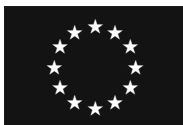


EUROPEAN PARLIAMENT

2004



2009

Committee on Employment and Social Affairs

2008/0142(COD)

9.12.2008

AMENDMENTS 22 - 206

Draft opinion
Iles Braghetto
(PE413.995v01-00)

on the proposal for a directive of the European Parliament and of the Council
on the application of patients' rights in cross-border healthcare

Proposal for a directive
(COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

AM_Com_LegOpinion

Amendment 22

Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

—

Text proposed by the Commission

Proposal for rejection

The European Parliament rejects the Commission proposal.

Or. en

Justification

There is neither a necessity for nor a competency of the European Union to regulate on health care matters by a separate Directive based on an internal market approach (Article 95 EC Treaty). Health care is not a matter of the internal market and Member States competencies

Amendment 23

Jan Cremers

Proposal for a directive

Title

Text proposed by the Commission

Amendment

Proposal for a Directive of the European Parliament and of the Council on the ***application of patients' rights in cross-border healthcare***

Proposal for a Directive of the European Parliament and of the Council on the ***use of healthcare abroad by individual patients***

Or. en

Amendment 24

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Citation 1

Text proposed by the Commission

Having regard to the Treaty establishing the European Community, and in particular **Article 95** thereof,

Amendment

Having regard to the Treaty establishing the European Community, and in particular **Articles 42, 152 and 308** thereof,

Or. en

Justification

There is neither a necessity for nor a competency of the European Union to regulate on health care matters by a separate Directive based on an internal market approach (Article 95 EC Treaty). Health care is not a matter of the internal market and Member States competencies in this field as laid down in Article 152 EC Treaty must be respected. In order to strengthen patients' rights in cross-border health care, the already existing framework of the coordination of social security systems - regulation 1408/71/EC and its successor, regulation 883/2004/EC - exclusively should be used and complemented.

Amendment 25

Jan Cremers

Proposal for a directive

Citation 1

Text proposed by the Commission

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Amendment

Having regard to the Treaty establishing the European Community, and in particular Article 95 **and 16** thereof,

Or. en

Amendment 26

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 2

Text proposed by the Commission

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

Amendment

(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are **not** fulfilled, the Community legislature shall rely on **the same** legal basis **as Regulation 883/2004/EC on the coordination of social security systems, and also shall take Article 152 of the Treaty into account.**

Or. en

Justification

There is neither a necessity for nor a competency of the European Union to regulate on health care matters by a separate Directive based on an internal market approach (Article 95 EC Treaty). Health care is not a matter of the internal market and Member States competencies in this field as laid down in Article 152 EC Treaty must be respected. In order to strengthen patients' rights in cross-border health care, the already existing framework of the coordination of social security systems - regulation 1408/71/EC and its successor, regulation 883/2004/EC - exclusively should be used and complemented.

Amendment 27

Harald Ettl

Proposal for a directive

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) The existing disparities between health-policy objectives and objectives of the internal market in services makes it necessary, where a conflict arises, always

to assign priority to health-policy objectives for compelling reasons relating to the public interest (i.e. public health, social-policy objectives, preservation of the financial balance of the social security system, etc.).

Or. de

Justification

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

Amendment 28
Gabriele Stauner

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission

Amendment

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

Or. de

Amendment 29
Gabriele Stauner

Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission

Amendment

(4b) The liberalisation of health services must not lead to even greater inequality of access to high quality healthcare.

Amendment 30
Stephen Hughes

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) The liberalisation of health services could lead to greater inequality of access to high-quality health care and is therefore not the aim of this Directive.

Or. en

Amendment 31
Anne Van Lancker

Proposal for a directive
Recital 5

Text proposed by the Commission

Amendment

(5) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, ***all types of medical care fall within the scope of the Treaty.***

(5) As confirmed by the Court of Justice on several occasions, while recognizing their specific nature, ***medical services provided for consideration fall within the scope of the EC Treaty provisions on the freedom to provide services.***

Or. en

Justification

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

Amendment 32
Gabriela Crețu

Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) Although there are advantages for patients in cross-border healthcare, this Directive is not intended to promote cross-border healthcare as an aim in itself.

Or. en

Justification

All patients are entitled to receive safe high quality healthcare in their own Member States. The majority of people wish to be treated as close to home as possible. Besides that, it is essential that Member States ensure that systems established to provide for and facilitate cross-border healthcare should not be disproportionate in scale and cost to the level of cross-border activity and should not have wider, unintended, consequences for national health systems as a whole.

Amendment 33

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive
Recital 6

Text proposed by the Commission

Amendment

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

(6) As health care was **rightfully** 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 **still** important for Member States to ensure the accessibility of their respective public health care systems for patients and to continue concluding bilateral agreements in order to achieve or improve cooperation which promotes and benefits the rights of patients for high quality health care and treatment according to

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

Article 152 of the EC Treaty.

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 for reintroducing the same issues (reimbursement of healthcare 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 34

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 8

Text proposed by the Commission

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

Amendment

(8) This directive aims to **complement Regulation (EEC) 1408/71 and its successor Regulation (EC) 883/2004 with regard to the** provision of safe, high quality and efficient cross-border healthcare in the Community and to ensure **the application of patients' rights in the framework of** patients mobility and a high level of protection of health, whilst fully respecting the responsibilities of the Member States for the definition of social security benefits related to health and 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 health care in another Member State.

Amendment 35

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Recital 8

Text proposed by the Commission

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

Amendment

(8) This directive aims to ***provide rules for the access to safe and high-quality healthcare in another Member State and establish cooperation mechanisms on healthcare between Member States, in full respect of national competence in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control. It fully respects*** the responsibilities of the Member States for ***healthcare according to the treaty including*** the definition of social security benefits related to health and the organisation and delivery of healthcare and medical care and social security benefits in particular for sickness.

Or. en

Amendment 36
Marie Panayotopoulos-Cassiotou

Proposal for a directive
Recital 8

Text proposed by the Commission

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

Amendment

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

Or. el

Amendment 37
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Recital 10

Text proposed by the Commission

(10) For the purpose of this Directive, the concept of "cross-border healthcare" covers the following modes of supply of healthcare:

- Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';***
- Cross-border provision of healthcare (i.e.: delivery of service from the territory***

Amendment

deleted

of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;

- Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,

- Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

Or. en

Amendment 38

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Recital 11

Text proposed by the Commission

(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance

Amendment

(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance

with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare ***which is itself necessary for achieving patients' mobility and free movement of provision of healthcare in the internal market as well as a high level of health protection.***

with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare.

Or. en

Amendment 39
Elizabeth Lynne

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) In order to ensure that new barriers to the free movement of healthcare workers are not created and to ensure patient safety, equal standards of occupational safety for healthcare workers must be provided, in particular with a view to avoiding risks from infections resulting from accidents at the workplace such as needlestick injuries that can lead to potentially fatal infections, including Hepatitis B, Hepatitis C and HIV, as referred to in the European Parliament's resolution with recommendations to the Commission of 6 July 2006 on the protection of healthcare workers from blood-borne infections due to needlestick injuries¹.

¹ OJ C 303 E, 13.12.2006, p.754.

Or. en

Justification

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

Amendment 40
Elizabeth Lynne

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

Amendment 41

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 19

Text proposed by the Commission

Amendment

(19) 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.

deleted

Or. en

Justification

To apply and implement the case law of the 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.

Amendment 42

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 21

Text proposed by the Commission

Amendment

(21) It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (EC) No. 1408/71 should be able to benefit from the principles of free movement of services in accordance with

deleted

the Treaty and the provisions of this Directive. Patients should be guaranteed assumption of the costs of that healthcare at least at the level provided for the same or similar healthcare had they been provided in the Member State of affiliation. This fully respects responsibility of the Member States to determine the extent of the sickness cover available to their citizens and prevents any significant effect on the financing of the national healthcare systems. Member States may nevertheless provide in their national legislation for reimbursement of the costs of the treatment at the tariffs in force in the Member State of treatment if this is more beneficial for the patient. This may be the case in particular for any treatment provided through European reference networks as mentioned in Article 15 of this Directive.

Or. en

Justification

To apply and implement the case law of the 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 is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured persons' Member State of affiliation, and it is more beneficial for patients than the reimbursement mechanism as proposed by the Commission, which entails upfront payments from the patients own pocket.

