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NOTE

from:	Permanent Representatives Committee (Part 1)
to:	Council
No. prev. doc.:	10344/09 SAN 154 SOC 371 MI 229 CODEC 777
Subject:	Council meeting (**Employment, Social Policy, Health and Consumer Affairs**) on 8 and 9 June 2009 Proposal for a Directive of the European Parliament and of the Council on the application of **patients' rights in cross-border healthcare** (LA) - *Progress report / Policy debate* [Public deliberation, pursuant to Article 8(1) CRP]

1. Following discussions at its meeting on 3 June 2009, the Permanent Representatives Committee agreed to submit the annexed progress report on the above-mentioned subject to the Council.

2. The Council (EPSCO) is invited to take note of this progress report and to hold a policy debate around the questions set out in the note number 10027/09 at its forthcoming session on 9 June 2009.

ANNEX

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE

PROGRESS REPORT

I. INTRODUCTION

1. On 2 July 2008 the Commission presented a proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.[1] This proposal comprises three pillars: ensuring safe, high-quality healthcare for all patients; helping patients make use of their rights to cross-border healthcare; and promoting cooperation between health systems. The purpose of the second pillar, in particular, was to codify the case law of the Court of Justice of the European Communities (ECJ) because, in its rulings, the ECJ repeatedly applied the free movement principles guaranteed by the EC Treaty (TEC) to health services and addressed the issue of reimbursement for cross-border healthcare in order to facilitate the right to provide and obtain health services.

2. Under the FR Presidency, Chapters I to III of the proposal were examined at the Council's Public Health Working Party (WP), which resulted in a compromise text submitted by the FR Presidency on the respective chapters[2].

3. A progress report was presented to the EPSCO Council at its meeting in December 2008.[3] A policy debate was held and several substantial questions were discussed in order to provide orientation for the continuation of the work within the WP under the incoming CZ Presidency.

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1 11307/08 SAN 136 SOC 389 MI 234 CODEC 904 (COM(2008) 414 final)
2 15655/08 SAN 261 SOC 687 MI 439 CODEC 1539
3 16514/08 SAN 302 SOC 760 MI 505 CODEC 1736

4. The Council took note of the progress achieved so far, confirmed that the orientations suggested by the FR Presidency provided a good basis for future discussions and invited the incoming CZ Presidency to build on the progress made and to overcome the remaining substantive reservations.

WORK DONE WITHIN THE COUNCIL BODIES

5. Under the CZ Presidency, eight full-day meetings were devoted to the proposal. Articles 10 and 12 of Chapter III, Chapters IV and V and the relevant recitals were discussed and subsequently, the CZ Presidency drafted a compromise proposal covering all articles and corresponding recitals of the Commission's proposal[4]. This text was presented on 18 March 2009 to the WP for examination. It was based on the FR Presidency compromise text as well as on the Commission's proposal as regards the remaining provisions.

6. Initial reactions to this compromise proposal were overall positive (the new structure of the text, clarifying responsibilities of Member States, and consistent use of definitions). While the majority of delegations welcomed the main orientations proposed by the Presidency, many also noted that further amendments would be needed and that some crucial issues remained outstanding, which are set out further in this document.

7. In order to progress with the discussions in the WP, the Presidency asked COREPER for guidance. On 6 May 2009, COREPER provided indications on the way forward on the following issues:

Codification of the ECJ case-law

- incorporation of healthcare providers into the scope of the Directive: More than half of the MS expressed their preference for limitation to providers contracted to the local public health insurance or otherwise defined public system only. However, the remaining MS supported the approach of the Presidency, i.e. that the Directive should incorporate all healthcare regardless of the status of the healthcare provider.

[4] 7379/09 SAN 49 SOC 173 MI 100 CODEC 329

- exclusion of certain types of care from the scope of the Directive: the discussion focused mainly on the issue of long term care. A significant number of MS requested an explicit exclusion of long term care from the scope of the Directive. Other examples of care that in the opinion of some MS should be excluded: organ transplantations and prevention programmes (such as vaccination).

- mutual recognition of prescriptions issued in another MS: MS generally endorsed this principle. However, there were still concerns about its implementation in practice and ways to make the principle workable. Some MS supported the use of the comitology procedure, some wished to let MS tackle this task themselves, and some expressed no preference.

Chapter IV on Cooperation on healthcare

- MS agreed that cooperation in the field of healthcare is needed and expressed their support for it. As in the previous point, however, their opinions varied as regards its form of realisation. During the discussion, there was no explicit call for the deletion of Chapter IV as a whole. However, over half of MS were opposed to the use of comitology procedures and some MS suggested that alternative mechanisms for promoting cooperation should be explored. About half of the MS indicated a willingness to consider some form of comitology, yet, at the same time, almost all of these MS agreed that measures taken via comitology should not be binding and the competences of MS always needed to be observed.

