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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

position of the Council at first reading on the adoption of a Directive of the European Parliament and of the Council on the application of patients' rights on cross-border healthcare

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1. BACKGROUND

Date of transmission of the proposal to the EP and the Council (document COM(2008)414 final – 2008/0142(COD)):	2nd July 2008
Date of the opinion of the European Economic and Social Committee:	4 December 2008
Date of the opinion of the Committee of the Regions:	12 February 2009
Date of the opinion of the European Parliament, first reading:	23 April 2009
Date of transmission of the amended proposal:	[*…].
Date of political agreement:	8 June 2010
Date of adoption of the Council position:	13 September 2010

* *Taking into account the developments in Council at the time of the European Parliament first reading, the Commission did not find necessary to prepare a revised proposal but expressed its views on the Parliament amendments in the document* **SP(2009)3507** *sent to the European Parliament on 20 October 2009.*

2. PURPOSE OF THE COMMISSION PROPOSAL

The overall aim of the proposed Directive is to establish a clear and transparent framework for the reimbursement of healthcare within the EU in cases where the care is provided in a Member State other than the country of affiliation (cross-border healthcare). This followed the Court of Justice jurisprudence confirming that independently of the rights to scheduled treatment in another Member State as granted by Regulations 883/2004 and 987/2009, there exist the rights of patients to benefit from medical treatment in another Member State under Article 56 of the Treaty on the Functioning of the European Union (TFEU).

In order to achieve this objective, the proposal is structured around three main areas: (1) ensuring that patients receive safe and high quality healthcare, (2) helping

patients to exercise their rights to reimbursement of cross-border healthcare, and (3) fostering EU cooperation on healthcare in the area of recognition of prescriptions, European reference networks, health technology assessment, and eHealth.

3. COMMENTS ON THE POSITION OF THE COUNCIL

3.1. General comments

The European Parliament adopted its position at the first reading on 23 April 2009. The Commission accepted in full, in part or in principle 92 out of 120 amendments adopted at the first reading as it considered that these amendments clarified or improved the Commission proposal and were consistent with the general aim of the proposal.

While the position of the Council at first reading adopted on 13 September 2010 contains elements departing from the Commission's proposal and creating risks of legal uncertainty, the Commission did not stand against it in order to allow the legislative process to move forward. However, the Commission indicated to the Council in the attached declaration that, during the second reading, it reserves the right to support European Parliament amendments substantially improving certain provisions of the position of the Council at first reading. Regulation 883/2004 on the coordination of the social security systems and its implementing Regulation 987/2009 already grants a right to planned treatment in another Member State . The Regulations, adopted on the basis of Article 48 of the Treaty on the Functioning of the European Union, grant a person authorised by his/her competent institution a right to receive health care in another Member state under the same conditions as the persons insured in that Member State, with a right to claim the complementary reimbursement if the financial conditions in the competent Member State are more favourable than the financial conditions in the Member state of treatment. The authorisation, which is always required by the Regulation 883/2004, can not be refused if the treatment in question is provided for by the legislation of the competent Member state and can not be delivered to the person within a medically justified time-limit.

Amendments made by the European Parliament at the first reading

Amendments accepted by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading:

With regard to the scope of the proposed Directive, the position of the Council at first reading clarifies that this Directive does not apply to services in the field of long-term care whose purpose is to support people in need of assistance in carrying out routine, everyday tasks. This covers amendment 38 made by the Parliament and is acceptable to the Commission.

In relation to organs, the position of the Council specifies that only the allocation and access should be excluded, given their particular nature, which is acceptable to the Commission, while Parliament called for the general exclusion of organ transplantation which is not acceptable for the Commission as organ transplantation

as such is a medical service covered by the principle of freedom to provide services enshrined in the TFEU.

Amendment 59 strengthens the Commission proposal on safety and quality standards imposing to the Member State of treatment the obligation to define clear safety and quality standards for healthcare provided on its territory. The Council confirmed that cross-border healthcare shall be provided according to safety and quality standards of the Member State of treatment but there is no explicit obligation for Member States to define clear safety and quality standards.