Amendment 43

Anne Van Lancker

Proposal for a directive

Recital 21

Text proposed by the Commission

(21) It is appropriate to require that also patients who go for healthcare to another

Amendment

(21) It is appropriate to require that also patients who go for healthcare to another

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

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

Or. en

Justification

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

Amendment 44

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 22

Text proposed by the Commission

Amendment

(22) For the patient, therefore, the two systems are coherent; either this directive applies or Regulation 1408/71. In any event, any insured person who requests an authorisation to receive a treatment appropriate to his/her condition in another Member State shall always be granted this authorisation under the conditions provided for in Regulation 1408/71 and 883/04 when the treatment in question cannot be given within the time medically justifiable, taking account his current state of health and the probable course of the disease. The patient should not be deprived of the more beneficial rights guaranteed by Regulation.1408/71 and 883/04 when the conditions are met.

deleted

Or. en

Justification

To apply and implement the case law of the 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 provide for an alternative mechanism on coverage of health care costs for treatment in another Member State by the proposed directive. The framework on patient mobility established by Regulation 1408/71/EC is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured persons' Member State of affiliation, and it is more beneficial for patients than the reimbursement mechanism as proposed by the Commission, which entails upfront payments from the patients own pocket.

Amendment 45

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 23

Text proposed by the Commission

Amendment

(23) The patient may choose which mechanism they prefer, but in any case, where the application of Regulation 1408/71 is more beneficial for the patient, the patient should not be deprived of the rights guaranteed by that Regulation.

deleted

Or. en

Justification

To apply and implement the case law of the 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 provide for an alternative mechanism on coverage of health care costs for treatment in another Member State by the proposed directive. The framework on patient mobility established by Regulation 1408/71/EC is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured persons' Member State of affiliation, and it is more beneficial for patients than the reimbursement of costs as proposed by the Commission, which entails upfront payments from the patients own pocket.

Amendment 46

Iles Braghetto

Proposal for a directive

Recital 24 a (new)

Text proposed by the Commission

Amendment

(24a) This Directive recognises that entitlement to treatment is not always determined by Member States at national level and that not all Member States have a defined list of the services they do or do not provide. Member States must retain the right to organise their own healthcare and social security systems in such a way

that availability of treatments and entitlement to them, can be determined at a regional or local level.

Or. en

Justification

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

Amendment 47

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 26

Text proposed by the Commission

Amendment

(26) This Directive does not provide either for transfer of social security entitlements between Member States or other coordination of social security schemes. The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State is to enable freedom to provide healthcare for both patients and healthcare providers and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation. Consequently the Directive fully respects the differences of national health-care systems and the Member States' responsibilities for organisation and delivery of health services and medical care.

deleted

Or. en

Justification

To apply and implement the case law of the 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 provide for an alternative mechanism on coverage of health care costs for treatment in another Member State by the proposed directive. The framework on patient mobility established by Regulation 1408/71/EC is sufficient for handling the coverage of costs resulting from provision of health care in another Member State than the insured persons' Member State of affiliation, and it is more beneficial for patients than the reimbursement mechanism as proposed by the Commission, which entails upfront payments from the patients own pocket.

Amendment 48

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Recital 26

Text proposed by the Commission

(26) This Directive does not provide either for transfer of social security entitlements between Member States or other coordination of social security schemes. ***The sole objective of the provisions regarding prior authorisation and reimbursement of healthcare provided in another Member State is to enable freedom to provide healthcare for both patients and healthcare providers and to remove unjustified obstacles to that fundamental freedom within the patient's Member State of affiliation.*** Consequently the Directive fully respects the differences of national health-care systems and the Member States' responsibilities for organisation and delivery of health services and medical care.

Amendment

(26) This Directive does not provide either for transfer of social security entitlements between Member States or other coordination of social security schemes. Consequently the Directive fully respects the differences of national health-care systems and the Member States' responsibilities for organisation and delivery of health services and medical care.

Or. en

Amendment 49
Anne Van Lancker

Proposal for a directive
Recital 30

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

Member State of affiliation is responsible for the assumption of costs, it is up to that Member State to draw up the list of hospital care.

Amendment 50

Anne Van Lancker

Proposal for a directive

Recital 31

Text proposed by the Commission

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

Amendment

(31) In the light of the case-law developed by the Court of Justice, Member States may make the assumption of costs of hospital care in another Member State by their statutory social security system subject to the granting of a prior authorisation. The prior authorisation requirement is justified by the need to preserve the financial balance of their social security system and by the need to plan the number of hospital infrastructures, their geographical distribution, the mode of their organisation, the equipment with which they are provided and even the nature of the medical services they are able to offer. The aims of hospital planning are to ensure, within each Member State, sufficient permanent access to a balanced range of high-quality hospital care, to assist in meeting a desire to control costs and, so far as it is possible, to prevent wastage of financial, technical or human resources. The same reasoning applies to specialized healthcare which requires planning because it involves treatments requiring the use of highly specialised and cost-intensive medical infrastructure or medical equipment or because it involves involving treatments presenting a particular risk for the patient or the population.

patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, the Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in Article 8.

Or. en

Justification

As the Court of Justice has consistently held, Member States are entitled to introduce or maintain a system of prior authorization for the assumption of hospital care provided in another Member State because it is justified by the need to preserve financial balance of the social security system and the need of hospital planning.

Amendment 51
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Recital 31

Text proposed par la Commission

Amendment

(31) *The evidence available indicates that*

(31) *The Court of Justice has recognised*

*the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems. However, the Court of Justice has recognised that **it cannot be excluded that the possible** risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for **hospital** care received in another Member State, **where the following conditions are met: had the treatment been provided on its territory, it would have been assumed by its social security system and the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of***

that **there is a** risk of seriously undermining a social security system's financial balance or the objective of maintaining a balanced medical and hospital service open to all may constitute overriding reasons in the general interest capable of justifying a barrier to the principle of freedom to provide services. The Court of Justice has also recognised that the number of hospitals, their geographical distribution, the way in which they are organised and the facilities with which they are provided, and even the nature of the medical services which they are able to offer, are all matters for which planning must be possible. This Directive should provide for a system of prior authorisation for assumption of costs for **health** care received in another Member State. **Prior authorisation is essential for all hospital and specialised care as it provides guarantee for patients that they will be treated and that the treatment will be covered by their social security system.**

the concerned Member. As the assessment of the precise impact of an expected outflow of patients requires complex assumptions and calculations, the Directive allows for a system of prior authorisation if there is sufficient reason to expect that the social security system will be seriously undermined. This should also cover cases of already existing systems of prior authorisation which are in conformity with conditions laid down in Article 8.

Or. en

Amendment 52

Anne Van Lancker

Proposal for a directive

Recital 32

Text proposed by the Commission

(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same or *similar healthcare* been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another

Amendment

(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had *the treatment which is* the same or *equally effective for the patient* been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned

Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Or. en

Justification

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

Amendment 53

Anne Van Lancker

Proposal for a directive Recital 33a (new)

Text proposed by the Commission

Amendment

(33a) Refusals to grant prior authorisation cannot be merely based on the existence of waiting lists enabling the supply of hospital care to be planned and managed on the basis of predetermined general clinical priorities, without carrying out in the individual case in question 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 authorization was made or renewed.

Justification

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

Amendment 54
Elizabeth Lynne

Proposal for a directive
Recital 34

Text proposed by the Commission

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

Amendment

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

information in accessible formats and potential sources of additional assistance for vulnerable patients, disabled people and people with complex needs.

Or. en

Justification

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

Amendment 55

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Recital 37

Text proposed by the Commission

(37) *Realising the potential of the internal market for cross-border* healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of

Amendment

(37) *Cross-border* healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of professional qualifications stipulates that free provision of services of

professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Community law, be restricted for any reason relating to professional qualifications. This Directive **should** be without prejudice to those provisions of Directive 2005/36/EC.

a temporary or occasional nature, including services provided by health professionals, in another Member State should not, subject to specific provisions of Community law, be restricted for any reason relating to professional qualifications. This Directive **shall** be without prejudice to those provisions of Directive 2005/36/EC.

