COUNCIL OF THE EUROPEAN UNION

Brussels, 30 April 2009

8903/09

Interinstitutional File: 2008/0142 (COD)

CODEC 585
SAN 79
SOC 263
MI 163

NOTE

from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare - Outcome of the European Parliament's first reading (Strasbourg, 21 to 24 April 2009)

I. INTRODUCTION

The Rapporteur, Mr John BOWIS (EPP/ED - UK), presented a report on behalf of the Committee on Environment, Public Health and Food Safety consisting of 115 amendments (amendments 1-115). In addition, the PES political group tabled five amendments (amendments 116-118 and 156-157), the IND/DEM political group tabled six amendments (amendments 119-124), the Greens/EFA political group tabled sixteen amendments (amendments 125-132 and 148-155), the ALDE political group tabled thirteen amendments (amendments 133-145), the EPP/ED political group tabled two amendments (amendments 146-147) and the EUL/NGL political group tabled eight amendments (amendments 158-165).

II. DEBATE

Speaking on behalf of the Rapporteur who was absent due to illness, Mr Philip BUSHILL-MATTHEWS (EPP/ED - UK) opened the debate, which took place on 23 April 2009, and:

- affirmed the right of European citizens to travel to another Member State for treatment;
- emphasised the need for politicians and not judges to provide legal certainty on cross-border healthcare issues;
- called for patients who do wish to travel to another Member State for treatment to be able to do so under terms that are transparent and fair. Patients must know how much they will be charged, what quality and safety standards they can expect, and what rights they have if something goes wrong;
- stated that such patient rights should not in any way detract from Member States' ability to provide high-quality health care for all their citizens. The amendments of the Committee on the Environment, Public Health and Food Safety would not tell Member States how to organise their own health systems. Nor do they lay down healthcare quality standards; and
- noted that the Committee's amendments would establish safeguards for Member States to help them to protect their own national health systems, for example by choosing a system of prior authorisation in certain circumstances. Such prior authorisation should nevertheless not be used to limit patient choice. To the contrary, the increased availability of cross-border health care should in turn help to encourage national systems to provide increasingly better health care.

Speaking on behalf of the Czech Presidency, Mrs Daniela FILIPIOVÁ:

- noted that the Czech presidency's compromise proposals for the Directive were still being keenly discussed within the Council's working parties. She was consequently unable at this stage to predict whether a political agreement could be reached before the end of the Czech presidency;
- stressed the importance of clarity, legal certainty and subsidiarity. Patients travelling to other Member States should receive full information and high-quality health care;
- stated that the Directive should codify all Community legislation concerning the single market aspects of health care, should complement the Regulation on the co-ordination of social security systems, and should enable Member States to make use of health care services in other Member States subject to prior authorisation;
- noted that the report of the Committee on the Environment, Public Health and Food Safety was a difficult compromise between different political groups within the Parliament; and

- stated that the Council would study all amendments with care and consider how it could take account of them in its common position in order to reach an agreement in second reading.

Commissioner VASSILIOU gave assurances that the proposed Directive would not impose changes in the organisation and financing of national healthcare systems.

Speaking on behalf of the Committee on Employment and Social Affairs, Mr Iles BRAGHETTO (EPP/ED - IT) stressed the need to monitor the efficiency of cross-border healthcare and the importance of ensuring the ethical conduct of healthcare workers.

Speaking on behalf of the Committee on Industry, Research and Energy, Mrs Françoise GROSSETÊTE (EPP/ED - FR):

- stated that the proposed Directive would not be a new Services Directive, but rather a refusal to leave European legislation to the Court of Justice rather than to politicians;
- affirmed the right of European citizens to have themselves treated in another Member State, but subject to conditions;
- stated that the proposed Directive would fully respect the sovereignty of Member States as regards their healthcare systems;
- stated that, contrary to what some opponents of the proposal assert, the proposed Directive would apply to all patients and provide them with cross-border healthcare which is at present available only to the most privileged members of society; and
- welcomed the greater equity, the greater amount of information that would be provided to citizens on available treatment, and the greater level of cooperation in new healthcare technologies that the proposed Directive would provide.

Speaking on behalf of the Committee on the Internal Market and Consumer Protection, Mrs Bernadette VERGNAUD (PES - FR):

- noted that the amendments tabled by the Committee on the Environment, Public Health and Food Safety, which had the support of most of the political groups but not of the PES, were no more than a response to the judgements of the European Court of Justice. Not only do the tabled amendments not respond to the main public health challenges, but they do not put an end to legal uncertainty for patients. Furthermore, they enshrine a free market vision of health care;
- stated that the vagueness of the criteria for the application of the currently proposed Directive, of Regulation 1408/1971 and soon of Regulation 883/2004 will only result in the Court being called upon yet again to deliver its judgement;
- opposed the single legal base of Article 95. Health should not be regarded as just another tradable commodity subject to the laws of supply and demand;
- warned that the amendments tabled by the Committee on the Environment, Public Health and Food Safety would lead to unequal access to health care to the advantage of affluent and well informed citizens who will be able to choose the best health care available anywhere within the Union. Others will have to be content with healthcare provision that has already broken down in many Member States and which will not be improved by the proposed Directive; and
- expressed her opposition to amendment 67 which will place the various national social security systems in competition with each other since all citizens would be free (provided that they could pay) to join whichever European system they wish.

Speaking on behalf of the Committee on Legal Affairs, Mrs Diana WALLIS (ALDE - UK):

- gave her support to the proposal and applauded the prospect of increased legal certainty;
- stated that the proposal does respect both subsidiarity and the integrity of national health systems; and
- stated that her committee had disagreed with the report of the Committee on the Environment, Public Health and Food Safety in only one respect, namely that her committee would have liked to see greater provision being made for patients in cases where treatment goes wrong. The applicable legal regime and jurisdiction rules are not set out sufficiently clearly. The proposal should be made more patient-oriented in this respect. Patients should be able to bring claims in their country of residence and should receive compensation according to the law of their country of residence.

Speaking on behalf of the EPP/ED political group, Mrs Avril DOYLE (EPP/ED - IE):

- stated that the report of the Committee on the Environment, Public Health and Food Safety was based on patients' needs and not patients' means;
- noted that the definitions of hospital care and prior authorisation had been discussed and agreed with the Council and the Commission;
- noted that quality standards would remain a Member State competence, but that safety standards would be a European competence;
- stressed the need for one-stop-shop equivalent sources of patient information; and
- stated that the provision of mutual recognition of prescriptions will be an important supplement to the currently proposed Directive and that it must be added quickly.

Speaking on behalf of the PES political group, Mrs Dagmar ROTH-BEHRENDT (PES - DE):

- welcomed the report of the Committee on the Environment, Public Health and Food Safety which included a number of important amendments that her political group had pushed for;
- stressed the importance of Member States being able to afford cross-border treatment. Prior authorisation is therefore critically important;
- welcomed the establishment of reference networks which will allow users to locate best practices, and the most successful and innovactive treatments. Specialists may know this information already, but not general practitioners who actually refer patients;
- stressed the importance of information points which will enable patients to ascertain their rights in their own language; and
- highlighted two points where she was dissatisfied with the Committee's report:
    - a dual legal basis including Article 152 of the Treaty is a 'sine qua non' for the PES political group; and
    - the provision in Article 8(4) of the Commission's proposal relating to prior authorisation needs to be improved. If this does not prove possible in first reading, it might nevertheless be possible in second reading.

