## **EUROPEAN PARLIAMENT**

2004 \*\*\*\* 2009

Committee on Economic and Monetary Affairs

2008/0142(COD)

10.3.2009

## **OPINION**

of the Committee on Economic and Monetary Affairs

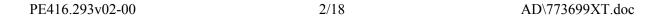
for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Harald Ettl

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#### SHORT JUSTIFICATION

The rapporteur welcomes the Commission's proposal for a directive on the application of patients' rights in cross-border healthcare, as the proposal seeks to increase transparency and legal certainty for patients. The growing quality of the services available at medical treatment institutions and better patient information suggest that patient mobility will increase. The advantages which can be derived for health policy from better-networked treatment institutions in Europe should be pursued with greater intensity. At the same time, it must be ensured that the proposal for a directive neither results in one-sided imposition of costs on Member States nor damages health care or the health services available within a country if disproportionate numbers of patients seek health services.

Health services were excluded from the scope of the Services Directive because these services are of overriding importance and should be recognised by separate European legislation. This being so, the European Parliament called on the Commission in an own-initiative report in May 2008 to propose a new European regulatory framework for cross-border health care. In July 2008, as part of the social package, the Commission published the proposal for a directive now under consideration, which is intended particularly to codify the case law of the Court of Justice of the EU concerning cross-border health care.

The rapporteur supports the Commission's proposal to facilitate cross-border patient mobility and to clarify patients' rights by means of secondary legislation. It ought to be possible at least to make full use of all synergies available in the field of medicine. This requires economic, insurance-related and organisational measures, for example relating to Member States' bed capacity and financial capacity. To avoid capacity problems in providing services to a Member State's own population on account of the numbers of patients coming from other Member States, patients should be afforded access to European establishments with due consideration for the capacities of each Member State and its financial resources.

Pursuant to Article 35 of the Charter of Fundamental Rights of the European Union and Article 152(1) of the EC Treaty, Member States must ensure a high level of health protection. At present the health services on offer vary substantially between Member States. This situation should be further developed and preserved with high standards of quality. Health is an overriding concern and should be supported by treaty policy, quality assurance and ombudsman's rules. The possibility of cross-border health care must not encourage individual Member States to cease to develop their health institutions, nor should it provide an incentive for them to promote treatment abroad.

The rapporteur endorses the approach of allowing Member States, if the financial balance of their health system and/or a Member State's capacity to provide hospital services is seriously undermined, to introduce a requirement to obtain prior authorisation of reimbursements of costs. In this context it is important to point out that Member States must have the option of charging the full cost of a service to the systems from which patients come. In some Member States, hospital treatment is funded partly from social insurance contributions and partly from tax revenue. If patients from abroad were charged only the social insurance rate, those Member States whose inadequate capacity may provide the inducement for patients to seek treatment in another Member State would derive an unjustified financial advantage from tax-payers in the country of treatment.

#### **AMENDMENTS**

The Committee on Economic and Monetary Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

#### Amendment 1

## Proposal for a directive Recital 2

Text proposed by the Commission

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

#### Amendment

(2) Given that that the conditions for recourse to Article 95 of the Treaty as a legal basis are 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 a high level of protection of human health should be guaranteed taking account in particular of any new development based on scientific facts.

## Justification

The aim of this directive should be to clarify patients' rights and not to harmonise the organisation of health care. This is a matter for which Member States bear sole responsibility.

#### Amendment 2

## Proposal for a directive Recital 4

Text proposed by the Commission

(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.

### Amendment

(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. They enjoy a special status among services of general interest on account of their priority objectives of ensuring patient safety and

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### protecting public health.

## Justification

Although the directive under consideration creates a separate set of rules for health services, which were excluded from the Services Directive, the subject of health is treated in a manner similar to that which it was intended to adopt previously under the Services Directive. It must be made clear that health services are an overriding concern, taking precedence over other services.

#### Amendment 3

## 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 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.

#### Amendment 4

## 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

#### Amendment

(15) Research suggests that *physical* 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 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

(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.

therefore limited only to actual costs of healthcare received. The Member State of affiliation should also reimburse other related costs, such as costs of therapeutic treatment.

## Justification

Although the directive under consideration creates a separate set of rules for health services, which were excluded from the Services Directive, the subject of health is treated in a manner similar to that which it was intended to adopt previously under the Services Directive. It must be made clear that health services are an overriding concern, taking precedence over other services.

