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DRAFT STATEMENT OF THE COUNCIL'S REASONS

Subject:	Position of the Council at first reading with a view to the adoption of a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the application of patients' rights in cross-border healthcare - Draft statement of the Council's reasons

I. INTRODUCTION

On 2 July 2008, the European Commission presented a proposal for a Directive on patients' rights in cross-border healthcare[1]. The proposal was based on Article 95 of the Treaty establishing the European Community (Article 114 of the Treaty on the Functioning of the European Union).

On 23 April 2009 the EP adopted its first-reading opinion[2], approving 122 amendments to the original Commission proposal. The Economic and Social Committee delivered its opinion on 4 December 2008[3] and the Committee of the Regions on 12 February 2009[4]. The European Data Protection Supervisor (EDPS) delivered his opinion on 2 December 2008[5].

In accordance with Article 294 of the Treaty, the Council adopted its position at first reading by qualified majority on [XX September 2010].

II. OBJECTIVE

The objective of the Directive is the establishment of an EU framework for the provision of cross-border healthcare within the EU, which fully respects national competence for organising and delivering healthcare. The original Commission proposal was structured around three main areas:

- **common principles in all EU health systems**: setting out which Member State is responsible for ensuring compliance with the common principles for healthcare, as recognised in the Council conclusions of 1-2 June 2006 on common values and principles in EU health systems[6], and what those responsibilities include, in order to ensure that there is clarity and confidence with regard to which authorities are setting and monitoring healthcare standards;

- **a specific framework for cross-border healthcare**: building on the existing Court of Justice of the EU case law, the Directive should make clear the entitlements of patients to receive healthcare in another Member State, including the limits that Member States can place on its

1 11307/08
2 8903/09
3 SOC/322 - CESE 1927/2008.
4 CdR 348/2008 fin - DEVE-IV-032.
5 16855/08
6 OJ C 146, 22.6.2006, p. 1.

provision as well as the level of financial coverage that would be provided for such healthcare; the financial coverage will be based on the principle that patients can obtain reimbursement up to the amount that would have been paid had they obtained the same treatment at home;

– **EU cooperation on healthcare**: the proposal establishes a framework for EU cooperation in areas such as European reference networks, health technology assessment, e-Health, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be put into practice effectively and sustainably.

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

a) General

The Council adopted in full amendments **23, 34, 39, 40, 41, 44, 46, 47, 54, 56, 58, 61, 84, 95, 96 and 98** and, in large part, amendments **14, 17 and 65**.

The following amendments were accepted in part: **20** (decentralised healthcare and social security systems); **22** (access to medicinal products or medical devices in the Member State of treatment); **30** (deletion of the reference to realising the potential of the internal market for cross-border healthcare); **32** (concerning sales of medicinal products and medical devices over the Internet); **45** (except the prevention part); **48** (except "medical practitioner"); **51** (except "private schemes"); **71** (access by patients to their medical records); **97** (information on the existence of national contact points); **101 and 144** (national rules governing dispensing, substitution or reimbursement of medicinal products); and **109** (data protection).

The Council included a double legal basis for the Directive (Article 114 and 168 of the Treaty), which was supported by the Commission.

b) Subject matter and scope (Article 1)

As regards the aim of the Directive, the Council takes the same line as the EP, that the Directive should on the one hand provide for rules to facilitate access to safe, high-quality cross-border healthcare and promote cooperation between the Member States, while on the other hand fully respecting national competence for organising and delivering healthcare, and it adopts amendment **37** in part.

The Council is of the opinion that Article 1(2) covers all the different types of healthcare systems in the Member States and therefore that the wording "*whether it is public or private*" is unnecessary and misleading.

Like the EP, the Council recognised the need to exclude long-term care from the scope of the Directive, thus following the EP (amendments **7 and 38**), and limited the exclusion of organ transplantation to access to and allocation of organs (amendments **8 and 38**). The Council added the exclusion of public vaccination programmes against infectious diseases.

The definition of "*healthcare*" is consistent with amendments **46 and 96** and covers healthcare that is provided (treatments) or prescribed (medicinal products and/or medical devices) while dropping the reference to professional mobility. The Council also accepted the main part of amendment **9** and deleted the reference to the different modes of supply of healthcare.

c) Relationship with Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems[7]

The Council agrees with the EP that the Directive should apply without prejudice to the existing framework on the coordination of social security systems as laid down in Regulation (EC) No 883/2004 (herein after "the Regulation"). This framework allows the Member States to refer patients abroad for treatment that is not available at home. The Council's position is that when the conditions of the Regulation are met, prior authorisation must be given pursuant to that Regulation, since in the majority of cases this will be more advantageous to the patient. This is consistent with the idea behind, and the relevant parts of, amendments **38, 66, 82, 117 and 128**. Nevertheless, the patient can always request to receive healthcare under the Directive.

[7] OJ L 166, 30.4.2004, p. 1.

d) Member State of treatment (MST) (Article 4)

The Council groups together all the responsibilities of the MST in one article. The main responsibilities of the MST are those that the EP asked for in amendments **59 and 140**. Furthermore, while recognising the principle of non-discrimination with regard to nationality against patients from other Member States, the Council introduced the possibility for the MST, where justified by overriding reasons of general interest, to adopt measures regarding access to treatment aimed at fulfilling its responsibility to ensure sufficient and permanent access to healthcare within its territory to its insured persons.