Speaking on behalf of the ALDE political group, Mr Jules MAATEN (ALDE - NL):

- stated that sick patients should not be forced to battle with cold-hearted bureaucrats or to go through endless legal procedures. A health ombudsman is needed;
- argued that prior authorisation is essential in order to prevent national healthcare systems from being undermined, but that exceptions could be made for life-threatening diseases; and
- called for a pan-European definition of hospital care.

Speaking on behalf of the Greens/EFA political group, Mr Claude TURMES (Greens/EFA - LU):

- noted that more than 30% of healthcare received by Luxemburgers is already carried out abroad. Reimbursement is not an issue;
- stated that the main benefit that will come from the present proposal is the prospect of improved information for patients as regards both centres of excellence and quality of care. He believed that many Member States still have much work to do on quality criteria and information. Furthermore, patients should know where to turn if they are abroad and develop health problems;
- argued that a prior authorisation system would not only allow European citizens to know in advance exactly when they would be reimbursed and to secure pre-funding, but that it would also facilitate planning by large hospital infrastructures;
- called for a double legal base; and
- called for specific legislation for rare diseases.

Speaking on behalf of the EUL/NGL political group, Mrs Kartika LIOTARD (EUL/NGL - NL):

- accused the Commission of trying to introduce the free market into health care;
- objected to the choice of Article 95 as a legal basis because it would subordinate patients' interests to commercial interests;
- argued that the requirement for reimbursement on the basis of home countries' healthcare schemes would introduce inequalities between European citizens;
- warned that there was a risk that it would soon be not a right but a duty for patients to go abroad for health care; and
- argued that a single legal basis of Article 95 alone could lead to the collapse and fragmentation of national health care systems and the loss of national control.

Speaking on behalf of the IND/DEM political group, Mrs Hanne DAHL (IND/DEM - DK):

- called for support for amendment 102 on prior authorisation;
- deplored the trend towards regarding individuals as consumers rather than as citizens; and
- argued that healthcare services are not commodities that should be subject to market rules.

Speaking on behalf of the Non-Attached Members, Mr Jim ALLISTER (NA - UK):

- emphasised the need to find the right balance between freedom of movement on the one hand and patient safety and accountability on the other;
- stated that national autonomy over regulatory aspects must be protected;
- opposed any harmonisation of standards down to the lowest common denominator;
- warned against the risk of pressure on local services increasing to the detriment of indigenous patients. This is a particular risk in areas where there are specialists that might attract considerable outside interest; and
- called for the issue of follow-up care after treatment abroad to be addressed adequately. He was concerned that services such as physiotherapy might be overstretched because of follow-up care demands.

Mr Colm BURKE (EPP/ED - IE) :

- advocated individuals being able to travel abroad to obtain high-quality health care, regardless of their means and/or geographical location;
- stated that patients should also be able to get high-quality health care near home, though this is not always possible;
- called for patients to be reimbursed up to the level of the cost that would have been incurred had they remained at home; and
- stressed the importance of national contact points.

Mr Guido SACCONI (PES - IT):

- stated that Member States should have some form of final right of prior authorisation in order to protect their own national health care systems;
- asked the Commissioner to give her opinion on the double legal basis issue; and
- urged the EPP/ED and ALDE political groups to consider whether they really wanted to go to second reading without the support of the PES political group that was needed to secure a large majority (amendments 116 and 125 on the dual legal base and amendments 156/118 on prior authorisation would be a key decision-making factor for the PES).

Mrs Karin RIIS-JØRGENSEN (ALDE - DK) called for patients travelling abroad in order to receive health care to be reimbursed in advance.

Mrs Ewa TOMASZEWSKA (UEN - PL):

- stated that patients should be informed in advance of their potential financial liability and also about the availability of pre-financing;
- called for patients to have guaranteed access to credible information about the quality of available treatment in recommended healthcare centres. There should be reference networks and information points;
- stated that patients should be guaranteed information about their legal rights in the case of harm arising from inappropriate treatment as well as information about mutual recognition of prescriptions; and
- called for cross-border healthcare to be monitored.

Mrs Margrete AUKEN (Greens/EFA - DK) called for specific legislation to cater for differing national standards and expectations. This is a particular issue in the case of rare diseases.

Mr Adamos ADAMOU (EUL/NGL - CY) called on the Commission to explain its decision regarding the legal basis.

Mr Péter OLAJOS (EPP/ED - HU):

- stated that the proposed Directive would revolutionise healthcare services, would increase cultural diversity, would boost tourism, would create jobs in food catering and other ancillary services, and would create jobs for healthcare brokers and translators; and
- argued that Member States will be encouraged to improve the quality of their health care provision and to reduce waiting lists in order to attract foreign business.

Mrs Anne VAN LANCKER (PES - BE):

- stated that the Directive is good for those who live in border regions, who would otherwise have to wait a long time to receive treatment or who need high-quality healthcare;
- emphasised the importance of Member States being able to organise and fund their own healthcare systems properly and with the good of all their citizens in mind. In this regard, she set out three red lines:
    - the Directive should only address the mobility of patients and not that of healthcare workers. The Directive is not intended to create a market in healthcare services;
    - Member States should be able to decide what services they provide and at what level will reimburse;
    - whilst cross-border access to ambulatory treatment should be facilitated as far as possible, prior authorisation must be the rule for hospital treatment. Hospital care is expensive and needs to be carefully planned.
- supported the double legal basis. Healthcare is a responsibility of national administrations towards their citizens. It cannot be left just to the market to organise and allocate.

Mrs Elizabeth LYNNE (ALDE - UK):

- asked why patients should suffer simply because there are long waiting lists in their Member States whilst there is free capacity in another Member State. It is the poorest who suffer most from differences in healthcare standards; and
- emphasised the special needs of disabled patients.

Mr Jens HOLM (EUL/NGL - SE):

- disagreed with the Commission's freemarket approach;
- argued that the Directive would only benefit those patients who had the financial means and/or good contacts in healthcare services; and
- stated that a single legal basis of Article 95 would not guarantee good quality healthcare services.

Mr Johannes BLOKLAND (IND/DEM-NL):

- stated that cross-border healthcare provision is already a reality. The task now is to ensure that it is properly regulated;
- insisted that healthcare must remain a national competence; and
- opposed the single legal basis of Article 95 because it would work against the subsidiarity principle and because it would constrain the freedom of manoeuvre of national administrations.

Mrs Lydia SCHENARDI (NI - FR) stated that the provision of healthcare services is a national competence and that Member States should be left to organise their healthcare facilities as they and they alone see fit.

Mrs María del Pilar AYUSO GONZÁLEZ (EPP/ED - ES):

- stated that the Directive would prioritise the rights and needs of patients;
- noted that Spain has many foreign patients already, but that it is not reasonable to provide better services to foreign patients than to national patients. It is therefore necessary to stipulate that foreign and domestic patients alike should receive the same standard of healthcare; and
- stated that she would have liked the Committee's report to be more ambitious, particularly as regards European citizens who are permanently resident in other Member States (and especially those with chronic diseases).

Mrs Edite ESTRELA (PES - PT):

- called for the legal basis to be changed. Healthcare provision and the free market do not mix. She said that she did not understand why the Commission had not included Article 152: and
- stressed the need for prior authorisation in order to guarantee safe and good quality health care.

Mrs Siiri OVIIR (ALDE - EE):

- stated that it is now time for politicians to take decisions on these complex and sensitive matters rather than lawyers; and
- argued that financial contraints should not be allowed to compromise patients' rights.

Mr Roberto MUSACCHIO (EUL/NGL - IT) opposed a free-market legal basis.

