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EUROPEAN UNION OF MEDICAL SPECIALISTS**

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**UEMS POSITION**

on the draft report 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))

**PROPOSED AMENDMENTS to EP DOCUMENT 2008/0142(COD)**

Adopted by the UEMS Enlarged Executive on 10<sup>th</sup> January 2009

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### ***Amendments***

Amendments by the European Parliament:  
Amended text is highlighted in ***black bold italics***.

Amendments or corrections by the UEMS:  
Amended text is highlighted as a track change, i.e. in ***red bold italics***.

## POSITION of the EUROPEAN UNION of MEDICAL SPECIALISTS (UEMS)

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))

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### Amendment 1

Proposal for a directive  
Recital 2 a (new)

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

***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<sup>1</sup>, in which it called for legal certainty and clarity on rights and procedures for patients, health professionals and Member States.***

<sup>1</sup> OJ 124 E, 25.5.2006, p. 543.

Or. en

**The UEMS supports this amendment.**

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### Amendment 2

Proposal for a directive  
Recital 4

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

(4) The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development. ***They are also part of the wider framework of services of general interest.***

(4) The health systems of the Community are a central component of Europe's high levels of social protection, and contribute to social cohesion and social justice as well as to sustainable development.

Or. en

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### Amendment 3

#### Proposal for a directive

##### Recital 6

*Text proposed by the Commission*

(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.**

*Amendment proposed by the European Parliament*

(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. **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.**

Or. en

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### Amendment 4

#### Proposal for a directive

##### Recital 10

*Text proposed by the Commission*

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

- Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
- Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;

*Amendment proposed by the European Parliament*

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

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

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

Or. en

**The UEMS strongly supports the issue of cross-border healthcare being addressed by the EU through this draft directive. However, the UEMS is equally strongly concerned by the withdrawal from the scope of this text of all aspects dealing with the mobility of health professionals.**

**While some areas relating to this particular topic are covered in the directive on the recognition of professional qualifications (2005/36/EC), several areas still need a proper solution and should therefore be addressed and incorporated in the current proposal.**

**What other text could guarantee the quality and safety of cross-border healthcare than the one on patients' rights?**

**Should the current version of the EP Report be endorsed, other initiatives will need to be put forward in order to guarantee European citizens with these rights, but in the context of professional mobility. According to the UEMS, the current text is not likely to achieve the legal clarity that was aimed for when proposing this text.**

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## Amendment 5

### Proposal for a directive Recital 11

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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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.

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Or. en

***See above, Comment on Amendment 4***

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## **Amendment 6**

### **Proposal for a directive**

#### **Recital 12**

##### *Text proposed by the Commission*

(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

##### *Amendment proposed by the European Parliament*

(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, such as through increasing waiting time for treatment.

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.

Or. en

**The UEMS is committed to the free movement of doctors between European countries whilst guaranteeing the highest standards in quality of care, *inter alia* by appropriate standards of medical education and training. The UEMS therefore advocates positively in favour of this principle. However, this should not supersede any other freedom enshrined in the EU Treaties. Seeing the current development of teleservices, there is an urgent need to address them as well, notably by means of this proposal. The UEMS firmly advocates these services must be subject to the same standards of quality and safety as other “regular” services. The UEMS therefore defends the non-restriction of the principles of free movement within the current text.**

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## Amendment 7

### Proposal for a directive Recital 15

#### *Text proposed by the Commission*

(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

#### *Amendment proposed by the European Parliament*

(15) Research suggests that harm arises from healthcare in around 10% of cases. Ensuring clear common obligations to deal with *alleged* harm arising from healthcare is therefore essential to avoid lack of confidence in those mechanisms acting as an obstacle to taking up cross-border

taking up cross-border healthcare. Coverage for harm and compensation by 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.

healthcare. Coverage for harm and compensation by 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.

Or. en

**The UEMS supports this amendment.**

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## Amendment 8

### Proposal for a directive Recital 18

*Text proposed by the Commission*

(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 State 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*

*Amendment proposed by the European Parliament*

(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 State 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. Community law does not detract from the power of the Member States to organise their healthcare and social security systems.

*introducing or maintaining unjustified restrictions on the exercise of that freedom in the healthcare sector.*

Or. en

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## Amendment 9

### Proposal for a directive Recital 21

#### *Text proposed by the Commission*

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

#### *Amendment proposed by the European Parliament*

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

Or. en

**The UEMS supports this amendment.**

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## Amendment 10

### Proposal for a directive Recital 24

*Text proposed by the Commission*

(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.