#### Amendment 5

## Proposal for a directive Article 2

Text proposed by the Commission

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

#### Amendment

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

#### Justification

'Cross-border' should be inserted, because otherwise the provision will be incompatible with Article 152 of the EC Treaty (complementary action by the Community).

#### Amendment 6

## Proposal for a directive Article 3 – paragraph 1 – point f

Text proposed by the Commission

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

#### Amendment

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

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(EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

17, 18, 19, 20, 27 and 28 of Council Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

## Amendment 7

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

Text proposed by the Commission

Amendment

(ga) Directive 2002/83/EC of the European Parliament and of the Council of 5 November 2002 concerning life assurance<sup>1</sup>:

<sup>1</sup> OJ L 345, 19.12.2002, p. 1.

#### Amendment 8

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

Text proposed by the Commission

Amendment

(gb) First Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking-up and pursuit of the business of direct insurance other than life assurance<sup>1</sup>; <sup>1</sup> OJ L 228, 16.8.1973, p. 3.

#### Amendment 9

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 (third non-life insurance Directive)<sup>1</sup>.

#### Amendment 10

## Proposal for a directive Article 3 – paragraph 2

Text proposed by the Commission

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

#### Amendment

Until the date of entry into force of Regulation (EC) No 883/2004, 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. However, whenever the conditions for granting an authorisation set out in Article 22(2) of Regulation (EC) No 1408/71 are fulfilled, the authorisation shall be accorded and the benefits provided in accordance with that Regulation. In that case Articles 6, 7, 8 and 9 of this Directive shall not apply.

#### Justification

The sentence which is to be deleted establishes an 'opt-in' from Regulation No 1408/71/EC to this directive: the consequences and administrative practicality of this are unclear, and it is undesirable to undermine Regulation No 1408.

#### Amendment 11

Proposal for a directive Article 3 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

From the date of entry into force of Regulation (EC) No 883/2004,

when the circumstances under which an authorisation to go to another Member

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

#### **Amendment 12**

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

Text proposed by the Commission

Amendment

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

Amendment 13

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

Text proposed by the Commission

Amendment

1a. Pursuant to Article 152 of the Treaty, the Member State of treatment is fully responsible for the organisation of the health care system and for the medical care provided.

Justification

*The 'recipient side' is not addressed; hence the reference to the EC Treaty here.* 

#### **Amendment 14**

## Proposal for a directive Article 5 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. In accordance with Article 12(2)(da), the authorities of the Member State of treatment shall be responsible for constant monitoring on the basis of the data obtained there. The authorities shall, if appropriate, on the basis of the results of that monitoring, take prompt measures to ensure public health and preserve the financial balance of the social security system.

## Justification

As the data are collected anyway, it should be possible to put them to immediate use to help Member States to plan their national health policies - to 'act instead of reacting'.

#### **Amendment 15**

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

Text proposed by the Commission

Amendment

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

### **Amendment 16**

Proposal for a directive Article 6 – paragraph 1

Text proposed by the Commission

Amendment

1. Subject to the provisions of this

1. Subject to the provisions of this

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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.

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. The competent institution of the Member State of affiliation shall reimburse the effective costs of the treatment to the insured person. 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, if they are not available in the 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.

## Justification

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

### **Amendment 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

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

### Justification

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

#### Amendment 18

# Proposal for a directive Article 6 – paragraph 4

Text proposed by the Commission

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

#### Amendment

4. Member States shall have a mechanism for calculation of costs that are to be reimbursed to the insured person by *the* statutory *health* system *concerned* 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.

### Justification

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

#### Amendment 19

## Proposal for a directive Article 8 – paragraph 2

Text proposed by the Commission

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

#### Amendment

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

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### referred to in Article 15.

#### Amendment 20

## 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 21

Proposal for a directive Article 8 a (new)

Text proposed by the Commission

#### Amendment

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

#### Amendment

#### Article 8a

Rejection of hospital and specialised care

8a. A Member State of treatment may permit an individual healthcare provider to refuse hospital or specialised care to patients in another Member State who seek treatment in that Member State if that would be detrimental to other patients with similar health needs, for example because of increased waiting time for treatment.

