

Council position

Amendment

5. Member States **may** adopt provisions in accordance with the Treaty aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

5. Member States **must** adopt provisions in accordance with the Treaty aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

Or.it

Amendment 172

Elżbieta Katarzyna Łukacijewska, Bogusław Sonik, Jolanta Emilia Hibner

Council position

Article 7 – paragraph 5

Council position

5. Member States may adopt provisions in accordance with the Treaty aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation.

Amendment

5. Member States may adopt provisions in accordance with the Treaty aimed at ensuring that patients enjoy the same rights when receiving cross-border healthcare as they would have enjoyed if they had received healthcare in a comparable situation in the Member State of affiliation. ***This includes treatment by healthcare providers that are in no way part of the public healthcare system of the Member State in which they operate, when the healthcare they provide is not funded by the public healthcare system in the patient's Member State of affiliation.***

Or.pl

Justification

The aim of this amendment is to ensure that there are no substantial differences between the situation in respect of patients travelling abroad to receive treatment and the situation in respect of patients who decide to remain in their Member State of affiliation. If the range of providers authorised to provide publicly reimbursable healthcare differed according to the place in which the healthcare was provided (within or outside the patient's Member State of affiliation) this would seriously undermine the principles of equal treatment and equal access to healthcare.

Amendment 173

Licia Ronzulli

Council position

Article 7 – paragraph 6

Council position

6. For the purposes of paragraph 4, Member States shall have a mechanism for

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.

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, **transparent and** 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.

Or.it

Amendment 174

Elżbieta Katarzyna Łukacijewska, Bogusław Sonik, Jolanta Emilia Hibner

Council position

Article 7 – paragraph 6

Council position

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.***

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. The mechanism shall be based on objective, non-discriminatory criteria known in advance ***and*** applied at the relevant ***(local, regional or national)*** administrative level.

Or.pl

Justification

Article 7(3) and (7) refer to various (local, regional and national) levels of the healthcare system, but ‘decentralised’ is not mentioned. There is therefore no reason to introduce the notion of ‘decentralisation’ as a feature of healthcare systems in Article 7(6). ‘Decentralised healthcare system’ is vague and could lead to misunderstandings. It has therefore been deleted. This amendment aims to make the Patients’ Rights Directive as easy to implement as possible, for the benefit of patients, other stakeholders and Member State authorities.

Amendment 175
Åsa Westlund, Marita Ulvskog, Dan Jørgensen

Council position
Article 7 a (new)

Council position

Amendment

Article 7a

Prior notification

Member States shall offer patients a voluntary system of prior notification whereby, in return for such notification, the patient receives 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 would be made directly to that hospital by the Member State of affiliation.

Or.en

Justification

First reading, part of amendment 91. Word "shall" from amendment 80.

Amendment 176
Andres Perello Rodriguez

Council position
Article 8 – paragraph 2 – introductory part

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:

Or.en

Justification

The healthcare subject to Prior Authorisation needs to be reflected in the Directive

explicatively and limited to the three cases gathered in this proposal, including the treatments that, due to well based doubts of its quality and security or the quality and security of the provider, could be a risk for the patient.

Amendment 177

Bernadette Vergnaud, Gilles Pargneaux

Council position

Article 8 – paragraph 2 – introductory part

Council position

2. Healthcare that may be subject to prior authorisation shall be limited to healthcare which:

Amendment

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:

Or.fr

Amendment 178

Marianne Thyssen

Council position

Article 8 – paragraph 2 – point c

Council position

(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.***

Amendment

(c) involves treatments presenting a particular risk for the patient or the population.

Or.nl

Justification

Under the consistent case law of the Court of Justice (Kohll/Decker judgments etc.), reimbursement of the cost of cross-border health care on the basis of a country's own rates of reimbursement is unconditional. Point (c) seems to call this principle into question by

referring to possible concerns about the quality of health care in another Member State.

Amendment 179

Dagmar Roth-Behrendt

Council position

Article 8 – paragraph 2 – point c

Council position

(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.*

Amendment

(c) involves treatments presenting a particular risk for the patient or the population.

Or.en

Amendment 180

Andres Perello Rodriguez

Council position

Article 8 – paragraph 2 – point c

Council position

(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.*

Amendment

(c) involves treatments presenting a particular risk for the patient or the population *including situations when those treatments could jeopardise patient safety or when a minimum level of quality of care to be provided cannot be ensured.*

Or.en

Justification

The healthcare subject to Prior Authorisation needs to be reflected in the Directive

explicatively and limited to the three cases gathered in this proposal, including the treatments that, due to well based doubts of its quality and security or the quality and security of the provider, could be a risk for the patient.