However, the Council proposes some additional provisions which may exercise some pressure on Member States to adopt safety and quality standards in this regard, including information of patients upon safety and quality standards, possibility for a Member State to refuse to grant prior authorisation in case of serious and concrete concerns on quality standards of a healthcare provider in another Member State and cooperation between Member States through the exchange of information on safety and quality standards. The Commission considers some of these provisions as an improvement on the status quo and does, therefore, not oppose the Council text.

The Parliament adopted several amendments related to national contact points (97, 98, and 99), clarifying the format of these contact points, including the involvement of stakeholders and access to information. These amendments are acceptable in principle to the Commission.

The Council confirmed the concept of the national contact points and the need of cooperation between them. However, it did not support their competence to provide help to patients in the event of harm and deleted any reference to the power of the Commission to adopt measures related to the functioning of these contact points.

Both Parliament and Council attributed the competence of providing information on quality and safety of care to the contact point in the Member State of treatment. The Commission considers that the national contact points in the Member State of affiliation should remain responsible for this, as initially proposed, to ensure an easy access for patients to all necessary information. Equally, these contact points should keep the competence to help patients protecting their rights in the event of harm.

Amendments rejected by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading:

Parliament adopted amendments 60, 94, and 100 addressing the difficulty for a patient to obtain information on health professionals established in another Member State. Three different types of solutions are suggested: information on registration or status of the health professional, information on disciplinary or criminal findings, and restricted access to competent authorities only.

In this context, data protection and presumption of innocence are important rules and principles to be taken into account, and that is why these amendments are fully or partly unacceptable to the Commission. Patients could receive information on the status of a particular health professional only through the assistance of national contacts points and within the limits imposed by the principles of data protection and presumption of innocence. This is the approach taken by the Council which is, therefore, acceptable to the Commission. However, it should be clarified that patients

can ask for the assistance of the national contact point in the Member State of affiliation which requests this information from the competent authorities in the Member State of treatment. This would represent a proportionate solution which could be implemented in compliance with data protection rules.

Amendments accepted by the Commission as such or subject to rewording, but not incorporated in the position of the Council at first reading:

A number of amendments mainly concerning recitals were accepted in principle by the Commission. These referred to equal treatment of men and women in the access to and supply of goods and services, the relation of the proposed Directive to other legislation, and subsidiarity. They were not fully incorporated in the position of the Council as it considered them to be redundant.

The Parliament proposed in amendment 91 a voluntary system of "prior notification" whereby patients receive a written confirmation of the maximum amount that will be paid directly to the hospital by the Member State of affiliation. The Commission can accept the principle of this amendment but this would need some clarification in order to differentiate the system of prior notification from the prior authorisation systems, either under this Directive or under the Regulation (EC) No 883/2004.

The Parliament calls in amendment 92 for a legislative proposal to establish a European Patients Ombudsman who should mediate on patient complaints with regard to prior authorisation, reimbursement of costs or harm. The Commission understands the concerns of the Parliament, but, given the limits of the Union competence in the field of health protection, it would favour the establishment of a network between national ombudsmen.

Amendments 68, 93 and 99 stipulating that particular attention should be paid to persons with disabilities have been accepted in principle by the Commission.

Amendments rejected by the Commission and the Council and not incorporated in the position of the Council at first reading:

The Parliament adopted several amendments (66, 83, 102, and 106) which aim at helping patients affected by rare diseases. The Commission cannot accept these amendments as adopted by Parliament, but is willing to promote alternative solutions, for instance under the Regulation (EC) No 883/2004.

In the context of cooperation on management of health technologies, the Parliament calls in amendment 135 for broad and full participation of all relevant stakeholders. For the Commission, stakeholders should be actively involved in the work of the network, but the final decisions on a health technology assessment should remain the sole competence of the national authorities.

Amendment 138 makes reference to Directive 2000/78/EC on equal treatment in employment and occupation which lies outside the scope of the Directive on cross-border healthcare and is thus not acceptable. Amendment 139 referring to the Commission proposal (2008)0426 on equal treatment between persons irrespective of religion, belief, disability, age or sexual orientation cannot be included as it has not yet been adopted.