Or. en

Justification

The provision of cross-border health care - and especially of such health care in border regions - is not an affair of the internal market. Cooperation on health care in border regions is currently regulated by bi- or multilateral agreements between Member States and/or cooperation in the framework of Euregios. This has proved to be very efficient and effective and should remain so. This cooperation has nothing to do with internal market principles.

Amendment 56

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Recital 45

Text proposed by the Commission

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

Amendment

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

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

Or. en

Amendment 57
Iles Braghetto

Proposal for a directive
Recital 45

Text proposed by the Commission

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

Amendment

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

Or. it

Justification

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

Amendment 58

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Article 1

Text proposed par la Commission

This Directive ***establishes a general framework for*** the provision of safe, high quality and efficient cross-border healthcare.

Amendment

This Directive ***aims at complementing the existing framework on the coordination of social security systems (Regulation (EEC) 1408/71 and its successor Regulation (EC) 883/2004) with a view to the application of patients' rights in the context of*** the provision of safe, high quality and efficient cross-border healthcare.

Or. en

Justification

There is neither a necessity for nor a competency of the European Union to regulate on health care matters by a separate Directive based on an internal market approach (Article 95 EC Treaty). Health care is not a matter of the internal market and Member States competencies in this field as laid down in Article 152 EC Treaty must be respected. In order to strengthen patients' rights in cross-border health care, the already existing framework of the coordination of social security systems - regulation 1408/71/EC and its successor, regulation 883/2004/EC - exclusively should be used and complemented.

Amendment 59
Anne Van Lancker

Proposal for a directive
Article 1

Text proposed by the Commission

This Directive establishes ***a general framework for the provision of safe, high quality and efficient*** cross-border healthcare.

Amendment

This Directive establishes ***common rules to ensure patient mobility and to coordinate specific areas of*** cross-border healthcare ***whilst fully respecting the responsibility for the definition of social security benefits related to health and the organisation and delivery of healthcare, medical care and social security benefits.***

Or. en

Justification

Article 1 does not clarify what the specific aim of the Directive is, namely ensuring free movement of patients and coordinating specific areas of cross-border health care, whilst ensuring Member States' responsibilities in the field of social security and delivery of health care. The amendment corresponds to recital 8 of the Commission's proposal.

Amendment 60
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 1

Text proposed by the Commission

This Directive ***establishes a general framework for the provision of safe, high quality and efficient*** cross-border healthcare.

Amendment

This Directive ***provides rules for the access to safe and high-quality*** healthcare ***in another Member State and establishes cooperation mechanisms on healthcare between Member States, in full respect of national competences in organising and delivering healthcare, in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control.***

Amendment 61
Jan Cremers

Proposal for a directive
Article 1

Text proposed by the Commission

This Directive establishes a general framework for the *provision* of safe, high quality and efficient *cross-border* healthcare.

Amendment

This Directive establishes a general framework for the *use* of safe, high quality and efficient healthcare *abroad by individual patients who choose, of their own accord, to travel for healthcare.*

Amendment 62
Patrizia Toia

Proposal for a directive
Article 1

Text proposed by the Commission

This Directive establishes a general framework for the provision of safe, high quality and *efficient* cross-border healthcare.

Amendment

This Directive establishes a general framework for the provision of safe, high quality and *efficacious* cross-border healthcare.

Justification

The term efficient could create misunderstanding. Healthcare is normally qualified in term of "quality, safety and efficacy".

Amendment 63
Milan Cabrnoch

Proposal for a directive
Article 1

Text proposed by the Commission

This Directive establishes a general framework for the provision of safe, high quality and efficient cross-border healthcare.

Amendment

This Directive establishes a general framework for the provision of safe, high quality, ***continuous*** and efficient cross-border healthcare.

Or. cs

Amendment 64
Ria Oomen-Ruijten

Proposal for a directive
Article 2

Text proposed by the Commission

This Directive shall apply to provision of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

Amendment

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

Or. nl

Amendment 65
Jan Cremers

Proposal for a directive
Article 2

Text proposed by the Commission

Amendment

1. The purpose of this Directive is to facilitate the movement of individual patients who choose, of their own accord,

This Directive shall apply to *provision* of healthcare regardless of how it is organised, delivered and financed or whether it is public or private.

to travel for healthcare.

2. This Directive shall apply to *the use* of healthcare *abroad* regardless of how it is organised, delivered and financed or whether it is public or private.

3. The Directive does not provide for the commissioning of cross-border healthcare or the sending of patients by a Member State's social security system to another Member State's social security system for the express purpose of receiving care.

Or. en

Amendment 66
Jan Cremers

Proposal for a directive
Article 2 a (new)

Text proposed by the Commission

Amendment

Article 2a

In order to accomplish the missions of general interest entrusted to their health care systems Member States shall follow in the application of this Directive the principles of general interest; i.e. universality, accessibility to good quality care, equity, solidarity, and affordability of health services. In order to guarantee a high level of public health as required by Article 152 of the EC Treaty, Member States should give prevalence to these principles, in the event that the provisions of this Directive conflict with the principles.

Or. en

Amendment 67
Stephen Hughes

Proposal for a directive
Article 2 a (new)

Text proposed by the Commission

Amendment

Article 2a

In order to accomplish the mission of general interest entrusted to their healthcare systems, Member States shall follow in the application of this Directive the principles of general interest; i.e. universality, accessibility to good quality care, equity, solidarity and affordability of health services. In order to guarantee a high level of public health as required by Article 152 of the EC Treaty, this Directive is without prejudice to that Article. In the event of conflict between the provisions of this Directive with the principles of Article 152, the latter should prevail.

Or. en

Amendment 68
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

(f) Regulations on coordination of social security schemes, in particular **Article 22** of Regulation (EC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security

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

systems.

security systems.

Or. nl

Amendment 69

Ria Oomen-Ruijten

Proposal for a directive

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

Text proposed by the Commission

Amendment

(ga) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (third non-life insurance Directive).

Or. nl

Amendment 70

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Article 3 – paragraph 2

Text proposed by the Commission

Amendment

2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71

deleted

shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Or. en

Justification

There is neither a necessity for nor a competency of the European Union to regulate on health care matters by a separate Directive based on an internal market approach (Article 95 EC Treaty). Health care is not a matter of the internal market and Member States competencies in this field as laid down in Article 152 EC Treaty must be respected. In order to strengthen patients' rights in cross-border health care, the already existing framework of the coordination of social security systems - regulation 1408/71/EC and its successor, regulation 883/2004/EC - exclusively should be used and complemented. There is no need to establish an alternative mechanism based on the reimbursement principle in this directive.

Amendment 71
Anne Van Lancker

Proposal for a directive
Article 3 - paragraph 2

Text proposed by the Commission

2. When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation

Amendment

2. This Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. Nor does this Directive affect patients' rights to be granted an authorisation for a treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular Article 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families

set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

moving within the Community and Article 20 of Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems are met.

Or. en

Justification

The wordings of Article 3, paragraph 2 are too complicated and do not provide clarity on the relationship with the regulation on the coordination of social security schemes. In line with Article 3, paragraph 1, point f) of this Directive, preference should be given to a clear and simple rule that this Directive does not address issues covered by this regulation. The text of the amendment corresponds to recital 20 of the Directive.

Amendment 72 **Ria Oomen-Ruijten**

Proposal for a directive **Article 3 – paragraph 2**

Text proposed by the Commission

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

Amendment

2. *Until the date on which Regulation (EC) No 883/2004 enters into force, the rule shall apply that* when the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 22 of Regulation (EC) No 1408/71 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation

shall not apply.

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

Or. nl

Amendment 73
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission

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

Amendment

2. This Directive does not address the assumption of costs of healthcare which become necessary on medical grounds during a temporary stay of insured persons in another Member State. Nor does this Directive affect patients' rights to be granted an authorisation for a treatment in another Member State where the conditions provided for by the regulations on coordination of social security schemes, in particular Article 22 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community and Article 20 of Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems are met. To the extent that this Directive covers situations that are also covered by Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004, those regulations shall apply and this Directive shall not apply.