Mrs Kathy SINNOTT (IND/DEM - IE):

- argued that patients' rights would be limited if prior authorisation is allowed to take precedence over medical diagnosis; and
- opposed those amendments that would overturn Court judgements and restore 'death by geography'.

Mrs María SORNOSA MARTÍNEZ (PES - ES):

- regretted the lack of a definition of fundamental patient rights and of prior authorisation;
- opposed the single legal basis; and
- warned that an exclusively free-market approach might well undermine national healthcare systems.

Mr Holger KRAHMER (ALDE - DE) stated that some of the amendments tabled by the Greens/EFA political groups and others smacked of the former East Germany.

Mrs Frieda BREPOELS (EPP/ED - BE):

- welcomed the prospect of greater certainty for patients;
- stated that a greater level of cross-border healthcare would lead to improvements in treatment, especially for rare diseases;
- stressed the need for prior authorisation in order to control cross-border flows and to avoid local patients being sidelined and placed on waiting lists; and
- supported the idea of pilot schemes in certain border regions.

Mrs Genowefa GRABOWSKA (PES - PL) supported a double legal base.

Mr Christofer FJELLNER (EPP/ED - SE) argued that prior authorisation is not really necessary and that it might constrain patients' rights. Some of those calling for such a requirement were doing so simply to undermine the Directive as a whole.

Minister FILIPIOVÁ once more took the floor and noted the agreement between the Council and the Parliament on many issues, though she also recognised that further discussion would be required on other amendments.

Commissioner VASSILIOU once more took the floor and:

- noted that inequalities of revenue clearly exist across the European Union and that this has serious consequences regarding access to a number of fundamental services such as health care. This issue needs to be addressed, but it poses a difficult challenge which has been rendered even more demanding by the current economic crisis. A significant and co-ordinated effort will be required of the European Union and the Member States at all levels;
- recalled that the Commission's proposal would permit Member States to offer direct assumption of the costs of cross-border treatment, for example with a system of written confirmation of the amount that would be paid. The Commission would welcome any move by the Parliament to make the text clearer on this point;
- noted that the Commission's proposal carefully respects Member States' responsibilities in organising healthcare. The Commission therefore sought to limit the financial impact of cross-border healthcare on national health systems and sickness insurance funds. The two objectives are not incompatible, however. It is up to the Member States to reconcile them as far as possible, paying attention to the interests of patients and of poorer patients in particular;
- agreed, with regard to the relationship of the proposed Directive with the Social Security Regulation, on the need for it to be clear that, once prior authorisation is requested by a patient and provided that the conditions of the Regulation are fulfilled but when there is undue delay, the Regulation should apply. It should be crystal clear that the tariffs of the Regulation shall apply so that patients can benefit from the most advantageous system;

- stated, regarding prior authorisation for hospital care, that the proposed provisions were based on two factors:
    - the Court had ruled that such a system could be justified under certain circumstances. This has been codified in Article 8(3); and
    - it would not be appropriate to go beyond such provisions with a looser or even unconditional system of prior authorisation, whether legally or de facto generalised in all Member States.

  It is clear that patient mobility will remain a very limited phenomenon. Its budgetary impact will therefore remain limited so there is no need to raise unnecessary barriers for patients. Prior authorisation for hospital treatment should remain a safeguard mechanism, applicable when justified;
- argued that systems of prior notification as proposed by the Rapporteur could amount to indirect and unnecessary obstacles for patients, even if this was not his intention. Such administrative mechanisms could be both cumbersome and arbitrary;
- expressed her concern regarding the definition of hospital care. This definition is vital because it sets the boundary for the prior authorisation system. The Commission proposed to define the concept of hospital care through a Community list based on the shared understanding of experts who would take account of the development of technologies. This would allow for a reasonable and modern approach to the concept of hospital care. Some Members of the Parliament and most Member States had called for national lists to be drawn up independently. If this approach were to prevail, such lists would need to be based on clearly defined criteria and subjected to a review process. Otherwise, patients' rights, as defined by the European judges, would be undermined;
- disagreed with those who had argued that the proposed Directive would only benefit a very few well informed patients. To the contrary, the Directive would give all patients the right to full information and to make an informed choice before they even left home;
- called for practical solutions to the problem of getting clear information on health professionals when seeking healthcare abroad, a question of patient safety. These solutions need to respect a number of key principles such as the right to personal data protection and the presumption of innocence;
- stated that the Commission could not accept amendment 67 on the relaxation of the rule for affiliations to social security systems;

- stated, regarding the single/dual legal basis issue, that it was difficult to have a definite view at this stage of the examination of the proposed Directive. This question needs to be addressed in the light of the text's development. The addition of Article 152 could certainly be considered if justified by the content of the final text;
- repeated her expectation that the mobility of patients would remain a limited phenomenon. It would therefore be disproportionate to give carte blanche to Member States to take measures to refuse patients in order to control inflows of patients from other Member States. Indeed, Member States are obliged to ensure that patients from other Member States are not subject to discrimination. Any form of control over incoming patients would have to be assessed as to whether it would amount to an acceptable exception to the principle of non-discrimination on the basis of nationality set out in the Treaty;
- stated that rare diseases should remain within the scope of the proposed Directive; and
- argued that organ transplantation is a medical procedure and that it is difficult to argue that patients should not have the right to benefit from it as cross-border health care, as ruled by the Court. The issue of organ allocation was a different matter, however. She had therefore asked the Commission's experts to see how organ allocation could be dealt with in a different context.

Mr BUSHILL-MATTHEWS once more took the floor and:

- expressed his understanding that, whilst it would not be possible to negotiate an agreement in first reading during the Czech presidency, there was already substantial agreement in principle within the Council thanks to the work that the Presidency had already done; and
- called for an early second reading under the Swedish presidency with a view to rapidly resolving any remaining difficulties.

III. VOTE

When it voted on 23 April 2009, the plenary adopted 122 amendments (amendments 1-2, 4-25, 27-42, 44-49, 51-66, 68-110, 112-113, 115, 117, 128, 135-141, 143-145, 149, 157).

The text of the legislative resolution is annexed to this note.

ANNEX
(23.04.2009)

Patients' rights in cross-border healthcare ***I

European Parliament legislative resolution of 23 April 2009 on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (COM(2008)0414 – C6-0257/2008 – 2008/0142(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0414),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0257/2008),

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 51 and 35 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Employment and Social Affairs, the Committee on the Internal Market and Consumer Protection, the Committee on Economic and Monetary Affairs, the Committee on Committee on Industry, Research and Energy, Committee on Legal Affairs and the Committee on Women's Rights and Gender Equality (A6-0233/2009),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Given that 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**,**	(2) Given 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.	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

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The European Parliament adopted on 9 June 2005, by 554 votes to 12, a resolution on patient mobility and healthcare developments in the European Union[1], in which it called for legal certainty and clarity on rights and procedures for patients, health professionals and Member States.
	[1] OJ C 124 E, 25.5.2006, p. 543.

Amendment 4

Proposal for a directive
Recital 5 a (new)

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

Amendment 5

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) Some issues related to cross-border healthcare, in particular reimbursement of healthcare provided in a Member State other than that in which the recipient of the	(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 general and effective application of principles developed by the Court of Justice on a case by case basis.	care is resident, have been already addressed by the Court of Justice. ***It*** is important to address these issues in a specific Community legal instrument in order to achieve a more general and effective application of principles developed by the Court of Justice on a case by case basis.