In the end, the COREPER referred the text back to the WP for further discussion.

8. On the basis of the discussion within the WP and COREPER, taking into account the opinion of the Council Legal Service on the legal basis of the proposal[5], which analysed the Presidency March compromise text, the Presidency revised its compromise proposal and on 14 May 2009 submitted to the WP its second version[6]. This text, however, aimed mainly at reflecting the state-of-play of the discussions, incorporating a significant number of comments made by delegations to the March compromise and noting the remaining reservations to be set out in footnotes**.** Due to the lack of time, the WP did not examine this revised compromise in detail, therefore all delegations have a general reserve on the entire Presidency compromise text; DK, SI, UK, RO and MT have a parliamentary scrutiny reserve.

9. The Commission has a general reserve on the entire Presidency compromise text. In particular it has major concerns with regard to the approach on quality and safety as provided for in Article 5; the approach on prior authorisation which in the Commission's view does not reflect the case law, including the definition of care that can be subject to prior authorisation, which has been significantly broadened; the articulation of what is said on prior authorisation under the Directive with the prior authorisation provisions under the Regulation 883/04; and the weakening of the cooperation provisions. The Commission draws the attention of the Council to their view that any exclusion of private healthcare providers has to be based on grounds directly related to quality or safety of care.

10. Work on the Commission's proposal for the Directive was carried out in parallel in the European Parliament and on 23 April 2009 the European Parliament voted on its resolution on the proposal in the first reading, approving 122 amendments to the original Commission's proposal.[7] These, however, have not been scrutinised by the WP yet.

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5 9431/09 JUR 207 SAN 97 SOC 300 MI 186 CODEC 675
6 9674/09 SAN 111 SOC 317 MI 198 CODEC 706
7 8903/09 CODEC 585 SAN 79 SOC 263 MI 163

II. KEY ASPECTS OF THE PRESIDENCY COMPROMISE AS SUBMITTED TO THE DELEGATIONS

11. In general, the Presidency compromise text suggested restructuring of the Commission's proposal and tried to find clearer wording and link between definitions and several other key terms, which are, subsequently, used systematically and precisely within the entire document. The WP welcomed this approach and general orientation put forward by Presidency. Where MS have signalled so far specific reserves, they are indicated in document Nr. 10231/09.

12. Aim of the Directive

The majority of MS supported the revised wording of the aim of the Directive. Nevertheless, the coherence with other provisions will be checked again by the time the text is finalised.

13. Scope of the Directive

The majority of MS agreed on the content of the relevant provision, however, potential problems remain, like exemptions from the scope as regards contracted and non contracted providers, long-term care and organ transplants (see also point 8).

Some MS have stated that not to cover certain types of providers (namely those not contracted to the public health system) is of great importance to them; in the view of some other MS an exclusion of such providers would not be in compliance with the provisions of TEC. The revised compromise in its recital does not propose blanket exclusion, but provides MS with the possibility to take measures in individual cases, where they could be justified with regard to TEC, so that the quality and safety of healthcare is not threatened. Whilst some MS have welcomed this approach, others have noted that this does not answer their concerns in particular regarding the potential impact on the sustainability of the health systems and on Member States' competences to organise these systems.

Concerning long-term care, as explained in the respective recital of the revised compromise, the Directive does not apply to the social part of long term care and to the services whose primary purpose is to support people in need of assistance in carrying out routine, everyday tasks, simply because it does not cover social services at all. On the other hand, there still remains a number of MS requesting an explicit exclusion of long term care as such from the scope of the Directive. Finally, there is still no common definition and understanding of the concept of long term care. Besides it was pointed out that, even with the exclusion of long-term care services as such from the Directive, the relevant provisions of TEC still apply directly. The revised compromise provides for certain limitations such as those related to management of inflow of patients as regards organ shortage. However, some MS requested explicit exclusion of organ transplantation and prevention programmes.

14. **Article 3** providing a list of Community provisions related to the Directive was amended according to the comments made by MS. It was agreed, however, that it needs to be examined again after complete finalisation of the text.

15. **Definitions**

The majority of the MS agreed upon most of the definitions provided in Article 4, though reservations still remain particularly with regard to the definition of "MS of affiliation" and "insured person". A certain level of agreement has been achieved on the definition of "healthcare", further discussion, however, is needed especially with regard to the coherency of the definition as used in the rest of the text of the Directive. A new definition of medical records was added.

16. **Responsibilities of Member States With Regard To Cross-Border Healthcare (Chapter II)**

In order to clarify the structure of the Commission's proposal, Chapter II was reformulated to include all provisions on responsibilities of the MS in general, i.e. both MS of treatment and MS of affiliation (originally Articles 5, 10 and 12), and renamed accordingly. One of the related amendments was the transfer of all provisions on access to medical records in both the MS of affiliation and MS of treatment to this Chapter.