## Justification

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

#### Amendment 22

## Proposal for a directive Article 9 – paragraph 1

Text proposed by the Commission

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, nondiscriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. *In any event*, an insured person shall *always* be granted the authorisation pursuant to Regulations on coordination of social security referred to in Art. 3.1 f) whenever the conditions of Art.22.1 c) and Art. 22.2 of Regulation 1408/71 are met.

#### Amendment

1. The Member State of affiliation shall ensure that administrative procedures regarding the use of healthcare in another Member State related to any prior authorisation referred to in Article 8(3), reimbursement of costs of healthcare incurred in another Member State and other conditions and formalities referred to in Article 6(3), are based on objective, nondiscriminatory criteria which are published in advance, and which are necessary and proportionate to the objective to be achieved. Until the date of entry into force of Regulation (EC) No 883/2004, an insured person shall be granted the authorisation pursuant to the regulations on the coordination of social security referred to in Article 3(1)(f) of this Directive, in accordance with Article 22(1)(c) and Article 22(2) of Regulation 1408/71. From the date of entry into force of Regulation (EC) No 883/2004, an insured person shall be granted the authorisation on the basis of the regulations concerning the coordination of social security schemes as referred to in Article 3(1)(f) in accordance with Article 20 of Regulation (EC) No 883/2004.

## **Amendment 23**

## Proposal for a directive Article 10 – paragraph 1

Text proposed by the Commission

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

#### Amendment

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

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State.

State. In regard to information relating to cross-border care, a clear distinction shall be made between the rights which patients have under this Directive and rights arising from regulations on the coordination of social security schemes as referred to in Article 3(1)(f).

#### Amendment 24

## Proposal for a directive Article 12 – paragraph 1

Text proposed by the Commission

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

### Amendment

1. Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission. *Member States shall ensure that patients' organisations, health insurance funds and care providers are involved in the work of those national contact points.* 

#### Amendment 25

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

Text proposed by the Commission

Amendment

(da) register all activities in the Member State of treatment pursuant to Articles 6, 7, 8, 9 and 15 and notify the competent authorities of the Member State of treatment thereof, with healthcare providers supplying the necessary information as soon as they receive it.

Justification

To ensure that the procedure runs as smoothly as possible.

#### **Amendment 26**

## Proposal for a directive Article 13 – paragraph 1

Text proposed by the Commission

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

#### Amendment 27

## Proposal for a directive Article 13 – paragraph 2

Text proposed by the Commission

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

#### **Amendment 28**

Proposal for a directive Article 15 a (new)

Text proposed by the Commission

## Amendment

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

#### Amendment

2. Member States shall facilitate cooperation in cross-border healthcare provision at *national*, regional and local level as well as through information and communication technologies *and* cross-border healthcare provided on a temporary or ad hoc basis, *and shall conclude agreements in this regard*.

Amendment

Article 15 a

**Border regions** 

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

## **Amendment 29**

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

Text proposed by the Commission

Amendment

The Commission shall be responsible for collecting the requisite information with a view to charting cross-border flows of patients and practitioners in order to be able to remedy any adverse effects promptly and further encourage positive effects. The Commission shall include that information in the report referred to in paragraph 1.

## **PROCEDURE**

Title	Patients' rights in cross-border healthcare
References	COM(2008)0414 - C6-0257/2008 - 2008/0142(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ECON 2.9.2008
Rapporteur Date appointed	Harald Ettl 22.10.2008
Discussed in committee	11.12.2008 20.1.2009
Date adopted	9.3.2009
Result of final vote	+: 24 -: 0 0: 7
Members present for the final vote	Zsolt László Becsey, Pervenche Berès, Sharon Bowles, Udo Bullmann, Jonathan Evans, Elisa Ferreira, José Manuel García-Margallo y Marfil, Jean-Paul Gauzès, Donata Gottardi, Benoît Hamon, Gunnar Hökmark, Sophia in 't Veld, Othmar Karas, Wolf Klinz, Kurt Joachim Lauk, Hans-Peter Martin, Gay Mitchell, Sirpa Pietikäinen, John Purvis, Bernhard Rapkay, Eoin Ryan, Antolín Sánchez Presedo, Olle Schmidt, Peter Skinner, Margarita Starkevičiūtė, Ivo Strejček, Ieke van den Burg, Cornelis Visser
Substitute(s) present for the final vote	Harald Ettl, Margaritis Schinas, Eva-Riitta Siitonen

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