Amendment 181
Christofer Fjellner

Council position
Article 8 – paragraph 5 – introductory part

Council position

5. *The* Member State of affiliation may refuse to grant prior authorisation for **reasons including, but not limited to**, the following:

Amendment

5. **Without prejudice to paragraph 3, the** Member State of affiliation may refuse to grant prior authorisation **only** for the following **reasons**:

Or.en

Amendment 182
Andres Perello Rodriguez

Council position
Article 8 – paragraph 5 – introductory part

Council position

5. The Member State of affiliation may refuse to grant prior authorisation for **reasons including, but not limited to**, the following:

Amendment

5. The Member State of affiliation may refuse to grant prior authorisation **only** for the following **reasons**:

Or.en

Amendment 183
Bernadette Vergnaud, Gilles Pargneaux

Council position
Article 8 – paragraph 5 – introductory part

Council position

5. The Member State of affiliation may refuse to grant prior authorisation for reasons **including, but not limited to, the**

Amendment

5. The Member State of affiliation may refuse to grant prior authorisation for **the**

following:

following reasons:

Or.fr

Amendment 184
Christofer Fjellner

Council position
Article 8 – paragraph 5 – point b

Council position

Amendment

(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;

deleted

Or.en

Amendment 185
Bernadette Vergnaud, Gilles Pargneaux

Council position
Article 8 – paragraph 5 – point b

Council position

Amendment

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;*

b) if this healthcare can be provided on its territory within a time-limit which is *acceptable on the basis of an objective medical assessment of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition* and the probable course of the illness *at the time when the request for authorisation is made;*

Or.fr

Justification

The amendment seeks to clarify the concept of an acceptable delay by reference to the original definition provided by the ECJ in its judgment in the Watts case (C-372/04).

Amendment 186
Antonyia Parvanova

Council position
Article 8 – paragraph 5 – point c

Council position

(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;

Amendment

(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. ***In the event of a patient suffering from a rare disease, this clinical evaluation shall be carried out by recognised experts in that field;***

Or.en

Amendment 187
Christofer Fjellner

Council position
Article 8 – paragraph 5 – point e

Council position

(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.

Amendment

deleted

Or.en

Amendment 188
Andres Perello Rodriguez

Council position
Article 8 – paragraph 5 – point e

Council position

(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.

Amendment

(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.

Or.en

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 be limited just to those cases.

Amendment 189
Marianne Thyssen

Council position
Article 8 – paragraph 6 a (new)

Council position

Amendment

6a. Patients with rare, life-threatening diseases shall not require prior authorisation for reimbursement of the cost of a treatment for the disease at least up to the level applied by the Member State where the treatment is provided.

Or.nl

Justification

In the case of rare, life-threatening conditions, increases in scale may benefit patients.

Certain treatments will not be available in all Member States, precisely because of the low incidence of the condition and/or possibly the expense of the treatment. If patients cannot find the treatment in the Member State where they have social insurance, even though the treatment has been validated by international medical science, they must be entitled to reimbursement of the cost of the treatment.

Amendment 190

Csaba Sándor Tabajdi

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, or electronically at the competent authority of the Member State of affiliation, when appropriate.

Or.en

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 191

Sirpa Pietikäinen

Council position

Article 8 – paragraph 6 a (new)

Council position

Amendment

6a. When prior authorisation is applied, the procedures involved should be applied equally to all patients.

Or.en

Amendment 192
Sirpa Pietikäinen

Council position
Article 8 – paragraph 6 b (new)

Council position

Amendment

6b. Where prior authorisation has been granted, the Member State of affiliation shall ensure that patients will receive the agreed reimbursement without undue delay.

Or.en

Amendment 193
Theodoros Skylakakis

Council position
Article 8 – paragraph 6 a (new)

Council position

Amendment

6a. If, for sufficiently justified reasons (such as cost-related, medical or administrative reasons), prior authorisation cannot be granted to patients suffering from rare illnesses within a reasonable period of time, those patients shall not be subject to the prior authorisation requirement.

Or.el

Justification

Rare illnesses do not all have the same characteristics. Consequently, in the event that the nature of diseases and their consequences makes prior authorisation unfeasible, it should be possible for patients to be exempted from the need to obtain prior authorisation for the provision of health care in another Member State under the terms of this Directive.

Amendment 194
Åsa Westlund, Marita Ulvskog, Dan Jørgensen

Council position
Article 9 – paragraph 1 a (new)

Council position

Amendment

1a. Member States shall seek to transfer funds directly between the funders and the providers of care.

Or.en

Justification

First reading, part of amendment 78.

Amendment 195
Sirpa Pietikäinen

Council position
Article 9 – paragraph 3 a (new)

Council position

Amendment

3a. In cases where prior authorisation is not needed, a patient seeking cross-border healthcare is required to pay a certain sum in advance a certain guarantee sum which is defined by the Member State of affiliation and which may be higher than upfront payment that the patient would have made in the Member State of affiliation.