3.2. New provisions introduced by the Council

Double legal basis: The position of the Council introduces Article 168 TFEU ("public health") as an additional legal basis for the text. This is acceptable to the Commission.

Definition of "Member State of affiliation": The Commission proposal defines the Member State of affiliation as the Member State where the patient will ask for the prior authorisation for the planned treatment abroad according to Regulation (EC) No 883/2004. Thus, the definition of the Directive is aligned with that of the Regulation 883/2004. The position of the Council at first reading clarifies that, in particular, for pensioners and their family members who reside in another Member State but seek treatment under the Directive in their home countries, if the home country is listed on Annex IV to the Regulation (EC) No 883/2004, it pays for the costs.

For all other insured persons, the solution found in the position of the Council is that for healthcare which is not subject to prior authorisation and is provided under the Directive in the Member State that bears the costs of the healthcare of that person according to the Regulation (EC) No 883/2004, costs shall be assumed by this Member State, in accordance with the terms, conditions, criteria of eligibility and regulatory and administrative formalities that apply.

The Commission can accept the changes, as they only apply to healthcare provided under the Directive and neither modify the provisions of Regulation (EC) No 883/2004, nor affect the system of sharing the financial burden for health as established by the Regulations 883/2004 and 987/2009.

Quality and safety: The Council text stipulates that the system of prior authorisation will apply to hospital and specialised care, as per the Commission's original proposal and, in addition, to healthcare which could raise serious and concrete concerns related to the quality or safety of the care with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union. For the same reason, Member States may refuse prior authorisation in individual cases.

For the Commission, an exclusion of certain providers, whether public or private, on the grounds of objective concrete and legitimate concerns over the quality and safety is compatible with EU law, but only in so far as it does not affect the professional qualification's Directive. Moreover, the meaning and modalities of implementation of this provision should be more clearly defined to ensure legal certainty.

Health technology assessment: The Council deleted provisions which would allow the Commission to adopt measures for the establishment and management of a network on health technology assessment. By contrast, a new paragraph was inserted stating that the network may receive EU aid which should be allocated through measures adopted by the Commission. The Commission does not object to this amendment, but is in favour of also maintaining elements of the original proposal, as supported by the Parliament.

Powers of the Commission to adopt measures: The comitology provisions in the Commission proposal have been revised in the light of the coming into force of the

Lisbon Treaty to take into account Articles 290 and 291 of the Treaty on the Functioning of the European Union. The Commission agrees with the framework, as defined by the Council, within which it can exercise the delegated or implemented powers (duration of the delegation, revocation, right of objection) but cannot fully agree with the choice made by the Council of the measures to be adopted through delegated acts or implementing acts. In particular, measures on e-prescription, e-Health, health technology assessment and on European reference networks should be adopted through delegated acts and not through implementing acts.

3.3. Major problems when adopting the position of the Council at first reading

The position adopted by the Council at first reading contains elements departing from the Commission's proposal and creating risks of legal uncertainty. They concern in particular, the prior authorisation for the reimbursement of cross-border healthcare and eHealth.

Scope of prior authorisation:

The Commission proposal foresees that the Member State of affiliation may not impose a system of prior authorisation for non-hospital care. However, as regards on one hand hospital care and on the other specialised care included in list established at Union level through a regulatory procedure, the proposal foresees that the Member State of affiliation may provide for a system of prior authorisation "to address the consequent outflow of patients due to the implementation" of the Directive and to prevent the financial balance of the Member State's social security system and/or the planning and rationalisation carried out in the hospital sector from being seriously undermined or being likely to be seriously undermined.

The position of the Council at first reading introduces the possibility for the Member State of affiliation to make the reimbursement of costs of certain types of cross-border healthcare (hospital, specialised care and healthcare which could raise serious and concrete concerns related to the quality or safety of the care) subject to prior authorisation without any explicit request to demonstrate an outflow of patients resulting from the freedom of mobility or any risk to the system. The text simply foresees that the system of prior authorisation shall be limited to what is necessary and proportionate and shall not constitute a means of arbitrary discrimination.