Amendment 6

Proposal for a directive
Recital 8

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

Amendment 7

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, the Directive does not apply to assistance and support for	(9) This Directive on the application of patients' rights in cross-border healthcare applies to all types of healthcare. As confirmed by the Court of Justice, neither their special nature nor the way in which they are organised or financed removes them from the ambit of the fundamental principle of freedom of movement. As regards long-term care, *this* Directive does not apply to assistance and support for

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

Amendment 8

Proposal for a directive
Recital 9 a (new)

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

Amendment 9

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(10) For the purpose of this Directive, the concept of "cross-border healthcare" covers the ***following modes of supply of healthcare:***	(10) For the purpose of this Directive, the concept of "cross-border healthcare" ***only*** covers the ***use of healthcare in a Member State other than that where the patient is an insured person. This is what is referred to as 'patient mobility'***;
– Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';	
– Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services,	

remote diagnosis and prescription, laboratory services;

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

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

Amendment 10

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving patients' mobility ***and free movement of provision of healthcare in the internal market*** as well as a high level of health protection.	(11) As recognised by the Member States in the Council Conclusions on Common values and principles in European Union Health Systems there is a set of operating principles that are shared by health systems throughout the Community. These operating principles include quality, safety, care that is based on evidence and ethics, patient involvement, redress, the fundamental right to privacy with respect to the processing of personal data, and confidentiality. Patients, professionals and authorities responsible for health systems must be able to rely on these shared principles being respected and structures provided for their implementation throughout the Community. It is therefore appropriate to require that it is the authorities of the Member State on whose territory the healthcare is provided, who are responsible for ensuring compliance with those operating principles. This is necessary to ensure the confidence of patients in cross-border healthcare, which is itself necessary for achieving patients' mobility as well as a high level of health protection. ***Notwithstanding those common values it is accepted that Member States take different decisions on ethical grounds as regards the availability***

of certain treatments and the concrete access conditions. This Directive is without prejudice to ethical diversity.

Amendment 11

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive. Member States' authorities have to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement within the internal market, non-discrimination inter alia with regard to nationality ***(or in the case of legal persons, with regard to the Member State in which they are established),*** necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs,	(12) Given that it is impossible to know in advance whether a given healthcare provider will supply healthcare to a patient coming from another Member State or a patient from their own Member State, it is necessary that the requirements to ensure that healthcare is provided according to common principles and clear quality and safety standards are applicable to all type of healthcare in order to ensure the freedom to provide and obtain cross border healthcare which is the aim of the directive. Member States' authorities have to respect the shared overarching values of universality, access to good quality care, equity and solidarity, which have been already widely recognised by the Community institutions and by all the Member States as constituting a set of values that are shared by health systems across Europe. Members States also have to ensure that these values are respected with regard to patients and citizens from other Member States, and that all patients are treated equitably on the basis of their healthcare need rather than their Member State of social security affiliation. In doing so, Member States must respect the principles of freedom of movement of ***individuals*** within the internal market, non-discrimination inter alia with regard to nationality, necessity and proportionality of any restrictions on free movement. However, nothing in this Directive requires healthcare providers to accept for planned treatment or to prioritise patients from other Member States to the detriment of other patients with similar health needs, such as through increasing waiting time for treatment. ***In order to enable patients to***

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

Amendment 136
Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) Moreover, patients from other Member States should enjoy equal treatment with the nationals of the Member State of treatment and, according to the general principles of equity and non discrimination, as recognized in Art.21 of the Charter they should in no way be discriminated upon on the basis of their sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation. Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds, such as in case of specific measures for women or for certain ages groups (e.g. free of charge vaccination for children or elderly people). Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, it has to be implemented and applied with due respect for the rights to equality before the law and the principle of non-discrimination in accordance with the general principles of law, as enshrined in Articles 20 and 21 of the Charter. This Directive applies without prejudice to	(13) Moreover, patients from other Member States should enjoy equal treatment with the nationals of the Member State of treatment and, according to the general principles of equity and non discrimination, as recognized in Art.21 of the Charter they should in no way be discriminated upon on the basis of their sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation. Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds, such as in case of specific measures for women or for certain ages groups (e.g. free of charge vaccination for children or elderly people). Furthermore, as this Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, it has to be implemented and applied with due respect for the rights to equality before the law and the principle of non-discrimination in accordance with the general principles of law, as enshrined in Articles 20 and 21 of the Charter. This Directive applies without prejudice to

Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, ***and other Directives*** giving effect to Article 13 of the EC Treaty. In the light of this, the Directive provides that patients shall enjoy equal treatment with the nationals of the Member State of treatment, including the benefit from the protection against discrimination provided for according to Community law as well as from the legislation of the Member State of treatment.	Directive 2000/43/EC of the Council of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, ***Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services[1], Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation[2], and the proposed directive on implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation (COM(2008)0426)*** giving effect to Article 13 of the EC Treaty. In the light of this, the Directive provides that patients shall enjoy equal treatment with the nationals of the Member State of treatment, including the benefit from the protection against discrimination provided for according to Community law as well as from the legislation of the Member State of treatment. ***[1] OJ L 373, 21.12.2004, p. 37.*** ***[2] OJ L 303, 2.12.2000, p. 16.***

Amendment 12

Proposal for a directive
Recital 13 a (new)

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

Amendment 13

Proposal for a directive
Recital 13 b (new)

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

Amendment 14

Proposal for a directive
Recital 14 a (new)

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

Amendment 15

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring ***clear common obligations*** to deal with ***circumstances of responding to*** harm arising from healthcare is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. Coverage for harm and compensation by the systems of the country of treatment should be without prejudice to the	(15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring ***that Member States of treatment have systems in place (including provision of aftercare)*** to deal with ***alleged*** harm arising from healthcare ***as defined by the Member State of treatment*** is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border healthcare. Coverage for harm and compensation by

possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.	the systems of the country of treatment should be without prejudice to the possibility for Member States to extend the coverage of their domestic systems to patients from their country seeking healthcare abroad, where this is more appropriate to the patient, in particular in the case of patients for whom use of healthcare in another Member State is necessary.

Amendment 16

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(17) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example in the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive.	(17) The right to the protection of personal data is a fundamental right recognised by Article 8 of the Charter of Fundamental Rights of the European Union. Ensuring continuity of cross-border healthcare depends on transfer of personal data concerning patient's health. These personal data should be able to flow freely from one Member State to another, but in the same time the fundamental rights of the individuals should be safeguarded. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data establishes the right for individuals to have access to their personal data concerning their health, for example in the patient's medical records containing such matters as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided. These provisions also apply in the context of cross-border healthcare covered by this Directive. ***The patient should be able to stop the release of his data at any point and receive confirmation that his data have been deleted.***

Amendment 17

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom ***to provide services include the freedom*** for the recipients of healthcare, including persons in need of medical treatment, to go to another Member Sate in order to receive it there. ***The same applies to recipients of healthcare seeking to receive healthcare provided in another Member State through other means, for example through e-health services. Whilst*** Community law does not detract from the power of the Member States to organise their healthcare and social security systems***, Member States must when exercising that power comply with Community law, in particular with the Treaty provisions on the freedom to provide services. Those provisions prohibit the Member States from introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector***.	(18) The right to reimbursement of the costs of healthcare provided in another Member State from the statutory social security scheme of patients as insured persons was recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions ***include*** the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member Sate in order to receive it there. Community law does not detract from the power of the Member States to organise their healthcare and social security systems.