Or.en

Amendment 196
Sirpa Pietikäinen

Council position
Article 9 – paragraph 3 b (new)

Council position

Amendment

3b. Member States of affiliation shall ensure that patients who have received prior authorisation for cross-border healthcare receive reimbursement without undue delay after they have applied for it and have provided the relevant documentation.

Or.en

**Amendment 197
Sirpa Pietikäinen**

**Council position
Article 9 – paragraph 3 c (new)**

Council position

Amendment

3c. The Commission shall conduct a follow-up study into the reimbursement practices of Member States within two years of the entry into force of this Directive in order to compare them and to facilitate equality between patients.

Or.en

**Amendment 198
Anne Delvaux**

**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.*

Or.fr

Amendment 199
Dagmar Roth-Behrendt

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

Council position

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:

Amendment

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:

Or.en

Amendment 200
Thomas Ulmer, Horst Schnellhardt

Council position
Article 11 – paragraph 2 – introductory part

Council position

(2) In order to facilitate implementation of paragraph 1, the Commission shall *adopt*:

Amendment

(2) For the purposes of paragraph 1, the Commission shall *support*:

Or.de

Amendment 201
Thomas Ulmer, Horst Schnellhardt

Council position
Article 11 – paragraph 2 – point a

Council position

(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;

**Note to OJ: please insert the date - 18 months after the entry into force of this Directive.*

Amendment

(a) ***processes at Member State level*** 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;

Or.de

Justification

Member States' technical requirements regarding electronic prescriptions and their interoperability cannot be considered separately from other electronic health services as referred to in Article 13. Otherwise electronic prescriptions will create preconditions which undermine the developing interoperability pursuant to Article 13.

Amendment 202
Anne Delvaux

Council position
Article 11 – paragraph 2 - point a

Council position

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;

Amendment

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 ***single EU prescription template and supporting interoperability of*** prescriptions;

Amendment 203
Thomas Ulmer, Horst Schnellhardt

Council position
Article 11 – paragraph 2 – point b

Council position

(b) **guidelines supporting** the Member States in developing the interoperability of ePrescriptions;

Amendment

(b) the Member States in developing the interoperability of ePrescriptions; **for this purpose it shall draw up guidelines in close collaboration with the Member States;**

Amendment 204
Anne Delvaux

Council position
Article 11 – paragraph 2 – point c

Council position

c) no later than...³² 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;

Amendment

c) no later than...³² measures to facilitate the correct identification of medicinal products, **such as priority use of** the International Non-proprietary Name **(INN);**

Amendment 205
Thomas Ulmer, Horst Schnellhardt

Council position
Article 11 – paragraph 2 – point c

Council position

(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;

**Note to OJ: please insert the date - 18 months after the entry into force of this Directive.*

Amendment

(c) *processes at Member State level* 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;

Or.de

Justification

Member States' technical requirements regarding electronic prescriptions and their interoperability cannot be considered separately from other electronic health services as referred to in Article 13. Otherwise electronic prescriptions will create preconditions which undermine the developing interoperability pursuant to Article 13.

Amendment 206
Thomas Ulmer, Horst Schnellhardt

Council position
Article 11 – paragraph 2 – point d

Council position

(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

Amendment

(d) *processes at Member State level* to facilitate the comprehensibility of the information to patients concerning the prescription, and the instructions included therein, on the use of the medicinal

devices.

products or medical devices.

**Note to OJ: please insert the date - 18 months after the entry into force of this Directive.*

Or.de

Justification

Member States' technical requirements regarding electronic prescriptions and their interoperability cannot be considered separately from other electronic health services as referred to in Article 13. Otherwise electronic prescriptions will create preconditions which undermine the developing interoperability pursuant to Article 13.

Amendment 207

Milan Cabrnoch

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

Or.en

Amendment 208

Thomas Ulmer, Horst Schnellhardt

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).

deleted

Or.de

Justification

Member States' technical requirements regarding electronic prescriptions and their interoperability cannot be considered separately from other electronic health services as referred to in Article 13. Otherwise electronic prescriptions will create preconditions which undermine the developing interoperability pursuant to Article 13.

Amendment 209

Antonya Parvanova

Council position

Article 12 – paragraph 2 – point e

Council position

(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice within and outside the networks;

Amendment

(e) facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice ***and, in particular, to foster developments of the diagnosis of rare diseases***, within and outside the networks;

Or.en

Amendment 210

Bas Eickhout, Michèle Rivasi

Council position

Article 12 – paragraph 3

Council position

3. Member States ***are encouraged to facilitate*** the development of the European reference networks:

(a) by identifying 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.