The introduction of a system of prior authorisation as proposed by the Presidency text is based on a very restrictive interpretation of the jurisprudence.

Furthermore, the position of the Council at first reading refuses the adoption of a list at EU level of specialised healthcare subject to prior authorisation. It only provides that the Member State of affiliation shall make publicly available which healthcare is actually subject to prior authorisation. The Parliament took the same approach. The Commission considers that a list at EU level would have provided better transparency and more legal certainty.

Conditions for refusal of a prior authorisation: The Council introduces a non-exhaustive list of criteria for refusing individual prior authorisation, which may, in the Commission's view, create legal uncertainty for the patients.

Firstly, the mere fact that the position of the Council at first reading provides for a non-exhaustive list of criteria creates legal uncertainty.

Secondly, without a clearer delineation of their scope and modalities of application, the criteria introduced by the Council do not provide enough legal certainty. In particular, this list includes a criterion whereby prior authorisation may be refused if healthcare can be provided on the territory of the Member State of affiliation within a time-limit which is medically justifiable. This criterion makes the distinction between the Regulation (EC) N° 883/2004 on the coordination of social security systems and the Directive very difficult and risks undermining the rights granted under Regulation (EC) N° 883/2004. Also, this provision should refer to the notion of "same or equally effective treatment".

This list also includes a criterion based on patient safety risk: it would be extremely useful to clarify that this criterion cannot be interpreted as allowing such ground for refusal, if the same assessment is not carried out for care received domestically.

eHealth: In its initial proposal the Commission had included an article on "eHealth" whose aim was to establish the framework for the adoption, through a comitology procedure, of measures to achieve the interoperability (standards and terminologies) of information and communication technology systems in the field of healthcare.

After some discussions, Member States have eventually agreed to initiate a formal cooperation on eHealth at EU level and have identified three concrete priority areas for patient safety and the continuity of cross-border healthcare: identification and authentication of health professionals; list of essential data to include in patient summaries; and use of medical information for public health and medical research.

The Commission believes that the Council text is more precise than the Commission's initial proposal, but lacks working methods, such as provisions giving the Commission the power to adopt measures to implement the work at EU level.

4. CONCLUSION

The Commission takes the view that the position of the Council at first reading contains elements departing from the Commission's proposal which may create risks of legal uncertainty. In order to allow the legislative process to move forward, the Commission did not stand against the position adopted by the Council by qualified majority in order to allow the legislative process to move forward.

The Commission indicated to the Council in the attached declaration that it reserves the right to support European Parliament amendments during second reading on eHealth, the scope of the prior authorisation, increasing legal certainty for patients, , and assuring that the proposed Directive does not undermine the rights granted under Regulation 883/2004.

ANNEX

Declaration by the Commission

In a spirit of compromise, the Commission will not stand against a qualified majority vote in favour of the Presidency text although it could have benefited from some more clarity.

In particular, the Commission considers that the scope of the prior authorisation scheme should be well defined and justified.

The Commission is convinced of the need to ensure that patients seeking healthcare in another Member State can exercise their rights as confirmed by the Court in its settled case-law and without undermining the rights granted under Regulation 883/2004. The Commission proposed the measures necessary to ensure that patients benefit from legal certainty in exercising those rights while respecting Member States' power to organise and deliver healthcare.

The Commission recalls that the conditions for access and exercise of health professions have been harmonised by the professional qualifications directive.

As regards eHealth, the Commission considers it necessary to contribute at Union level to creating the conditions for ensuring continuity of care, patient safety by enabling use of medical information across borders, with the highest level of security and protection of personal data.

As the position of the European Parliament on prior authorisation and eHealth is more favourable to the patients, closer to the Commission's proposal and to its reading of the existing case-law, the Commission reserves the right to support the European Parliament's amendments on these issues during the second reading and will continue to collaborate closely with both institutions with the aim of further improving the text.