Amendment 18

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) ***It is appropriate to require that also patients who go for healthcare to another Member State in other circumstances than those envisaged for coordination of social security schemes established by the Regulation (EC) No. 1408/71 should be able to benefit from the principles of free***	(21) Patients should be guaranteed assumption of the costs of healthcare ***and goods connected with healthcare provided in another Member State*** at least at the level provided for ***treatment which is*** the same or ***equally effective,*** had they been provided ***or purchased*** in the Member

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.	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.

Amendment 19

Proposal for a directive
Recital 24

Text proposed by the Commission	*Amendment*
(24) The patient should, in any event, not derive a financial advantage from the healthcare provided in another Member State ***and*** the assumption of costs should *be therefore* limited only to actual costs ***of healthcare received***.	(24) The patient should, in any event, not derive a financial advantage from the healthcare provided ***or goods purchased*** in another Member State***.*** The assumption of costs should *therefore be* limited only to ***the*** actual costs. ***Member States may decide to cover other related costs, such as therapeutic treatment, provided that the total cost does not exceed the amount payable in the Member States of affiliation.***

Amendment 20

Proposal for a directive
Recital 25

Text proposed by the Commission	*Amendment*
(25) This Directive does not aim either to create entitlement for reimbursement of treatment in another Member State, if such	(25) This Directive does not aim either to create entitlement for reimbursement of treatment ***or of the cost of purchasing***

a treatment ***is*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare provided in another Member State according to its provisions.	***goods*** in another Member State, if such a treatment ***or such goods are*** not among the benefits provided for by the legislation of the patient's Member State of affiliation. Equally this Directive does not prevent the Member States from extending their benefits in kind scheme to healthcare ***and goods*** provided in another Member State according to its provisions. ***This Directive recognises that entitlement to treatment is not always determined nationally by Member States and that Member States may organise their own healthcare and social security systems to provide for entitlement to treatment to be determined at a regional or local level.***

Amendment 21

Proposal for a directive
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) If there are several methods available for treating a certain disease or injury, the patient should have the right to reimbursement for all methods of treatment that are sufficiently tried and tested by international medical science, even if they are not available in the patient's Member State of affiliation.

Amendment 22

Proposal for a directive
Recital 27

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

Amendment 23

Proposal for a directive
Recital 30

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

Amendment 24

Proposal for a directive
Recital 32

Text proposed by the Commission	*Amendment*
(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had the same or ***similar healthcare*** been	(32) In any event, if a Member State decided to establish a system of prior authorisation for assumption of costs of hospital or specialised care provided in another Member States in accordance with the provision of this Directive, the costs of such care provided in another Member State should also be reimbursed by the Member State of affiliation up to the level of costs that would have been assumed had ***treatment which is*** the same or ***equally***

provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.	***effective for the patient*** been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received. However, when the conditions set out in Article 22(2) of Regulation (*EEC*) No 1408/71 are fulfilled the authorisation should be granted and the benefits provided in accordance with that Regulation. This applies in particular in instances where the authorisation is granted after an administrative or judicial review of the request and that the person concerned has received the treatment in another Member State. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply. This is in line with the case law of the Court of Justice which has specified that patients who received a refusal of authorisation subsequently held to be unfounded, are entitled to have the cost of the treatment obtained in another Member State reimbursed in full according to the provisions of the legislation in the Member State of treatment.

Amendment 25

Proposal for a directive
Recital 32 a (new)

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

Amendment 145
Proposal for a directive
Recital 32 b (new)

Text proposed by the Commission	*Amendment*
	(32b) Patients with a life-threatening condition who are on a waiting list for

	medical treatment in their home country and who are in urgent need of care may not be subject to prior authorisation, as this procedure could prevent patients from having timely treatment in another Member State.

Amendment 27

Proposal for a directive
Recital 34

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

Amendment 28

Proposal for a directive
Recital 35

Text proposed by the Commission	*Amendment*
(35) When healthcare is received by a patient in a Member state, which is not the country where he is insured, it is essential for the patient to know in advance which rules shall be applicable. An equivalent level of clarity is needed ***in case where healthcare providers temporarily move to another Member State to provide their medical services there or*** when healthcare is provided cross-border. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment in accordance with the general principles set out in Art.5, given that in accordance with Art. 152(5) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.	(35) When healthcare is received by a patient in a Member state, which is not the country where he is insured, it is essential for the patient to know in advance which rules shall be applicable. An equivalent level of clarity is needed when healthcare is provided cross-border***, such as telemedicine***. In those cases, the rules applicable to healthcare are those provided by the legislation of the Member State of treatment in accordance with the general principles set out in Art.5, given that in accordance with Art. 152(5) of the Treaty the organisation and delivery of health services and medical care is of responsibility of Member States. This will help the patient in making an informed choice, and will avoid misapprehension and misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.

Amendment 29

Proposal for a directive
Recital 36

Text proposed by the Commission	*Amendment*
(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. ***The***	(36) The Member States should decide on the form of those national contact points as well as the number of them. The national contact points may be also incorporated in or build on activities of existing information centres provided that it is clearly indicated that they are also national contact points for cross-border healthcare. The national contact points should have appropriate facilities to provide information on the main aspects of cross-border healthcare and to provide practical assistance to patients if needed. ***The***

Commission should work together with the Member States in order to facilitate cooperation regarding national contact points for cross-border healthcare, including making relevant information available at Community level, such as through the European Health Portal. The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system.	***Member States should ensure the participation of bodies representing health professionals in these activities.*** The existence of national contact points should not preclude Member States from establishing other linked contact points at regional or local level, reflecting the specific organisation of their healthcare system. ***The national contact points should be able to provide patients with relevant information on cross-border healthcare and to assist them. This should not include legal advice.***

Amendment 30

Proposal for a directive
Recital 37

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

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.

Amendment 31

Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(39) Where medicinal products are authorised within the patient's Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be ***medically*** recognised and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products.	(39) Where medicinal products are authorised within the patient's Member State in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, ***including the future legislation on falsified medicinal products (Directive XXXX/XX/EC) and pharmacovigilance (Directive ZZZZ/ZZ/EC),*** and have been prescribed in another Member State for an individual named patient, it should be in principle possible for such prescriptions to be recognised ***medically or in pharmacies*** and used in the patient's own Member State. The removal of regulatory and administrative barriers to such recognition is without prejudice to the need for appropriate agreement of the patients' treating physician or pharmacist in every individual case, if this is warranted by protection of human health and is necessary and proportionate to that objective. Such medical recognition should also be without prejudice to the decision of the Member State of affiliation regarding the inclusion of such medicinal products within the benefits covered by the social security system of affiliation ***and without prejudice to the validity of national pricing and payment rules***. The implementation of the principle of recognition will be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of

medicinal products.

Amendment 32

Proposal for a directive
Recital 41 a (new)

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

Amendment 33

Proposal for a directive
Recital 43

Text proposed by the Commission	*Amendment*
(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***Cooperation in the evaluation of new health technologies can support Member States through economies of scale and avoiding duplication of effort, and provide a better basis of evidence for optimal use of new technologies to ensure safe, high-quality and efficient healthcare. This will also contribute to the internal market by maximising the speed and scale of diffusion of innovations in medical science and health technologies. Such cooperation requires sustained structures involving all the relevant authorities of all the Member States, building on existing***	(43) The constant progress of medical science and health technologies presents both opportunities and challenges to the health systems of the Member States. ***However, the assessment of health technologies and the possible restriction of access to new technologies by certain decisions by administrative bodies raise a number of fundamental social issues which require contributions from a wide range of stakeholders and the establishment of a viable governance model. Accordingly any cooperation should involve not only the competent authorities of all the Member States but also all the stakeholders concerned, including health professionals and representatives of patients and industry.***

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

Amendment 34

Proposal for a directive
Recital 45

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

Amendment 35

Proposal for a directive
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) The Member State of affiliation and the Member State of treatment should by prior bilateral cooperation and in consultation with the patient ensure that appropriate aftercare and support is made available in either Member State following the authorised medical

	treatment and that clear information is available to patients about aftercare options and costs. To do this, Member States should adopt measures to ensure that:
	(a) the necessary medical and social care data are transferred with due regard to patient confidentiality; and
	(b) medical and social care professionals in both countries are able to consult each other to ensure the highest quality treatment and aftercare (including social support) for the patient.