Amendment

3. ***The Commission supports the*** Member States ***in*** the development of the European reference networks:

(a) by identifying appropriate healthcare providers and centres of expertise throughout ***the Member States*** national territory;

(b) by fostering the participation of healthcare providers and centres of expertise in the European reference networks.

Justification

The development of the European reference networks can only work if the Member States effectively identify appropriate providers and foster participation, and not if they are just encouraged to do so. However, it is not appropriate either for the Commission to be in charge of this, as the rapporteur suggests. The Member States should be the primary actors, but supported by the Commission.

Amendment 211**Michèle Rivasi****Council position****Article 12 – paragraph 4 – point c a (new)***Council position**Amendment*

c a) part-finance the establishment of the said networks.

Or.fr

Justification

The Commission should help finance the establishment of the networks in question.

Amendment 212**Milan Cabrnoch****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 ***and*** the Member States ***shall work*** towards delivering sustainable economic and social benefits of European ***eHealth*** 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.

Amendment 213
Jorgo Chatzimarkakis

Council position
Article 13 – paragraph 1

Council position

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.

Amendment

1. The Commission shall support the Member States *in promoting* continuity of care and *optimising cross-border* access to safe and quality healthcare *by using and further developing e-health systems. To this end the Commission may propose, in close cooperation with Member States and health service providers, guidelines for promoting the interoperability of ICT systems in the health sector. In its support measures and its proposal on interoperability, the Commission shall take into account developments in health technology and medical science, including telemedicine, to lastingly increase economic and social benefits. It shall respect the data protection provisions in force in the individual Member States and the fundamental right to the protection of personal data.*

Or.de

Amendment 214
Milan Cabrnoch

Council position
Article 13 – paragraph 2 – point a

Council position

(a) *draw up guidelines in close collaboration* with the *Member States on*:

Amendment

(a) *adopt, by means of delegated act, in accordance with Article 16 and subject to the conditions of Articles 17 and 18, the following measures:*

Amendment 215
Milan Cabrnoch

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

Council position

(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

Amendment

(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 216
Milan Cabrnoch

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

Council position

(ii) *effective methods for enabling* the use of medical information for public health and research;

Amendment

(ii) *a technical framework to enable* the use of medical information for public health and research.

Amendment 217
Milan Cabrnoch

Council position
Article 13 – paragraph 2 – point b

Council position

(b) *support the Member States in developing common* identification and authentication measures to *facilitate* transferability of data in cross-border healthcare.

Amendment

(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 procedure referred to in Article 15.

Or.en

Amendment 218
Milan Cabrnoch

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.

Or.en

Amendment 219
Antonyia Parvanova

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.

Or.en

Amendment 220
Bernadette Vergnaud, Gilles Pargneaux

Council position
Article 14 – paragraph 1

Council position

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.*

Amendment

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 the national authorities or bodies responsible for health technology assessment designated by the Member States. That network shall be based on the principles of good governance, including transparency, objectiveness, fairness of procedures, and broad and full stakeholder participation of all relevant groups, including - but not limited to - health professionals, patients' representatives, social partners and scientists, whilst respecting Member States' competence in the area of health technology assessment.*

Or.fr

Amendment 221
Antonyia Parvanova

Council position
Article 14 – paragraph 2 – point b

Council position

(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 to enable an effective exchange of this information between the national authorities or bodies.

Amendment

(b) support Member States in the provision of objective, reliable, timely, transparent, ***comparable*** and transferable scientific information on the ***relative efficacy in real conditions of use or application, 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.

Or.en

Amendment 222
Christofer Fjellner

Council position
Article 14 – paragraph 2 – point b a (new)

Council position

(ba) avoid duplications of the decisions and 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;

Amendment

Or.en

Amendment 223
Christofer Fjellner

Council position
Article 14 – paragraph 2 – point b b (new)

Council position

Amendment

(bb) produce non-binding recommendations on the basis of dialogue and close coordination with all stakeholders

Or.en

Amendment 224
Karin Kadenbach

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, and shall provide a report on those consultations.

Or.en

Amendment 225
Milan Cabrnoch

Council position
Article 19 – paragraph 2 – subparagraph 1

Council position

Amendment

The report shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and on the functioning of the European reference

The report shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and on the functioning of the European reference

networks and national contact points. To this end, the Commission shall conduct an assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patient mobility.

networks and national contact points. ***The Commission should always evaluate the eHealth situation in cross-border healthcare.*** To this end, the Commission shall conduct an assessment of the systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Union legislation relating to patient mobility.

Or.en

Amendment 226
Dagmar Roth-Behrendt

Council position
Article 20 – paragraph 1 – subparagraph 1

Council position

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.

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

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.

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

Or.en

Amendment 227
Antonyia Parvanova

Council position
Article 20 – paragraph 1 – subparagraph 1

Council position

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.

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

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.

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