*Amendment proposed by the European Parliament*

(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. ***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.***

Or. en

**The UEMS supports this amendment.**

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## Amendment 11

### Proposal for a directive Recital 35

*Text proposed by the Commission*

(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

*Amendment proposed by the European Parliament*

(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 misunderstanding. It will also establish a high level of trust between the patient and the healthcare provider.

and the healthcare provider.

Or. en

**The UEMS supports this amendment.**  
**See also Comment on Amendments 6, 35 and 35a (new)**  
*(Telemedicine should be subject to the same standards as “regular” services)*

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## Amendment 12

### Proposal for a directive Recital 37

#### *Text proposed by the Commission*

(37) Realising the potential of **the internal market for** cross-border healthcare requires cooperation between providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high quality and efficient care across borders. This is particularly the case for cooperation in border regions, where cross-border provision of **services** may be the most efficient way of organising **health services** for the local populations, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States. Such cooperation may concern joint planning, mutual recognition or adaptation of procedures or standards, interoperability of respective national information and communication technology systems, practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis. Directive 2005/36/EC on the recognition of professional qualifications stipulates that free provision of services of a temporary or occasional nature, including services provided by health professionals, in another Member State should not,

#### *Amendment proposed by the European Parliament*

(37) Realising the potential of 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 **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. 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 another Member State should not, subject

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.

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.

Or. en

**The UEMS supports this amendment.**

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## **Amendment 13**

### **Proposal for a directive**

#### **Recital 39**

*Text proposed by the Commission*

(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.

*Amendment proposed by the European Parliament*

(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. *Where a prescription*

*is issued in the Member State of treatment for drugs which are not normally available on prescription in the Member State of affiliation it should be for the latter to decide whether to authorise exceptionally or to provide an alternative drug deemed to be similar.*

Or. en

**The UEMS supports this amendment.**

**In addition, the UEMS calls for appropriate mechanisms of medical monitoring to be put in place in order to ensure the safe continuity of healthcare and drug therapy.**

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## Amendment 14

### Proposal for a directive Article 5 – paragraph 1

*Text proposed by the Commission*

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

(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;*

(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;*

*Amendment proposed by the European Parliament*

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:

(a) *when healthcare is provided in a Member State other than that where the patient is an insured person, or in a Member State other than that where the healthcare provider resides, is registered or established, such healthcare is provided according to the legislation of the Member State of treatment.*

(b) *healthcare referred to in paragraph 1(a) is provided according to standards and guidelines on quality and safety defined by the Member State of treatment ensuring that:*

(i) *patients and healthcare providers from other Member States can be provided with*

***(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;

(d) patients have a means of making complaints and are guaranteed remedies and compensation ***when they suffer harm arising from the healthcare they receive***;

(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;

(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.

***information on such standards and guidelines, including provisions on supervision, inter alia by electronic means***;

***(ii) patients and healthcare providers from other Member States can be provided with information*** on availability, prices and outcomes of the healthcare provided and details of ***the healthcare provider's*** insurance cover or other means of personal or collective protection with regard to their professional liability;

(d) patients have ***the*** means of making complaints ***when they suffer harm arising from the healthcare they receive*** and are guaranteed remedies and ***the right to seek*** compensation;

(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;

(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.

***(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***;

***(gb) 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 practice, notably through the delivery of high quality education and training as well as support for the development of European-wide harmonised curricula and for the accreditation of healthcare professionals;

(gc) 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;

Or. en

**The UEMS supports the amendment proposed. However, the UEMS calls for the current proposal to be further amended by re-establishing the provisions originally proposed by the Commission in order to guarantee mechanisms whereby the principles of universality, equity, solidarity, quality, safety and access to healthcare can effectively be met by the Member States.**

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## Amendment 15

### Proposal for a directive Article 5 – paragraph 3

*Text proposed by the Commission*

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.

*Amendment proposed by the European Parliament*

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 and with experts from the patient and professional groups concerned, ~~may~~ shall develop guidelines to facilitate the implementation of paragraph 1.