Amendment 36

Proposal for a directive
Recital 46 b (new)

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

Amendment 37

Proposal for a directive
Article 1

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

Amendment 38

Proposal for a directive
Article 2

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

Amendment 39

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

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

Amendment 137
Proposal for a directive
Article 3 – paragraph 1 - point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) Council Directive 2004/113/EC of

	13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services;

Amendment 138
Proposal for a directive
Article 3 – paragraph 1 - point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) Council Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation;

Amendment 139
Proposal for a directive
Article 3 – paragraph 1 - point e c (new)

Text proposed by the Commission	*Amendment*
	(ec) Commission proposal for a Council directive on implementing the principle of equal treatment between persons irrespective of religion or belief, disability, age or sexual orientation (COM(2008)0426);

Amendment 40

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

Text proposed by the Commission	*Amendment*
	(ga) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components[1];
	[1] OJ L 33, 8.2.2003, p. 30.

Amendment 41

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

Text proposed by the Commission	*Amendment*
	(gb) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[1];
	[1] OJ L 102, 7.4.2004, p. 48.

Amendment 42

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

Text proposed by the Commission	*Amendment*
	(gc) Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance[1], as regards the implementing powers conferred on the Commission.
	[1] OJ L 228, 11.8.1992, p.1.

Amendments 117 and 128
Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***When the circumstances under which an authorisation to go to another Member State in order to receive appropriate treatment under*** Article 22 of Regulation ***(EC)*** No 1408/71 ***must be granted are met, the provisions of that Regulation shall apply and the provisions of Articles 6, 7, 8 and 9 of this Directive shall not apply. Conversely, when an insured person seeks healthcare in another Member State in other circumstances, Articles 6, 7, 8 and 9 of this Directive apply and Article 22 of Council Regulation (EC) No 1408/71 shall not apply. However, whenever the conditions for granting an authorisation***	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 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 ***and Article 20 of Regulation (EC) No 883/2004, are met.***

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 44

Proposal for a directive
Article 3 - paragraph 3

Text proposed by the Commission	*Amendment*
3. If the provisions of this Directive conflict with a provision of another Community act governing specific aspects of healthcare, the provision of the other Community act shall prevail and shall apply to those specific situations concerned. These include:	***deleted***
(a) Directive 2005/36/EC on the recognition of professional qualifications;	
(b) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.	

Amendment 45

Proposal for a directive
Article 4 – point a

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

Amendment 141

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

Text proposed by the Commission	*Amendment*
	(aa) "health data" means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual, which may include: information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify that individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance; and identification of a person (healthcare professional) as provider of healthcare to the individual;

Amendment 46

Proposal for a directive
Article 4 - point b

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

Amendment 47

Proposal for a directive
Article 4 - point c

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

Amendment 48

Proposal for a directive
Article 4 - point d

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

Amendment 49

Proposal for a directive
Article 4 - point e

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

Amendment 51

Proposal for a directive
Article 4 - point g

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

Amendment 52

Proposal for a directive
Article 4 - point h

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

Amendment 53

Proposition de directive
Article 4 – point h, subparagraph 2(new)

Text proposed by the Commission	*Amendment*
	Where, due to the application of Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004 respectively, the health insurance body in the Member State of residence of the patient is responsible for the provision of benefits in accordance with the legislation of that state, then that Member State is regarded as the Member State of

affiliation for the purposes of this Directive;

Amendment 54

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

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

Amendment 55

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

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

Amendment 56

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

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

Amendment 57

Proposal for a directive
Article 4 - point l

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

constitutes harm may vary from Member State to Member State.

Amendment 58

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

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

Amendments 59 and 140

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare**.** In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality ***and safety*** standards for healthcare provided on their territory, and ensure that:	1. The Member States of treatment shall be responsible for the organisation and the delivery of healthcare**.** In such a context and taking into account principles of universality, access to good quality care, equity and solidarity, they shall define clear quality standards for healthcare provided on their territory, and ensure ***compliance with existing EU legislation on safety standards***, ***and*** that:
(a) ***mechanisms are in place for ensuring that healthcare providers are able to meet such standards, taking into account international medical science and generally recognised good medical practices;***	(a) ***when healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare is provided in accordance with the legislation of the Member State of treatment;***
(b) ***the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate standards are not met, taking into account progress in medical science and health technology;***	(b) ***healthcare referred to in point (a) is provided in accordance with standards and guidelines on quality defined by the Member State of treatment;***
	(ba) patients and healthcare providers from other Member States are provided with information by the national contact

	point of the Member State of treatment, inter alia by electronic means, on quality standards and guidelines, including provisions on supervision, and on availability, quality and safety, treatment options, prices, outcomes of the healthcare provided, accessibility for persons with disabilities and details of the healthcare provider's registration status and insurance cover or other means of personal or collective protection with regard to their professional liability;
(c) healthcare providers provide all relevant information to enable patients to make an informed choice***, in particular on availability, prices and outcomes of the healthcare provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability***;	(c) healthcare providers provide all relevant information to enable patients to make an informed choice;
(d) patients have ***a*** means of making complaints and ***are guaranteed remedies and*** compensation when they suffer harm arising from the healthcare they receive;	(d) patients have ***the*** means of making complaints and ***the right to seek*** compensation when they suffer harm arising from the healthcare they receive ***and there are mechanisms in place to guarantee remedies***;
(e) systems of professional liability insurance or a guarantee or similar arrangement, ***which are equivalent or essentially comparable as regards their purpose and*** which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;	(e) systems of professional liability insurance or a guarantee or similar arrangement, which are appropriate to the nature and the extent of the risk are in place for treatment provided on their territory;
(f) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;	(f) the fundamental right to privacy with respect to the processing of personal data is protected in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC;
(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment.	(g) patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against ***direct or indirect*** discrimination ***on the grounds of racial or ethnic origin, sex, religion or belief, disability, age, or sexual orientation*** provided for according to Community law

and national legislation in force in the Member State of treatment. ***However, this Directive shall not oblige healthcare providers in a Member State either to provide healthcare to an insured person from another Member State or to prioritise the provision of healthcare to an insured person from another Member State to the detriment of a person who has similar health needs and is an insured person of the Member State of treatment.***

(ga) patients who have received treatment are entitled to a written or electronic record of such treatment and of any medical advice for the continuity of their care;

1a. The public authorities in the Member State of treatment shall monitor regularly the accessibility, quality and financial state of their healthcare systems on the basis of the data collected under Article 18.