Or. en

Amendment 74
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

2a. From the date on which Regulation (EC) No 883/2004 enters into force, the rule shall apply that when the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under Article 20 of Regulation (EC) No 883/2004 must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 20 of Council Regulation (EC) No 883/2004 shall not apply. However, whenever the conditions for granting an authorisation set out in Article 20(2) of Regulation (EC) No 883/2004 are fulfilled, the authorisation shall always be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

Or. nl

Amendment 75
Anne Van Lancker

Proposal for a directive
Article 4 - point a

Text proposed by the Commission

Amendment

(a) "healthcare" means a health service provided by or under the supervision of a

(a) "healthcare" means a health service provided by or under the supervision of a

health professional *in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private;*

health professional *to patients in order to assess, maintain or restore their state of health. For the purpose of Articles 6, 7, 8, 9, 10 and 11, healthcare means treatments that are among the benefits provided for by the legislation of the Member State of affiliation;*

Or. en

Justification

The definition of "healthcare" on the basis of the sole criterion "provided by or under supervision of a health professional" does not provide legal certainty, because - for most of the health professions - being qualified a health professional will vary from one country to another. As regards the use of healthcare in another Member State, the definition of healthcare needs to be linked with the benefits provided for by the legislation of Member State of affiliation (this is in line with Article 6).

Amendment 76

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Article 4 – point a)

Text proposed by the Commission

(a) "healthcare" means a health service provided *by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private;*

Amendment

(a) "healthcare" means a health service provided *to patients in order to assess, maintain or restore their state of health. For the purpose of Articles 6, 7, 8, 9, 10 and 11, healthcare means treatments that are among the healthcare benefits provided for by the legislation of the Member State of affiliation;*

Or. en

Amendment 77
Jan Cremers

Proposal for a directive
Article 4 – point b

Text proposed by the Commission

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

Amendment

(b) "cross-border healthcare" means healthcare ***received by a patient in another*** Member State than that where the patient is an insured person;

Or. en

Amendment 78
Jan Cremers

Proposal for a directive
Article 4 – point c

Text proposed by the Commission

(c) "use of healthcare in another Member State" means healthcare ***provided*** in the Member State other than that where the patient is an insured person.

Amendment

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

Or. en

Amendment 79
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 4 – point f

Text proposed by the Commission

(f) "patient" means any natural person who ***receives or wishes to receive healthcare in a*** Member State;

Amendment

(f) ***for the purposes of this Directive*** "patient" means any natural person who ***intends to travel to another*** Member State ***with the purpose of receiving healthcare***

there;

Or. en

Amendment 80
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

(iia) an insured person as defined in the policy conditions of private sickness insurance schemes;

Or. nl

Amendment 81
Jan Cremers

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 82
Iles Braghetto

Proposal for a directive
Article 4 – point 1

Text proposed by the Commission

(1) **"harm"** means ***adverse outcomes or injuries stemming from*** the provision of healthcare.

Amendment

(1) **"adverse event"** means ***an unintended injury or complication, which would not ordinarily be an outcome of the condition treated or*** the provision of healthcare ***required.***

Or. en

Justification

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

Amendment 83
Iles Braghetto

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

Text proposed by the Commission

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ***ensure*** that:

Amendment

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ***take into account*** that:

Justification

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

Amendment 84
Harlem Désir

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

Text proposed by the Commission

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. ***In such a context and taking into account*** principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Amendment

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

Or. fr

Justification

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

Amendment 85
Jan Cremers

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

Text proposed by the Commission

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and ***taking into account*** principles of universality, access to good quality care, equity and solidarity, they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Amendment

1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare. In such a context and ***on the basis of*** principles of universality, access to good quality care, equity and solidarity they shall define clear quality and safety standards for healthcare provided on their territory, and ensure that:

Or. en

Amendment 86
Jan Cremers

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

Text proposed by the Commission

Amendment

(aa) These quality and safety standards are made publicly available in a clear and accessible format for citizens;

Or. en

Amendment 87
Elizabeth Lynne

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

Text proposed by the Commission

(b) the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken

Amendment

(b) the application of such standards by healthcare providers ***and the competence of health professionals*** in practice is

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

regularly monitored and corrective action taken when appropriate ***to promote excellence and to ensure appropriate standards are met***, taking into account progress in medical science and health technology;

Or. en

Justification

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

Amendment 88
Milan Cabrnoch

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

Text proposed by the Commission

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Amendment

(c) healthcare providers provide all relevant information to enable patients to make an informed choice, in particular on availability, ***quality, safety***, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability;

Or. cs

Amendment 89
Elizabeth Lynne

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

Text proposed by the Commission

(d) patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm

Amendment

(d) patients, ***health providers and the public*** have a means of making complaints and are ***given*** guaranteed ***recourse to appropriate*** remedies and compensation

arising from *the* healthcare *they receive*.

when they suffer harm *or become aware of harm caused* arising from *cross-border* healthcare. *This is set in the context of an effective health system and professional regulation.*

Or. en

Amendment 90
Iles Braghetto

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

Text proposed by the Commission

(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.

Amendment

(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment. ***However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.***

Or. en

Justification

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

Amendment 91
Jan Cremers

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

Text proposed by the Commission

Amendment

(ga) The public authorities in the Member State of treatment shall monitor regularly the accessibility, quality and financial state of their healthcare systems on the basis of the data collected under Article 18. They shall take timely measures to maintain the level of public health and the financial sustainability of the social security systems.

Or. en

Amendment 92
Jan Cremers

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 93
Dieter-Lebrecht Koch

Proposal for a directive
Article 5 – paragraph 3

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

While § 1 of the Article is a clear declaration of the Commission's belief in the subsidiarity principle, § 3 interferes with the national competence of the Member States. There is no added value of such a competence of the Commission and these matters would be better dealt within a framework like the Open Method of Coordination.

Amendment 94
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

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

Or. nl

Amendment 95
Iles Braghetto

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare (*planned care*) there or seeking to receive healthcare (*planned care*) provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. it

Justification

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

Amendment 96
Gabriela Crețu

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs ***to the insured person***, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. en

Justification

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

Amendment 97
Ria Oomen-Ruijten

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons **deliberately** travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. nl

Amendment 98
Anne Van Lancker

Proposal for a directive
Article 6 - paragraph 1

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of

receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or *similar healthcare* been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had *the same treatment or treatment which is equally effective for the patient* been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. en

Justification

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

Amendment 99

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive Article 6 – paragraph 1

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular **Articles 7, 8 and 9**, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another

Amendment

1. Subject to the provisions of this Directive, in particular **Articles 6, 7 and 9**, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another

Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. ***The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.***

Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled, ***according to the same mechanisms as provided for by Regulation (EEC)1408/71 and its successor Regulation (EC) 883/2004.***

Or. en

Justification

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

Amendment 100 **Harald Ettl**

Proposal for a directive **Article 6 – paragraph 1**

Text proposed by the Commission

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure

Amendment

1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure

that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory *social security* system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The *competent institution of the* Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory *health* system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. de

Justification

Clarification that it is not the Member State but the social insurance institution(s) concerned that should reimburse the costs. Clarification that not only the costs to be covered by the statutory social security system but also those to be covered by the State-financed health systems are to be reimbursed.

Amendment 101 **Harald Ettl**

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

Text proposed by the Commission

2. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without

Amendment

2. The costs of healthcare provided in another Member State shall be reimbursed by *the competent institution of the* Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of

exceeding the actual costs of healthcare received.

affiliation, without exceeding the actual costs of healthcare received.

Or. de

Justification

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

Amendment 102

Jan Cremers

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

Text proposed by the Commission

The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received

Amendment

The costs of healthcare provided in another Member State shall be reimbursed ***or paid for*** by the ***social security system of*** the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States may decide to cover other related costs, such as accommodation and travel costs.***

Or. en

Amendment 103

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

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

Text proposed by the Commission

2. The costs of healthcare provided in another Member State shall be reimbursed

Amendment

2. Member States must ensure that physicians and service providers which

by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.

are working as contract partners of their respective national health systems or statutory social security systems are obliged to accept the European Health Insurance Card (EHIC), E-112 form etc. and treat patients showing their EHIC on the same conditions as stipulated by Regulation (EEC)1408/71 and its successor Regulation (EC) 883/2004 Member States must oblige service providers to post an EHIC symbol in the lobby of the service provider (e.g. in a similar way to credit cards in shops and restaurants) to indicate that the EHIC is accepted there in line with those Regulations.