Or. en

**Being committed to ensuring the highest standards in the provision of healthcare across Europe, the UEMS strongly endorses the development of European-wide guidelines. It is the UEMS's firm opinion that these can only be developed, adopted and implemented by the involvement of healthcare professionals and their representative organisations.**

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## Amendment 16

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

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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 Member State of treatment or*** 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. ***If there are several methods available for treating a certain disease or injury, the patient shall 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.*** In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided.

Or. en

**The UEMS supports this amendment.**

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**Amendment 17****Proposal for a directive  
Article 6 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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. ***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.***

Or. en

**The UEMS supports this amendment.**

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**Amendment 18****Proposal for a directive  
Article 8 – title**

*Text proposed by the Commission*

Hospital ***and specialised*** care

*Amendment proposed by the European Parliament*

Hospital care

Or. en

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## Amendment 19

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

*Text proposed by the Commission*

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

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

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

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

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

*Amendment proposed by the European Parliament*

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

(a) healthcare which ***is highly specialised and/or*** requires ***use of cost-intensive medical infrastructure or medical equipment; or***

(b) healthcare ***involving treatments presenting a particular risk for the patient or the population.***

Or. en

**The UEMS supports this amendment.**

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## Amendment 20

### Proposal for a directive Article 8 – paragraph 2

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

***deleted***

Or. en

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## Amendment 21

### Proposal for a directive Article 8 – paragraph 4

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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

Or. en

**The UEMS supports this amendment.**

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## Amendment 22

### Proposal for a directive Article 8 – paragraph 5

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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.***

Or. en

**The UEMS supports this amendment.**

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## Amendment 23

### Proposal for a directive

#### Article 9 – paragraph 3 a (new)

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

***3a. Member States may offer patients a voluntary system of prior authorisation whereby, in return for such authorisation, the patient shall receive a voucher indicating the maximum reimbursable cost. This voucher can then be taken to the hospital of treatment and reimbursement would then be made direct from the Member State of affiliation.***

Or. en

**While it supports this proposal for amendment, the UEMS calls for appropriate mechanisms to be put in place in order to guarantee the effective functioning of such direct reimbursements.**

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## Amendment 24

### Proposal for a directive

#### Article 9 – paragraph 5 a (new)

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

***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.***

Or. en

**The UEMS supports this amendment.  
See also above, Comment on Amendment 23**

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## Amendment 25

### Proposal for a directive Article 10 – paragraph 1

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

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 the terms and conditions that would apply, ***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,*** inter alia, whenever harm is caused as a result of healthcare received in another Member State.

Or. en

**The UEMS supports this amendment.**

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## Amendment 26

### Proposal for a directive Article 10 – paragraph 2

*Text proposed by the Commission*

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

*Amendment proposed by the European Parliament*

***deleted***

Or. en

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## Amendment 27

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

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

***2a. Member States shall ensure that information is available through a secure system to the health professionals advising a patient. This information shall include details of registered health professionals in the Member State of treatment and any disciplinary proceedings against them. Member States shall proactively notify each other of any such disciplinary proceedings and subsequent findings immediately.***

Or. en

**The UEMS supports this amendment.**

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## Amendment 28

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

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

(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;

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

Or. en

**The UEMS supports this amendment.**

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**Amendment 29****Proposal for a directive****Article 12 – paragraph 2 – point d a (new)**

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

***(da) facilitate patient access to European  
Patient Networks;***

Or. en

**The UEMS supports this amendment.**

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**Amendment 30****Proposal for a directive****Article 14 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

(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;***

Or. en

**The UEMS supports this amendment.  
See also above, Comment on Amendment 13**

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## Amendment 31

### Proposal for a directive

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

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

*(ca) measures to identify and prevent counterfeit medicinal products reaching pharmacies;*

Or. en

**The UEMS supports this amendment.  
See also above, Comment on Amendment 13**

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## Amendment 32

### Proposal for a directive

#### Article 14 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment proposed by the European Parliament and corrected by the UEMS*

*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 **similar** medicinal product ~~deemed to be similar~~.*

Or. en

**The UEMS supports this corrected amendment.  
See also above, Comment on Amendment 13**

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## Amendment 33

### Proposal for a directive

#### Article 15 – paragraph 3 – point a

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

(a) a list of specific criteria and conditions that the European reference networks must

(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:

fulfil, including the *list of rarer disease areas to be covered and* 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:

Or. en

**While it supports this proposal for amendment, the UEMS calls for sufficient flexibility to be provided regarding the development of such a list. The UEMS also advocates for the involvement of relevant experts in this process. Hence the following proposal for a new amendment:**

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**Amendment 33a (new)**

**Proposal for a directive  
Article 15 – paragraph 3**

*Text proposed by the Commission*

*Amendment proposed by the UEMS*

3. The Commission shall adopt:

3. The Commission, *in collaboration with relevant experts and stakeholders,* shall adopt:

Or. en

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**Amendment 34**

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

*Text proposed by the Commission*

*Amendment proposed by the European  
Parliament*

*(ixa) have appropriate and effective  
relationships with technology providers.*

Or. en

**The UEMS supports this amendment.**

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## Amendment 35

### Proposal for a directive Article 16

#### *Text proposed by the Commission*

The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever Member States decide to introduce them. Those measures shall reflect developments in health technologies and medical science and respect the fundamental right to the protection of personal data *in accordance with the applicable law*. They shall specify in particular the necessary standards and terminologies for inter-operability of relevant information and communication technology systems to ensure safe, high-quality and efficient provision of cross-border health services.

#### *Amendment proposed by the European Parliament and corrected by the UEMS*

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 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.

Or. en

#### **The UEMS supports this amendment.**

**However, the UEMS does not see the need to have specific mention of different “telespecialties” as this could be seen as detrimental to other specialties. Whilst acknowledging the particular difficulty in ensuring interoperability of systems in a field such as psychiatry, a similar case could be made for other “telespecialties”. Hence, the UEMS strongly advocates for the inclusion of telemedicine, but without any particular provisions to specific fields.**

**Interoperability and data protection in teleservices and e-Health should be seen as encompassing all areas of medicine.**

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**Amendment 35a (new)**

**Proposal for a directive**  
**Article 16 – paragraph 2 (new)**

*Text proposed by the Commission*

*Amendment proposed by the UEMS*

**2. 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.**

Or. en

**The UEMS is concerned about the potential misuse of information and communication technologies in healthcare, with associated potential risks to patients. Therefore, the UEMS insists on the same level of guarantee, in terms of quality and safety, being applied to these services as compared to “standard” medical acts.  
See also above, Comment an Amendment 6**

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**Amendment 36**

**Proposal for a directive**  
**Article 17 – title**

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

Cooperation on management of **new** health technologies

Cooperation on management of health technologies

Or. en

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**Amendment 37****Proposal for a directive  
Article 17 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for health technology assessment.

*Amendment proposed by the European Parliament*

1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for health technology assessment. ***Member States shall set up a system based on the principles of good governance including transparency, objectiveness, fair procedures, and full stakeholder participation of all relevant groups, including health professionals, patients, scientists and industry, for the operation of the network.***

Or. en

**The UEMS supports this amendment.**

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**Amendment 38****Proposal for a directive  
Article 17 – paragraph 2 – point b a (new)**

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

***(ba) to find sustainable ways to balance the objectives of access to medicines, reward for innovation and management of healthcare budgets.***

Or. en

**The UEMS supports this amendment.**

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**Amendment 39****Proposal for a directive  
Article 17 – paragraph 4**

*Text proposed by the Commission*

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.*

*Amendment proposed by the European Parliament*

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.

Or. en

**The UEMS supports this amendment.**

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**Amendment 40****Proposal for a directive  
Article 17 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment proposed by the European Parliament*

*4a. The Commission shall only allow such authorities to join the network which fulfil the principles of good governance as defined in paragraph 1.*

Or. en

**The UEMS supports this amendment.**

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**Amendment 40a (new)****Proposal for a directive  
Article 19 – paragraph 1**

*Text proposed by the Commission*

*Amendment proposed by the UEMS*

1. The Commission shall be assisted by a Committee, consisting of representatives of

1. The Commission shall be assisted by a Committee, consisting of representatives of

the Member States and chaired by the Commission representative.

the Member States and chaired by the Commission representative. *In doing so, 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.*

Or. en

**It is the firm opinion of the UEMS that the implementation of such an ambitious piece of legislation can only be achieved through the involvement of all interested parties. Therefore, the UEMS advocates appropriate mechanisms of consultation being put in place to assist this “cross-border healthcare committee”.**

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#### **Amendment 41**

##### **Proposal for a directive Article 20 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment proposed by the European Parliament*

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.

Or. en

**The UEMS supports this amendment.**