Amendment 60

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

Text proposed by the Commission	*Amendment*
	1b. In order to maximise patient safety the Member States of treatment and affiliation shall ensure that:
	(a) patients have a means of making complaints, and are guaranteed remedies and compensation when they suffer harm arising from the healthcare they receive;
	(b) the quality and safety standards of the Member State of treatment are made public in a language and format that is clear and accessible to all citizens;
	(c) there is a right to continuity of care, notably by means of the forwarding of relevant medical data concerning the patient with due respect to the provisions of paragraph 1 - point (e) and pursuant to Article 13 and patients who have received

	treatment are entitled to a written or electronic record of such treatment and of any medical advice for the continuity of their care;
	(d) in the event of complications resulting from healthcare provided abroad or if a particular medical follow-up proves necessary, the Member State of affiliation guarantees to provide healthcare equivalent to that received on its territory;
	(e) they immediately and proactively inform each other about health providers or health professionals when regulatory action is taken against their registration or their right to provide services;
	1c. The Commission shall in accordance with the regulatory procedure referred to in Article 19(2), adopt measures necessary for achieving a common security level of health data at national level, taking into account existing technical standards in this field.

Amendment 61

Proposal for a directive
Article 5 – paragraph 2

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

Amendment 62

Proposal for a directive
Article 5 – paragraph 3

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

Amendment 63

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

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

Amendment 64

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

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

Amendment 65

Proposal for a directive
Article 6 – title

Text proposed by the Commission	*Amendment*
Article 6	*Article 6*

Healthcare provided in another Member State	*Responsibilities of authorities of the Member State of affiliation*

Amendment 66

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had ***the same or similar*** healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.	1. Subject to the provisions of this Directive, in particular Articles 7, 8 and 9, the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation, ***administrative regulations, guidelines and codes of conduct of the medical professions,*** of the Member State of affiliation to which the insured person is entitled. ***Without prejudice to Regulation (EEC) No 1408/71 and, as from its date of application, Regulation (EC) No 883/2004,*** the Member State of affiliation shall reimburse the costs to ***the Member State of treatment or*** the insured person, which would have been paid for by its statutory social security system had ***equally effective*** healthcare been provided in its territory. ***If a Member State of affiliation rejects the reimbursement of this treatment, that Member State shall have to give a medical justification for its decision.*** In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided. ***Patients affected by rare diseases should have the right to access healthcare in another Member State and to get reimbursement even if the treatment in question is not among the benefits provided for by the legislation of the Member State of affiliation.***

Amendment 68

Proposal for a directive
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed ***had the same or similar healthcare been provided*** in the Member State of affiliation, without exceeding the actual costs of healthcare received.	2. The costs of healthcare provided in another Member State shall be reimbursed ***or paid directly*** by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed ***in respect of the same medical condition under the same conditions as laid down in paragraph 1*** in the Member State of affiliation, without exceeding the actual costs of healthcare received. ***Member States may decide to cover other related costs, such as therapeutic treatment and accommodation and travel costs.***
	2a. The extra costs which persons with disabilities might incur when receiving healthcare in another Member State due to one or more disabilities shall be reimbursed by the Member State of affiliation in accordance with national legislation and on the condition that sufficient documentation setting out these costs exists.

Amendment 69

Proposal for a directive
Article 6 – paragraph 3

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

	medical devices, and are known in advance. This may include a requirement that the insured person is assessed for the purposes of applying those conditions, criteria or formalities by a health professional or healthcare administrators providing services for the statutory social security system of the Member State of affiliation, where such an assessment would also be required for accessing health services in the Member State of affiliation.

Amendment 70

Proposal for a directive
Article 6 – paragraph 4

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

Amendment 71

Proposal for a directive
Article 6 – paragraph 5

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

medical records, in conformity with national measures implementing Community provisions on the protection of personal data, in particular Directives 95/46/EC and 2002/58/EC.	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, or a right of remote access to, those records. Data shall be transmitted only with the express consent in writing of the patient or the patient's relatives.***

Amendment 72

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

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

Amendment 73

Proposal for a directive
Article 7

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

Amendment 74

Proposal for a directive
Article 8 – title

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

Amendment 75

Proposal for a directive
Article 8 – paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall ***mean***:	1. For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, ***the definition of*** hospital care***, as established by the Member State of affiliation,*** shall ***be limited to***:
(a) healthcare which requires overnight accommodation of the patient in question for at least one night***.***	(a) healthcare which requires overnight accommodation of the patient in question for at least one night***; or***
(b) healthcare***, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:***	(b) healthcare ***which is highly specialised and/or requires use of cost-intensive medical infrastructure or medical equipment; or***
- healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or	***(ba)*** healthcare involving treatments presenting a particular risk for the patient or the population.
- 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).	

Amendment 76

Proposal for a directive
Article 8 – paragraph 3

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

Amendment 77, 149 and 157

Proposal for a directive
Article 8 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prior authorisation system shall be limited to what is necessary and proportionate ***to avoid such impact***, and	4. The prior authorisation system ***shall apply without prejudice to Article 3(2) and*** shall be limited to what is necessary and

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

Amendment 78

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

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

Amendment 79

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

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

Amendment 80

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

Text proposed by the Commission	*Amendment*
	4c. Patients seeking to receive healthcare provided in another Member State shall

be guaranteed the right to apply for prior authorisation in the Member State of affiliation.

Amendment 81

Proposal for a directive
Article 8 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3.	5. The Member State shall make publicly available all relevant information on the prior authorisation systems introduced pursuant to the provisions of paragraph 3***, including appeal procedures in the event of a refusal to give authorisation***.

Amendment 82

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

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

Amendment 83

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

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

Amendment 84

Proposal for a directive
Article 9 – paragraph 2

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

Amendment 85

Proposal for a directive
Article 9 – paragraph 3

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

Amendment 86

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

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

Amendment 87

Proposal for a directive
Article 9 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall, when setting out	4. Member States shall, when setting out

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

Amendment 88

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

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

Amendment 89

Proposal for a directive
Article 9 – paragraph 5

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

Amendment 90

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

Text proposed by the Commission	*Amendment*
	5a. The Commission shall conduct a feasibility study into the establishment of a clearing house to facilitate the reimbursement of costs under this Directive across borders, healthcare systems and currency zones within two years of the entry into force of this Directive and shall report back to the European Parliament and the Council and, if appropriate, present a legislative proposal.

Amendment 91

Proposal for a directive
Article 9 a (new)

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

Amendment 92

Proposal for a directive
Article 9 b (new)

Text proposed by the Commission	*Amendment*
	Article 9b
	European Patients Ombudsman

	The Commission shall present a legislative proposal to establish a European Patients Ombudsman within 18 months after the entry into force of this Directive. The European Patients Ombudsman shall consider, and if appropriate, mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. The European Patients Ombudsman shall only be engaged once all the complaint options within the relevant Member State have been exhausted.

Amendment 93

Proposal for a directive
Article 10 – paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
1. The Member States of affiliation shall ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State.	1. The Member States of affiliation shall ensure that there are ***easily accessible*** mechanisms in place***, including by electronic means, promptly*** to provide patients on request with information on receiving healthcare in another Member State, ***and shall include information on patients' entitlements, on procedures for accessing those entitlements and on systems of appeal and redress if the patient is deprived of such entitlements,*** and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State. ***This information shall be published in formats accessible to persons with disabilities. Member States shall consult stakeholders, including patients' organisations, to ensure information is clear and accessible. In information about cross-border healthcare, a clear distinction shall be made between the rights which patients have by virtue of this Directive and rights arising from regulations on coordination of social security schemes as referred to in Article 3(1)(f).***
2. The information referred to in	

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

Amendment 94

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

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

Amendment 95

Proposal for a directive
Article 10 – paragraph 3

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

Amendment 96

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. When healthcare is provided in a Member State other than that where the patient is an insured person, ***or in a Member State other than that where the***	1. When healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare service is provided according to

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.	the legislation of the Member State of treatment in accordance with Art.5.