Or. en

Justification

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

Amendment 104 **Anne Van Lancker**

Proposal for a directive **Article 6 - paragraph 2**

Text proposed by the Commission

2. The costs of healthcare provided in another Member State shall be reimbursed

Amendment

2. The costs of healthcare provided in another Member State shall be reimbursed

by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or **similar healthcare** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.

by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had **the same treatment or treatment which is equally effective for the patient** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.

Or. en

Justification

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

Amendment 105 **Iles Braghetto**

Proposal for a directive **Article 6 – paragraph 3**

Text proposed by the Commission

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

Amendment

3. The Member State of affiliation may impose on a patient seeking healthcare provided in another Member State, the same conditions, criteria of eligibility and regulatory and administrative formalities for receiving healthcare and reimbursement of healthcare costs as it would impose if **this** healthcare was provided in its territory, in so far as they are neither discriminatory nor an obstacle to freedom of movement of persons. ***This may include a requirement that the insured person be assessed for the purposes of applying those conditions, criteria or formalities, by a health professional providing services for the statutory social security system of the Member State of affiliation.***

Justification

For the sake of clarity and in order to respect Member States' responsibilities for managing their own healthcare systems and for determining healthcare entitlements for their own citizens it is suggested deleting the wording "same or similar". In a number of Member States, decisions made by General Practitioners or other health professionals affiliated to the state health system are an integral part of the "regulatory and administrative formalities" which determine entitlements to healthcare for individual patients. It is important to explicitly recognise this in the text of the Directive to ensure that there will not be extension of the range of entitlements from the system of the Member State of affiliation.

Amendment 106
Anne Van Lancker

Proposal for a directive
Article 6 - paragraph 3

Text proposed by the Commission

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

Amendment

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

Justification

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

Amendment 107

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Article 6 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Member States *must ensure that physicians and service providers which are working as contract partners of their respective national health systems or statutory social security systems are prohibited from treating patients from another Member State on a private basis or demanding upfront cash payments from them, in such cases that the patient can prove her or his status as an insured person of the respective statutory social security system of the respective Member State of affiliation by virtue of, for example, the European Health Insurance Card, and the E-112 form..*

Or. en

Justification

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

Amendment 108

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios

Toussas

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

Amendment 109
Harald Ettl

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. de

Justification

Clarification that not only the costs to be covered by the statutory social security system but also those to be covered by the State-financed health systems or mixed systems are to be reimbursed.

Amendment 110
Anne Van Lancker

Proposal for a directive
Article 6 - paragraph 4

Text proposed by the Commission

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed

Amendment

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by the statutory social security system for healthcare provided in another Member State. This mechanism shall be based on objective, non-discriminatory criteria known in advance and the costs reimbursed

according to this mechanism shall be not less than what would have been assumed had the same or *similar healthcare* been provided in the territory of the Member State of affiliation.

according to this mechanism shall be not less than what would have been assumed had *the same treatment or treatment which is equally effective for the patient* been provided in the territory of the Member State of affiliation.

Or. en

Justification

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

Amendment 111

Gabriela Crețu

Proposal for a directive

Article 6 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

reimbursed to the insured person, this possibility is excluded.

Amendment 112
Milan Cabrnoch

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

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

Amendment

5. Patients travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC. ***If the medical records are held in electronic form, patients shall have a guaranteed right to obtain a copy of these records or a right of remote access to these records.***

Or. cs

Amendment 113

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

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

Amendment

5. Patients receiving healthcare ***in a Member State other than their Member State of affiliation*** or seeking to receive healthcare provided in another Member State shall be guaranteed access to their medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives

Justification

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

Amendment 114
Anne Van Lancker

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

Text proposed by the Commission

Amendment

5a. The provisions of this chapter shall not affect the conclusion of cross-border contractual arrangements for planned healthcare.

Justification

Chapter III of this Directive deals with the assumption of healthcare costs for individual patients. It is important to clarify that these provisions do not prevent the conclusion of cross-border contractual arrangements for planned healthcare. In this case, contracting parties decide to choose to follow the rules of the social security coordination or apply specific rules and tariffs established through negotiation between the contractual partners.

Amendment 115
Iles Braghetto

Proposal for a directive
Article 7

Text proposed by the Commission

Amendment

Article 7

deleted

Non-hospital care

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system

Or. en

Justification

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

Amendment 116
Anne Van Lancker

Proposal for a directive
Article 7

Text proposed by the Commission

Amendment

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its **statutory** social

system.

security system.

Or. en

Justification

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

Amendment 117
Dieter-Lebrecht Koch

Proposal for a directive
Article 7

Text proposed by the Commission

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.

Amendment

The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care ***and non-specialised care*** provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system.

Or. en

Amendment 118
Iles Braghetto

Proposal for a directive
Article 8 – Title

Text proposed by the Commission

Hospital and specialised care

Amendment

Prior authorisation

Or. en

Justification

This amendment recognises that prior authorisation systems can be valuable to patients in

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

Amendment 119

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive

Article 8

Text proposed par la Commission

Amendment

Article 8

deleted

Hospital and specialised care

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:

(a) healthcare which requires overnight accommodation of the patient in question for at least one night.

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or

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

2. This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure

with scrutiny referred to in Article 19(3).

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:

(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and

(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:

(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3.

Or. en

Justification

According to Article 152 EC Treaty, it is the exclusive competency of the Member States to decide how to organise and finance their health care systems, and this includes their competency to define what is to be considered as hospital care. The European Union and especially the European Commission has no competencies in this field, and therefore Article 8 needs to be deleted. Secondly, the Commission proposal on prior authorisation schemes concerning hospital care in another Member States goes well beyond the case law of the European Court of Justice and needs to be equally rejected.

Amendment 120 **Dieter-Lebrecht Koch**

Proposal for a directive **Article 8 – paragraph 1 – introductory part (new)**

Text proposed by the Commission

Amendment

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean healthcare which requires overnight accommodation of the patient in question for at least one night.

Or. en

Amendment 121 **Dieter-Lebrecht Koch**

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

Text proposed by the Commission

Amendment

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean **healthcare, included in a specific national list that does not require overnight accommodation of the patient for at least one night. This list shall be limited to healthcare that requires use of highly specialised and cost-intensive medical**

*infrastructure or medical equipment; or
healthcare involving treatments
presenting a particular risk for the patient
or the population.*

Or. en

Amendment 122
Jean Lambert & Elisabeth Schroedter

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

Text proposed by the Commission

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall **mean**:

Amendment

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital **and specialised** care shall **include at least**:

Or. en

Amendment 123
Marie Panayotopoulos-Cassiotou

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

Text proposed by the Commission

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:

Amendment

1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care **and specialised care** shall mean **healthcare as defined by the legislation of the Member State of affiliation**.

Or. el

Amendment 124
Marie Panayotopoulos-Cassiotou

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

Text proposed by the Commission

Amendment

(a) healthcare which requires overnight accommodation of the patient in question for at least one night.

deleted

Or. el

Amendment 125
Harlem Désir

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

Text proposed by the Commission

Amendment

(a) healthcare which requires overnight accommodation of the patient in question for at least one night.

(a) healthcare which requires overnight accommodation of the patient in question for at least one night **or which is defined as such by the national law of the Member State of affiliation.**

Or. fr

Justification

The definition provided by the Commission does not correspond to the real nature of the services provided in the Member States. It does not, for example, take account of outpatient surgery.

In order to correspond to the real nature of the services provided in practice, the definition of hospital care should refer to the definition in force in the patient's Member State of affiliation.

Amendment 126
Dieter-Lebrecht Koch

Proposition de directive
Article 8 – paragraph 1 – points a

Text proposed by the Commission

Amendment

(a) healthcare which requires overnight accommodation of the patient in question for at least one night.

deleted

Or. en

Amendment 127
Marie Panayotopoulos-Cassiotou

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

Text proposed by the Commission

Amendment

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:

deleted

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or

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

Or. el

Amendment 128
Anne Van Lancker

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

Text proposed by the Commission

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall ***be limited to***:

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
- healthcare involving treatments presenting a particular risk for the patient or the population.

Amendment

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night ***and for which planning is necessary in order to maintain balanced geographical distribution of healthcare, to control costs and to prevent any significant wastage of financial, technical and human resources.*** This list shall ***cover at least***:

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment;
- healthcare involving treatments presenting a particular risk for the patient or the population.