The Council followed the thrust of amendment **15** on the necessity for systems to be in place for making complaints, and mechanisms for patients to seek remedies in accordance with the legislation of the MST if they suffer harm arising from the healthcare they have received. In addition, the Council included additional guarantees for patients (e.g. application of the same scale of fees by healthcare providers to cross-border patients).

e) Member State of affiliation (MSA) (Article 5)

As a general principle for reimbursement of the costs of cross-border healthcare, the MSA would have to have a mechanism for calculation of such costs. It can also introduce a system for prior authorisation based on non-discriminatory criteria, limited to what it is necessary and proportionate and applied at the appropriate administrative level. This goes along with what the EP proposed in amendments **63, 70, 79 and 88**. These criteria will guarantee insured persons seeking healthcare abroad the same conditions, criteria of eligibility and regulatory and administrative formalities (gate-keeper) as patients staying in the MSA. This approach is in line with amendment **69**.

According to the Council position, the MSA would have to ensure that there are systems of appeal and redress if the patient considers that his/her rights have not been respected. This covers amendment **81**.

f) Prior authorisation (Article 7(8) and 8)

The Council agreed to the general principle that reimbursement of the costs of cross-border healthcare must not be subject to prior authorisation in line with amendment **73**. The prior authorisation system that the MSA may introduce pursuant to the Directive, and as an exception to the above-mentioned principle, has to be based on clear and transparent criteria, should avoid unjustified obstacles to the freedom of movement of persons and thus reflects the thrust of amendments **77, 149 and 157**.

The MSA may limit the application of the rules on reimbursement for cross-border healthcare by overriding reasons of general interest or to providers that are affiliated to a system of professional insurance in the MST. In this respect, the Council opted for a different approach than proposed by the EP in amendment **76**.

The basic principles for the procedure for granting the prior authorisation are detailed in the Council's position, and include the obligation to give the reasons for refusal, e.g. the healthcare is provided by providers that raise serious and concrete concerns related to compliance with the applicable quality and safety standards and guidelines. Article 8 of the Council's position refers to the importance of transparency in the operation of the prior authorisation system in line with amendment **25**. The Council has also included urgency and individual circumstances among the aspects to evaluate when taking administrative decisions on granting the prior authorisation, taking into account the spirit of amendments **87 and 145**.

The Council limited the healthcare that may be subject to prior authorisation to healthcare that the EP defined as "*Hospital care*" in its amendment **75** and took the approach of focusing on the factors justifying it (Article 8(2)). The Council agrees with the EP that there should not be a common EU-wide list of healthcare, but that it is for the Member States to define it.

g) Pensioners living abroad (Article 7.2)

When pensioners and members of their families whose MSA is listed in Annex IV to the Regulation reside in a different Member State, this MSA has to provide them with healthcare at its own expense when they stay on its territory.

If the healthcare provided in accordance with the Directive is not subject to prior authorisation, is not provided in accordance with Chapter 1 of Title III of the Regulation, and is provided in the territory of the Member State that, according to the Regulation, is, in the end, responsible for reimbursement of the costs, the costs should be assumed by that Member State.

h) Direct payment and the concepts of prior notification and of vouchers

The Council rejects amendments **78 and 86** as it considers them contrary to the competence of the Member States to organise their health systems, in particular when it comes to the regulation of upfront payments. The Council considers the content of amendment **91** unfeasible in practice as the healthcare that a patient might receive abroad and its cost cannot be known beforehand.

i) Equal treatment of patients and extension of entitlements to reimbursement

The Council has not incorporated amendments **19, 21, 66, 68 and 83** in order to respect the principle of equal treatment for all insured persons from the same MSA regardless of the MST. The explicit reference to particular pieces of legislation on equal treatment (amendments **136, 137 and 138**) is unnecessary as the principle is embodied in the Council's text (Article 4, 7, 8, 9 and 11). The Council's position states that the Member States have to ensure that all patients are treated equitably on the basis of their healthcare needs, which reflects amendment **13**.

j) Goods used in connection with healthcare

The Council has not included the definition of "*goods used in connection with healthcare*" proposed in amendment **55** and prefers to use the definitions of "*medical device*" and "*medicinal product*" that already exist in EU legislation and would not pose transposition and implementation problems. Therefore, the Council has not incorporated the amendments **18, 19 and 20** that make use of these terms.

k) Continuity of care

The Council considered that ensuring continuity of care is an important aspect of the provision of cross-border healthcare and that it should be achieved through practical mechanisms, the transfer of personal data, e-health and sharing of information between health professionals. In agreeing on these aspects (recitals 23 and 45 and Article 13) the Council drew on the relevant parts of amendments **35 and 60**.

l) Information for patients and the National Contact Points (NCPs) (Article 6)

The Member States must provide patients on request with relevant information on the safety and quality of the healthcare provided as well as on their entitlements and rights. This is in line with parts of amendments **11 and 93**.