Amendment 97

Proposal for a directive
Article 12 – paragraph 1

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

Amendment 98

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

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

Amendment 99

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The national contact point in the Member State of affiliation shall, ***in close***	2. The national contact point in the Member State of affiliation shall provide

cooperation with other competent national authorities, and with national contact points in other Member States, in particular in the Member State of treatment, and with the Commission:

and disseminate information to patients ***and health professionals, on a website if appropriate, on receiving healthcare in another Member State, and on the terms and conditions which apply***, in particular on ***patients'*** rights related to cross-border healthcare ***as laid down in Article 6***. ***The national contact point shall help patients to protect their rights and seek appropriate redress in the event of harm caused by the use of healthcare in another Member State;***

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

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

2a. The national contact point in the Member State of treatment shall provide and disseminate information to patients, on a website if appropriate, on issues referred to in Article 5(1)(ba) and on the protection of personal data, the level of accessibility to healthcare facilities for people with disabilities, procedures for complaints and means of redress available for healthcare received in the Member State of treatment. It shall in particular inform patients ***and health professionals, where necessary,*** about ***the means by which professionals and providers are regulated and the means by which regulatory action can be taken,*** the options available to settle any dispute, ***and*** help to identify the appropriate out-of-court settlement scheme for the specific case***.***

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

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

2b. The national contact point in a

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

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

Amendment 100

Proposal for a directive
Article 13 - paragraphs 2a, 2b and 2c (new)

Text proposed by the Commission	*Amendment*
	2a. Member States, particularly neighbouring countries, may conclude agreements with one another concerning the continuation or potential further development of cooperation arrangements.
	2b. Member States shall guarantee that registers in which health professionals are listed can be consulted by relevant authorities of other Member States.
	2c. Member States shall immediately and proactively exchange information about disciplinary and criminal findings against health professionals where they impact upon their registration or their right to provide services.

Amendments 101 and 144

Proposal for a directive
Article 14 - paragraphs 1, 2 and 3

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

and that any restrictions on recognition of individual prescriptions are prohibited unless they:	***product*** can be used in their territory and that any restrictions on recognition of individual prescriptions are prohibited unless they:
(a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory or	(a) are limited to what is necessary and proportionate to safeguard human health and are non-discriminatory or
(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription.	(b) are based on legitimate and justified doubts about the authenticity or content of an individual prescription, ***or the status of the prescriber.***
	The recognition of such prescription shall not affect:
	(i) national rules governing prescribing and dispensing, including generic substitution;
	(ii) national rules governing the reimbursement of Community cross-border prescriptions;
	(iii) any professional or ethical duty that would require the pharmacist to refuse to dispense had the prescription been issued in the Member State of affiliation.
2. For facilitating the implementation of paragraph 1, the Commission shall adopt:	2. For facilitating the implementation of paragraph 1, the Commission shall adopt:
(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions;	(a) measures enabling a pharmacist or other health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by an authorised person through developing a Community prescription template, and supporting interoperability of ePrescriptions; ***data protection safeguards shall be taken into account and incorporated from the initial stage of this development process***;
(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible;	(b) measures to ensure that medicinal products prescribed in one Member State and dispensed in another are correctly identified and that the information to patients concerning the product is comprehensible***, including clarity as to different names used for the same medicinal product;***
	(ba) measures to ensure, if needed, contact between the prescribing party and

	the dispensing party in order to ensure complete understanding of the treatment, whilst maintaining confidentiality of patient's data.
(c) measures to exclude specific categories of medicinal products from the recognition of prescriptions provided for under this article where necessary in order to safeguard public health.	
	2a. Where a prescription is issued in the Member State of treatment for medicinal products which are not normally available on prescription in the Member State of affiliation, it shall be for the latter to decide whether to authorise exceptionally or to provide an alternative medicinal product deemed to be as effective.
3. The measures referred to in points (a) ***and*** (b) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 19(2). ***The measures referred to in point (c) of paragraph 2, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).***	3. The measures referred to in points (a)***,*** (b) ***and (ba)*** of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 19(2).

Amendment 102

Proposal for a directive
Article 15 - paragraph 1

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

Amendment 103

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

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

Amendment 104

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

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

Amendment 105

Proposition de directive
Article 15 - paragraph 3 - introductory part

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

Amendment 106

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

Text proposed by the Commission	*Amendment*
(a) a list of specific criteria and conditions that the European reference networks must fulfil, including the conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular, that the European reference networks:	(a) a list of specific criteria and conditions that the European reference networks must fulfil, including ***also a list of rarer disease areas to be covered and*** the conditions and criteria required from healthcare providers wishing to join the European reference networks, in order to ensure, in particular,

that the European reference networks:

Amendment 107

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

Text proposed by the Commission	*Amendment*
	(ixa) have appropriate and effective relationships with technology providers.

Amendment 108

Proposal for a directive
Article 15 a (new)

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

Amendment 109

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data ***in accordance with the applicable law***. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication	The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall ***conform to the applicable data protection laws in each Member State and shall also*** reflect developments in health technologies and medical science, ***including telemedicine and telepsychiatry,*** and respect the fundamental right to the protection of personal data. They shall specify in particular the necessary

technology systems to ensure safe, high-quality and efficient provision of cross-border health services.	standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.

Amendment 110

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

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

Amendment 135
Proposal for a directive
Article 17

Text proposed by the Commission	*Amendment*
Cooperation on management of ***new*** health technologies	Cooperation on management of health technologies
1. ***Member States shall facilitate development and functioning*** of a network connecting the national authorities or bodies responsible for health technology assessment.	1. ***The European Commission shall, in consultation with the European Parliament, facilitate the establishment*** of a network connecting the national authorities or bodies responsible for health technology assessment. ***This network shall be based on the principles of good governance including transparency, objectiveness, fairness of procedures, and broad and full stakeholder participation of all relevant groups, including - but not limited to - health professionals, patients' representatives, social partners, scientists and industry, whilst respecting Member States' competence in the area of health***

	technology assessment.
2. The objective of the health technology assessment network shall be:	2. The objective of the health technology assessment network shall be:
(a) to support cooperation between national authorities or bodies;	(a) to support cooperation between national authorities or bodies;
	(aa) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets;
(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies**.**	(b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies***;***
	(ba) to analyse the nature and type of information that can be exchanged.
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.	3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.
4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment ***and*** the management of this network ***and specifying the nature and type of the information to be exchanged***.	4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment**,** the management ***and the transparent functioning*** of this network.
	4a. The Commission shall only allow such authorities to join the network which fulfil the principles of good governance as defined in paragraph 1.

Amendment 112

Proposal for a directive
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall collect statistical ***and other additional*** data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the	1. Member States shall collect statistical data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes. They shall

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.	collect such data as part of their general systems for collecting healthcare data, in accordance with national and Community law for the production of statistics and on the protection of personal data***, and specifically Article 8(4) of Directive 95/46/EC***.

Amendment 113

Proposal for a directive
Article 19 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative.	1. The Commission shall be assisted by a Committee, consisting of representatives of the Member States and chaired by the Commission representative. ***In this process, the Commission shall ensure the consultation of experts from the relevant patient and professional groups in an appropriate manner, especially in the context of the implementation of this Directive, and shall provide a reasoned report on these consultations.***

Amendment 143
Proposal for a directive
Article 19 – paragraph 2

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

Amendment 115

Proposal for a directive
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.	The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive***, including statistics on patient outflows and inflows resulting from this Directive,*** and submit it to the European Parliament and to the Council.