Or. en

Justification

In according with ECJ jurisprudence, the proposed amendment reflects the idea that the notion of hospital care is inextricably linked with the need for planning. Planning ensures that there is sufficient and permanent access to a balanced range of high-quality hospital treatment whilst controlling costs and safeguarding the sustainability of the social security system.

Amendment 129
Dieter-Lebrecht Koch

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

Text proposed by the Commission

(b) healthcare, included in a specific list, that does not require overnight

Amendment

deleted

accommodation of the patient for at least one night. This list shall be limited to:

- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or

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

Or. en

Amendment 130

Jean Lambert & Elisabeth Schroedter

Proposal for a directive

Article 8 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:

*- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
- healthcare involving treatments presenting a particular risk for the patient or the population.*

(b) healthcare, that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or healthcare involving treatments presenting a particular risk for the patient or the population.

Or. en

Amendment 131

Patrizia Toia

Proposal for a directive

Article 8 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) health care for patients suffering from chronic illnesses who require care and/or medicines which are not supplied

through common distribution channels and cannot be self-administered, so that they require administration or supply by hospital units or specialised units.

Or. it

Justification

Healthcare has to be guaranteed also to people who suffer from rare and chronic diseases and need medicines that cannot be self-medicated.

Amendment 132
Milan Cabrnoch

Proposal for a directive
Article 8 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) healthcare that does not require overnight accommodation of the patient for at least one night and which the Member State regards as hospital care under its own national law, on condition that at least a qualified majority of other Member States agree with this (in the context of a discussion in the committee referred to in Article 19);

Or. cs

Amendment 133
Jean Lambert & Elisabeth Schroedter

Proposition de directive
Article 8 – paragraph 1 – points b a (new)

Text proposed by the Commission

Amendment

(ba) Healthcare for which planning is necessary in order to maintain universal access, affordability and equal territorial accessibility, to control costs and to

prevent any significant wastage of financial, technical and human resources.

Or. en

Amendment 134
Iles Braghetto

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

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

Amendment 135
Marie Panayotopoulos-Cassiotou

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

Amendment

2. This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by

deleted

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

Or. el

Amendment 136
Anne Van Lancker

Proposal for a directive
Article 8 - paragraph 2

Text proposed by the Commission

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

Amendment

2. The competent authorities of the Member States of affiliation shall set up this list and notify it to the Commission.

Or. en

Justification

Given the fact that the Member State of affiliation is responsible for the reimbursement of healthcare costs, it is up to that Member State of affiliation to draw up the list of hospital care.

Amendment 137
Dieter-Lebrecht Koch

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

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

Amendment

2. This *national* list shall be set up and may be regularly updated by the *Member State of affiliation*.

Amendment 138
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

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

Amendment

2. *The competent authorities of the Member State of affiliation shall set up a list of treatments considered as hospital or specialised care and notify it to the Commission.*

Amendment 139
Ria Oomen-Ruijten

Proposal for a directive
Article 8 – paragraph 2

Text proposed by the Commission

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

Amendment

2. This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3). *In drawing up this list, the Commission shall take account of the special position of European reference networks as referred to in Article 15.*

Amendment 140
Iles Braghetto

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care ***provided in another Member State where the following conditions are met:***

(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and

(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:

(i) the financial balance of the Member State's social security system; and/or
(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care ***and other specialised care as defined by each individual Member State.***

Or. en

Justification

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

proportionality, are simple and straightforward, and provide timely responses to requests.

Amendment 141
Anne Van Lancker

Proposal for a directive
Article 8 - paragraph 3

Text proposed by the Commission

3. The Member State of affiliation may ***provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:***

(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and

(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:

(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment

3. The Member State of affiliation may ***make the assumption of the costs of hospital care in another Member State by its statutory social security system subject to the granting of prior authorisation.***

Or. en

Justification

As the Court of Justice has consistently held, Member states are entitled to introduce or maintain a system of prior authorization for the assumption of hospital care provided in

another Member State because it is justified by the need to preserve financial balance of the social security system and the need of hospital planning.

Amendment 142
Dieter-Lebrecht Koch

Proposal for a directive
Article 8 – paragraph 3 – introductory part

Text proposed by the Commission

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of **hospital** care provided in another Member State where the following conditions are met:

Amendment

3. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of **specialised** care provided in another Member State where the following conditions are met:

Or. en

Amendment 143
Jan Cremers

Proposal for a directive
Article 8 – paragraph 3 – introductory part

Text proposed by the Commission

The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State **where the following conditions are met:**

Amendment

The Member State of affiliation may provide for a system of prior authorisation for reimbursement **or payment** by its social security system of the cost of hospital care provided in another Member State **where, had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system. The purpose of the system is:**

Or. en

Amendment 144
Jan Cremers

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

Text proposed by the Commission

(a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and

Amendment

(a) to maintain the financial balance and sustainability of the Member State's social security system; and

Or. en

Amendment 145
Jan Cremers

Proposal for a directive
Article 8 – paragraph 3 – point b

Text proposed by the Commission

(b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Article and to prevent it from seriously undermining, or being likely to seriously undermine:

(i) the financial balance of the Member State's social security system; and/or

(ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment

(b) to ensure that patients are protected and are guaranteed, by a prior authorisation system, financial coverage of the treatment they receive in the member state of treatment; and

(ba) to guarantee the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment 146
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 8 – paragraph 3 – point b

Text proposed by the Commission

(b) the purpose of the system is to address ***the consequent outflow of patients*** due to the implementation of the present Article and to prevent it from ***seriously*** undermining, or being likely to seriously undermine:

Amendment

(b) the purpose of the system is to address ***significant patient flows*** due to the implementation of the present Article and to prevent it from undermining, or being likely to undermine:

Amendment 147
Jean Lambert & Elisabeth Schroedter

Proposition de directive
Article 8 – paragraph 3 – point b – subpoint ii

Text proposed by the Commission

(ii) the planning and rationalisation carried out in the ***hospital*** sector to avoid ***hospital*** overcapacity, imbalance in the supply of ***hospital care*** and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment

(ii) the planning and rationalisation carried out in the ***healthcare*** sector to avoid overcapacity, imbalance in the supply of ***healthcare*** and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Amendment 148
Jean Lambert & Elisabeth Schroedter

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

Text proposed by the Commission

Amendment

(ba) The competent authorities of the Member State of affiliation shall establish criteria in order to be able to identify when the financial balance of the Member State's social security system, or the planning and rationalisation carried out in its healthcare sector is undermined or is likely to be undermined.

Or. en

Amendment 149
Jan Cremers

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

Text proposed by the Commission

Amendment

3a. Nothing in the Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment.

Or. en

Amendment 150
Jean Lambert & Elisabeth Schroedter

Proposal for a directive
Article 8 – paragraph 4

Text proposed by the Commission

4. The prior authorisation system shall be limited to what is necessary and proportionate to *avoid such impact*, and shall not constitute a means of arbitrary discrimination.

Amendment

4. The prior authorisation system shall be limited to what is necessary and proportionate to ***enable the Member State to organise and deliver safe high quality healthcare within its territory in accordance with the principles of universal access, solidarity, affordability, equal territorial accessibility and democratic control***, and shall not constitute a means of arbitrary discrimination.

Or. en

Amendment 151
Ria Oomen-Ruijten

Proposal for a directive
Article 8 – paragraph 4

Text proposed by the Commission

4. The prior authorisation system shall be limited to what is necessary and proportionate to avoid such impact, and shall not constitute a means of arbitrary discrimination.

Amendment

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

Or. nl

Amendment 152
Véronique De Keyser

Proposal for a directive
Article 8 – paragraph 4

Text proposed by the Commission

4. The prior authorisation system shall be **limited to what is necessary and proportionate to avoid such impact**, and shall not constitute a means of arbitrary discrimination.

Amendment

4. The prior authorisation system shall be **evaluated by the two Member States concerned** and shall not constitute a means of arbitrary discrimination.

Or. fr

Justification

The incoming flow of patients must be taken into consideration. Without reciprocal checks by the two Member States concerned, the prior authorisation system would be unusable and would constitute a threat to healthcare planning in the Member State of treatment.

Amendment 153
Jan Cremers

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 154
Elizabeth Lynne

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 155
Jan Andersson, Ole Christensen

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

Text proposed by the Commission

Amendment

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

Or. en

Justification

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

boarder health care less attractive for those with a low income and thus not equally available to all.