The NCPs have to cooperate with each other and with the Commission (amendment **99**). In addition, the NCPs have to provide patients with information concerning healthcare providers, and, on request, on any restrictions on their practice. They should also provide information to patients on procedures for complaints and for seeking remedies and on provisions on supervision and assessment of healthcare providers. All this information should be easily accessible, including by electronic means, which reflects the thrust of amendments **27, 29 and 94**.

m) Data collection and protection

The Council's text includes several provisions creating obligations in relation to the protection of personal data on the MST (Article 4(2)(b) and (f)) and MSA (Article 5(c)) and in relation to e-Health (Article 13(3)) reflecting the existing EU legislation on protection of personal data. In this manner amendments **16 and 112** have been taken into account.

n) Other

The Council's position at first reading also includes a number of changes in Chapter V (Implementing and final provisions). The Council did not accept amendments **105, 113** and **143** as the involvement of stakeholders or of the European Data Protection Supervisor in the procedures for the exercise of implementing powers conferred on the Commission is not provided for in Council Decision 1999/468/EC.

Given the entry into force of the TFEU, the Council included new Articles 16, 17 and 18 on the exercise of powers to adopt delegated acts conferred to the Commission, their revocation and objections to them in relation to the exclusion of specific categories of medicinal products or medical devices from the recognition of prescriptions (Article 11(5)).

The Council has completed amendment **115** by including information on patient flows (as the EP requested) and on the financial dimension of patients' mobility among the contents of the reports on the operation of the Directive. The Council has not followed amendment **90** requesting the Commission to conduct a feasibility study into the establishment of a clearing house for the reimbursement of costs.

The Council's position does not reflect a number of amendments because they are deemed unnecessary and/or in conflict with the Council's position. In particular:

- Amendment **1**: Article 114 of the Treaty says that approximation measures proposed by the Commission in the field of health must have as a base a high level of protection;
- Amendment **2**: does not relate to any operational provision of the Directive;
- Amendment **4 and 10**: refer to ethical issues that are not appropriate for regulation at EU level;
- Amendment **5**: healthcare is excluded from the scope of Directive 2006/123/EC (the Services Directive, Article 2(2)(f));
- Amendment **6**: is rejected due to its mainly linguistic nature;
- Amendment **12**: it is not acceptable to suggest that a Member State could try to oblige a patient to receive treatment abroad;
- Amendment **24**: the Council found it unfeasible to compare "a priori" healthcare in terms of its effectiveness for the patient;
- Amendment **28 and 110**: despite the fact that the Council has not included this amendment, telemedicine is among the types of healthcare covered by the Directive and is subject to the same professional and quality and safety requirements as any other healthcare;
- Amendment **31 and 139**: reference to draft legislation is legally undesirable;
- Amendment **33 and 135**: health technology assessment have to be performed in an independent manner and protected from stakeholder involvement;

- Amendment **36**: it is not for the Directive to put forward a hypothesis about its effects on competition between service providers;
- Amendment **42**: was not accepted as the possible relationship of the Directive with the Union legislation quoted in the amendment was not clear;
- Amendment **49**: was not followed by the Council, that preferred a broader definition of "*healthcare provider*" in order to cover all types present in the Member States;
- Amendment **52 and 53**: the Council opted for a more comprehensive definition of "*Member State of affiliation*" based on existing Union legislation;
- Amendment **57**: the definition of "*harm*" was not included as it only refers back to the definition of harm fixed by national legislation and is therefore unnecessary;
- Amendment **62 and 64**: were not accepted as there is no need to have Commission guidelines or third party involvement in the responsibilities of the MST in cases of cross-border healthcare;
- Amendment **72**: its justification was not understood and its inclusion rejected;
- Amendment **74**: the Council opted for a general term, "healthcare", that includes hospital and specialised care and also treatments, medicinal products, medical devices, etc.
- Amendment **80**: is unnecessary as Member States have a legal obligation to ensure patients have access to prior authorisation schemes, if they have decided to introduce them;
- Amendment **85**: was rejected as in contradiction with amendment 25;
- Amendment **89**: the Council did not find any justification for this amendment;
- Amendment **92**: the Council did not accept this amendment as how it would relate to existing national arrangements is unclear. It should be noted that the Commission has the right of initiative in proposing EU legislation and cannot be obliged to make a legislative proposal by a legislative act;
- Amendment **102, 103, 104, 106 and 107**: the Council found these amendments too prescriptive and restrictive of the activities of the European reference networks;
- Amendment **100 and 108**: bilateral agreements between Member States exist already in the field of cross-border healthcare and there is no need to include this possibility in the Directive; in addition the Council saw a risk of overlap between the "trial areas" and existing ongoing projects on healthcare across border regions;
- Amendment **141**: the Council considered the definition of "*health data*" unclear because it mixed information on health status and administrative information.

IV. CONCLUSION

The Council believes that its position at first reading represents a fair balance between the rights of patients in cross-border healthcare and the responsibilities of the Member States for the organisation and delivery of health services and medical care.

It looks forward to constructive discussions with the European Parliament at second reading with a view to early adoption of the Directive.