Amendment 156
Dieter-Lebrecht Koch

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

Text proposed by the Commission

Amendment

4a. The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State.

Or. en

Amendment 157
Dieter-Lebrecht Koch

Proposal for a directive
Article 8 – paragraph 5

Text proposed by the Commission

Amendment

5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of ***paragraph 3***.

5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of ***paragraphs (3) 4 and 5***.

Or. en

Amendment 158
Anne Van Lancker

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

Text proposed by the Commission

Amendment

5a. The Member State of treatment may take appropriate measures to address the inflow of patients and to prevent it from seriously undermining, or being likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

The Member State of treatment shall refrain from discriminating with regard to nationality and shall ensure that the measures restricting free movement shall be limited to what is necessary and proportionate.

The Member State of treatment shall notify the measures to the Commission.

Or. en

Justification

The Directive establishes common rules to ensure the individual right to free movement of patients. Article 8 of the Directive is written from the perspective of Member States of affiliation which are confronted with the consequences linked with the outflow of patients. The Directive remains however silent about the consequences for Member States of treatment that are confronted with the inflow of patients.

Amendment 159
Harald Ettl

Proposal for a directive
Article 8 a (new)

Text proposed by the Commission

Amendment

Article 8a

***Rejection of hospital treatments and
special treatments***

Member States of treatment may permit individual health service providers to refuse hospital treatment and special treatment for patients who go to another Member State to seek treatment if this would be detrimental to other patients with similar health needs, for example because it increased waiting time for treatment.

Or. de

Justification

Inclusion of the last clause of Recital 12. This vital clause from the recitals is lacking in the body of the text of the directive: in the interests of legal certainty and greater clarity, it would be preferable to include this clause here. The aim of providing health care for patients as close as possible to their place of residence or work must not be made impossible on account of unlimited access for patients from other Member States.

Amendment 160

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission

Amendment

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in **Article 8(3)**,

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in **Art.22.1 c) and**

reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in **Article 6(3)**, are based on objective, non-discriminatory criteria which are published in advance, **and which are necessary and proportionate to the objective to be achieved**. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.

Art. 22.2 of Regulation (EEC) 1408/71, coverage of costs of healthcare incurred in another Member State and other conditions and formalities referred to in **Article 6(1)**, are based on objective, non-discriminatory criteria which are published in advance. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation (EEC) 1408/71 are met.

Or. en

Justification

According to Article 152 EC Treaty, it is the exclusive competency of the Member States to decide how to organise and finance their health care systems, and this includes their competency to set up prior authorisation schemes for hospital treatment abroad respecting the case law of the European Court of Justice. Again, the Commission proposal on prior authorisation schemes goes well beyond the case law of the European Court of Justice and needs to be equally rejected.

Amendment 161 **Ria Oomen-Ruijten**

Proposal for a directive **Article 9 – paragraph 1**

Text proposed by the Commission

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be

Amendment

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, non-discriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be

achieved. In any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.

achieved. ***Until the date on which Regulation (EC) No 883/2004 enters into force, the rule shall apply that***, in any event, an insured person shall always be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met. ***From the date on which Regulation (EC) No 883/2004 enters into force, the rule shall apply that when the circumstances referred to in Article 20 of Regulation (EC) No 883/2004 are met, an insured person shall always be granted authorisation by virtue of the regulations concerning coordination of social security schemes as referred to in Article 3(1)(f).***

Or. nl

Amendment 162

Jiří Maštálka, Gabriele Zimmer, Ilda Figueiredo, Dimitrios Papadimoulis & Georgios Toussas

Proposal for a directive Article 9 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Member States shall specify in advance and in a transparent way the criteria for refusal of the prior authorisation.

Or. en

Justification

According to Article 152 EC Treaty, it is the exclusive competency of the Member States to decide how to organise and finance their health care systems, and this includes their competency to set up prior authorisation schemes for hospital treatment abroad respecting the case law of the European Court of Justice. Again, the Commission proposal on prior authorisation schemes goes well beyond the case law of the European Court of Justice and needs to be equally rejected.

Amendment 163
Anne Van Lancker

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

Text proposed by the Commission

Amendment

3a. The Member State of affiliation may refuse the prior authorisation referred to in Article 8(3) where the treatment which is among the benefits provided for by its legislation, can be provided to the patient on its territory within a time limit which is medically justifiable, taking into account his/her current state of health and the probable course of his/her illness.

Or. en

Justification

The current proposal does not include the rule established by ECJ case law that a prior authorization may be refused provided that the treatment can be provided to the patient on its territory within a time limit which is medically justifiable. The wording of the amendment corresponds to the wordings of Article 20 of Regulation No 883/2004.

Amendment 164
Jan Cremers

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

Text proposed by the Commission

Amendment

Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account:

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

Or. en

Amendment 165
Gabriela Crețu

Proposal for a directive
Article 9 – paragraph 4 – point b a

Text proposed by the Commission

Amendment

(ba) the urgency of the treatment or of the medical procedure in question;

Or. en

Justification

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

Amendment 166
Anne Van Lancker

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

Text proposed by the Commission

Amendment

(da) the medical history of the patient.

Or. en

Justification

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

Amendment 167
Véronique De Keyser

Proposal for a directive
Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

Information for patients concerning the use of healthcare in another Member State

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

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

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

Or. fr

Justification

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

Amendment 168
Elizabeth Lynne

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission

1. The Member State of *affiliation* shall ensure that there are mechanisms in place to *provide patients on request with* information *on* receiving healthcare in *another* Member State, *and the terms and conditions* that *would* apply, *inter alia*, *whenever* harm is caused as a result of healthcare received in *another* Member State.

Amendment

1. The Member State of *treatment* shall ensure that there are mechanisms in place to *make* information *publicly available including about* receiving healthcare *and registered health professionals and providers* in *that* Member State, *the quality and safety standards* that apply, *the regulatory system in place, and the process for making complaints where* harm is caused as a result of healthcare received in *that* Member State.

Or. en

Amendment 169
Ria Oomen-Ruijten

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission

10. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Amendment

10. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State. *In information about cross-border care, a clear distinction shall be made between the rights which patients have by*

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

Or. nl

Amendment 170
Harlem Désir

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Amendment

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State. ***The Member States of affiliation shall ensure that the information provided to patients corresponds to public health considerations and is impartial, comparative and complete.***

Or. fr

Justification

Information on the nature and the quality of the healthcare services available must come from a public authority and must comply with public health considerations and be impartial, comparative and complete, in order to allow patients to make informed choices (such as the position of the Mutualité Française on the information provided to patients relating to medicinal products).

Amendment 171
Marian Harkin

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Amendment

1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, ***including information outlining the risks associated with receiving healthcare in another Member State***, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Or. en

Justification

It is essential that patients can access appropriate information so that they can make an informed choice about the treatment. It is essential that the information provided to patients by health service providers is fair and balanced; not only advertising the benefits of certain treatments / service providers but also outlining the risks associated, and information about a patient's course of redress in the event that they are dissatisfied with or are harmed in any way by the service.

Amendment 172
Elizabeth Lynne

Proposal for a directive
Article 10 – paragraph 2

Text proposed by the Commission

2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the

Amendment

2. The information referred to in paragraph 1 shall be made easily accessible, including by electronic means, ***in formats easily accessible to people with disabilities at no extra cost***, and shall include information on patients' entitlements, on procedures for

patient is deprived of such entitlements.

accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements.

Or. en

Amendment 173

Marian Harkin

Proposal for a directive

Article 10 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Justification

In the interests of patients availing of cross-border services, there is also a need for greater transparency of health professional and health service regulation. Public registers of health professionals and health service providers should be available in Member states so that patients can easily identify prescribers, professionals and other treatment providers and if necessary to verify and validate the professional standing of the health professionals providing care. The international evidence illustrates that the most practical way for patients to have access to information on their current or prospective healthcare providers is via the publication of public registers of such practitioners. Such registers should now be available via the Internet and should allow the patient to access the relevant data by searching either via the name or via the registration number of the healthcare provider (or indeed by searching via geographical area). The relevant data that should be in the public domain should be, at a minimum, the name, registration number and practice address of the healthcare professional, the date of their first registration on that register, the expiry date of

their current registration, and any conditions or restrictions on their practice or suspensions should this be the case. Healthcare professionals, who are not registered, be it for voluntary reasons or if struck off for whatever reason, should not appear on such register.

Amendment 174
Véronique De Keyser

Proposal for a directive
Article 10 (new)

Text proposed by the Commission

Amendment

Article 10

The Member State of treatment shall ensure that:

a. Patients receive upon their request information on guarantees of quality and safety of healthcare provided.

b. Healthcare providers in the Member State of treatment provide information on availability, prices and outcomes of healthcare provided, including procedures for complaints and means of redress available for healthcare provided.

Or. fr

Justification

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

Amendment 175
Jan Cremers

Proposal for a directive
Article 11 – Title

Text proposed by the Commission

Applicable rules to healthcare ***provided*** in another Member State

Amendment

Applicable rules to healthcare ***received*** in another Member State

Or. en

Amendment 176
Jan Cremers

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission

When healthcare is ***provided*** in a Member State other than that where the patient is an insured person, ***or in a Member State other than that where the healthcare provider resides, is registered or established***, such healthcare service is provided according to the legislation of the Member State of treatment in accordance with Art. 5.

Amendment

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

Or. en

Amendment 177
Ria Oomen-Ruijten

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact

Amendment

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. ***Member States***

details to the Commission.

shall ensure that patients' organisations, health insurance funds and care providers are involved in these national contact points.

Or. nl

Amendment 178

Marie Panayotopoulos-Cassiotou

Proposal for a directive

Article 12 – paragraph 1

Text proposed by the Commission

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission.

Amendment

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

Or. el

Amendment 179

Elizabeth Lynne

Proposal for a directive

Article 12 – paragraph 2 – point a

Text proposed by the Commission

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

Amendment

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and quality and safety ***standards***, protection of personal data, procedures for complaints, ***the means by which professionals and providers are regulated and the means by which regulatory action can be taken, the*** means of redress available for healthcare provided in ***that*** Member State, and the terms and conditions applicable;

Amendment 180
Véronique De Keyser

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

Text proposed by the Commission

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

Amendment

(a) provide and disseminate information to patients in particular on their rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided;

Or. fr

Justification

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

Amendment 181
Gabriela Crețu

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

Text proposed by the Commission

(a) provide and disseminate information to patients in particular on ***their*** rights related

Amendment

(a) provide and disseminate information to patients ***and healthcare professionals*** in

to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

particular on *the patients'* rights related to cross-border healthcare and the guarantees of quality and safety, protection of personal data, procedures for complaints and means of redress available for healthcare provided in another Member State, and on the terms and conditions applicable;

Or. en

Justification

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

Amendment 182

Marian Harkin

Proposal for a directive

Article 12 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) competent healthcare regulatory bodies in each Member State shall define and share transparent and relevant information with other competent healthcare regulatory bodies with regard to the mobility of health professionals; this information shall include information that covers sanctions and undertakings arising from criminal behaviour, professional misconduct and sanctions imposed as a result of impaired fitness to practice;

Or. en

Justification

This is information that patients should have access to in the event of patient mobility for healthcare in order to ensure patient safety.

Amendment 183
Véronique De Keyser

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

Text proposed by the Commission

(b) help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare **in another Member State**; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;

Amendment

(b) help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare; the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;

Or. fr

Justification

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

Amendment 184
Gabriela Crețu

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

Text proposed by the Commission

(b) help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State; the national contact point shall in particular inform patients

Amendment

(b) **provide information on what to do in cases of redress and harm**, help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State;

about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;

the national contact point shall in particular inform patients about the options available to settle any dispute, help to identify the appropriate out-of-court settlement scheme for the specific case and help patients to monitor their dispute where necessary;

Or. en

Justification

Information on what to do in cases of redress and harm from the Member State of treatment must be available at the national contact points.

Amendment 185

Harald Ettl

Proposal for a directive

Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Or. de

Justification

To ensure that the procedure runs as smoothly as possible.

Amendment 186
Marie Panayotopoulos-Cassiotou

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.

Amendment

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

Or. el

Amendment 187
Ria Oomen-Ruijten

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

1. Member States shall render such mutual assistance as is necessary for the implementation of this Directive.

Amendment

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

Or. nl

Amendment 188
Ria Oomen-Ruijten

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border

Amendment

Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border

cooperation.

cooperation, *and shall conclude agreements on this subject.*

Or. nl

Amendment 189
Gabriela Crețu

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Amendment

2. Member States shall facilitate cooperation in cross-border healthcare provision at regional and local level and *communication between healthcare providers abroad and continued healthcare providers at home*, as well as through information and communication technologies, cross-border healthcare provided on a temporary or ad hoc basis and other forms of cross-border cooperation.

Or. en

Justification

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

Amendment 190
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

2a. Member States, particularly neighbouring countries, may conclude

agreements among themselves as referred to in paragraphs 1 and 2 concerning, inter alia, worthwhile cooperative frameworks which must remain in existence or be allowed more scope for development, the inflow and outflow of patients between these Member States, planning systems and certain intramural forms of care.

Or. nl

Justification

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

Amendment 191 **Elizabeth Lynne**

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 192
Milan Cabrnoch

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

Text proposed by the Commission

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

Amendment

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

Or. cs

Amendment 193
Iles Braghetto

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

Text proposed by the Commission

(a) are limited to what is necessary **and** proportionate to safeguard human health and are **non-discriminatory** or

Amendment

(a) are **not** limited to what is necessary, **are not** proportionate to safeguard human health and are **discriminatory** or

Or. it

Justification

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

Amendment 194
Iles Braghetto

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

Text proposed by the Commission

Amendment

(ba) imply a modification to the right of Member States to determine the benefits which the States themselves decide to grant.

Or. it

Justification

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

Amendment 195
Dieter-Lebrecht Koch

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

Text proposed by the Commission

Amendment

(ba) The reimbursement is based only on relevant provisions of the Members State of affiliation.

Or. en

Justification

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

Amendment 196
Harald Ettl

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

Text proposed by the Commission

Amendment

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

Or. de

Justification

Otherwise there would be a contradiction with Article 11.

Amendment 197
Marian Harkin

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

Text proposed by the Commission

Amendment

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

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

Or. en

Justification

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

Amendment 198
Milan Cabrnoch

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

Text proposed by the Commission

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

Amendment

(a) measures enabling a pharmacist or other health professional to verify the authenticity of the *ePrescription* and whether the prescription was issued in another Member State by an authorised person through supporting interoperability of ePrescriptions;

Or. cs

Amendment 199
Harlem Désir

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

Text proposed by the Commission

(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible;

Amendment

(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible; *prescriptions issued using this Community form must be formulated in accordance with the international non-proprietary name (INN) system;*

Or. fr

Justification

In order to be readable anywhere in Europe, prescriptions made out on the basis of a Community form should use a common language, the International Non-proprietary Name

(INN) system, which identifies medicinal products by their molecules and not by their commercial names, which may vary from one country to another.

Amendment 200

Iles Braghetto

Proposal for a directive

Article 14 – paragraph 2 – point c

Text proposed by the Commission

(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.

Amendment

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

Or. it

Justification

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

Amendment 201

Elizabeth Lynne

Proposal for a directive

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

Text proposed by the Commission

Amendment

(ca) measures to ensure that prescriptions issued and information given about medicinal products prescribed are accessible to people with disabilities.

Or. en

Amendment 202
Ria Oomen-Ruijten

Proposal for a directive
Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15a
Trial areas

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

Or. nl

Amendment 203
Elizabeth Lynne

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

Text proposed by the Commission

Amendment

Those contracting e-health services from providers and professionals in other Member States shall ensure they are appropriately regulated and qualified and that they have demonstrated, via the relevant competent authority, that they are fit to practise and to provide e-health services.

Or. en

Amendment 204
Marian Harkin

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission

1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.

Amendment

1. Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. ***They shall also monitor trends and patterns in relation to adverse incidents or systems failures in respect of cross-border care.*** They shall collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data.

Or. en

Justification

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

Amendment 205
Anne Van Lancker

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

Text proposed by the Commission

Amendment

3a. The collection of data within the framework of this Article shall be done in close cooperation with the collection of data foreseen by the Administrative Commission on Social Security for Migrant Workers.

Justification

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

Amendment 206
Ria Oomen-Ruijten

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

Text proposed by the Commission

Amendment

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