In general, the MS supported this new approach as well as the detailed specification of responsibilities of MS of treatment and MS of affiliation.

As regards responsibilities of the MS of treatment, the Presidency followed the orientation given by the FR Presidency in the December 2008 progress report. Here the Presidency attempted at tackling the issue of management of patient inflows to avoid seriously undermining, or to the likelihood of seriously undermining, accessibility of healthcare and the financial balance of the MS of treatment's statutory social security or public health system. Patients from other MS shall enjoy equal treatment with nationals of the MS of treatment, yet, as inflows of patients may create a demand exceeding the existing capacities, the MS will, in exceptional cases, retain the possibility to remedy the situation on the ground of public health, in accordance with the TEC, although without prejudice to obligations under Regulation no (EC) 883/2004. This solution appeared to be generally acceptable to the MS, although a number of reservations remain, particularly on the balance between the text and recitals.

The description of responsibilities of the MS of affiliation now includes the explicit reiteration of responsibilities related to reimbursement and application of prior authorisation.

As regards national contact points (NCPs), the revised proposal now specifies, by request of the MS, that MS should provide patients only with information directly related to their own national systems and not the systems of other MS, so that its relevance and regular updating can be ensured; this is also important for bearing responsibility for information that has been provided. Consequently, separate listing of information responsibilities of the MS of treatment and MS of affiliation was proposed. The original concept of using comitology procedures to establish an NCP network was not supported and therefore, the related comitology provision was deleted. Also provisions on providing information and help as regards settling cross-border legal disputes, and particularly out-of-court schemes, were not considered appropriate and therefore deleted.

A minimum number of reservations remain with issues described in the last two paragraphs.

17. Reimbursement of costs of cross-border healthcare (Chapter III)

In general, the wording of Chapter III was received positively. Yet, several MS keep their reservations concerning practical implementation, prior authorisation, relation to Regulation (EC) no. 883/2004 and a definition of "reimbursement/assumption of costs" was requested. With respect to the restructuring mentioned in point 12, Chapter III of the revised compromise includes only articles related to reimbursement of costs of cross-border healthcare. Although not explicitly mentioned in the text, provisions of this Chapter relate also to reimbursement of costs incurred by an insured person for medicinal products or medical devices which also fall under the present definition of healthcare.

In comparison with the Commission's proposal, no substantial changes were made to the general principles mentioned in Article 8 of the revised compromise concerning patients' entitlements to receive reimbursement of costs of cross-border healthcare.

However, on the basis of orientations provided by the FR Presidency in the December 2008 progress report, the revised compromise further develops arrangements for controlling patient outflows in such a way as to remain compatible with the principles of free movement and non-discrimination.

For the Member States of affiliation to determine, in its legislation, which healthcare may be subject to prior authorisation, specific conditions necessary for introduction of system of prior authorisation (e.g. overnight accommodation, use of highly specialised and cost intensive medical infrastructure or medical equipment, treatments presenting a particular risk for the patient or the population) as well as concrete procedures regarding requests for granting a prior authorisation were further developed. When dealing with a request for prior authorisation by an insured person, the MS of affiliation shall take into account urgency and all the individual circumstances further specified in recitals. On the basis of its findings, it shall check whether the conditions of Regulation (EC) no. 883/2004 are met, and if that is the case, the prior authorisation shall be granted pursuant to that Regulation unless otherwise requested by the insured person (although some MS do not support the possibility to give to the insured person the choice).

In the same context, the issue of gatekeeping was also tackled in the revised compromise. The MS may maintain the same criteria of eligibility and regulatory and administrative formalities for reimbursement of costs in relation to patients seeking health in another MS, whether set at a local, regional or national level, as they would impose if this healthcare was provided in its territory, including any assessment by a health professional or healthcare administrator providing services for the statutory social security or public health system of the Member State of affiliation. This solution received a general support among the MS. However, some of them underlined that gatekeepers shall be affiliated to the healthcare system of patient's MS of affiliation.

The revised proposal also aims at limiting the risk of "double gatekeeping". Several delegations, however, still keep their reservations on the wording of the respective provision in recitals, as they are analysing how it could work in practice.

18. Cooperation on healthcare (Chapter IV)

With respect to the discussion within the WP and the COREPER, and taking into account the opinion of the Council Legal Service on the legal basis of the March Presidency proposal (see footnote 5), the Presidency proposed to amend the wording of the respective articles in Chapter IV with the aim that they comply with the Community competences and *provide incentives* for voluntary cooperation between the MS, without affecting their national competences for organising their health systems.

The use of the comitology procedure in the Commission's proposal was strongly opposed, particularly in articles concerning cooperation on development of European reference networks (ERNs), eHealth and health technology assessment. It was stressed that the proposal has to be proportionate in terms of expected costs and scope in relation to the number of expected patients who will benefit from the use of cross-border healthcare. Also, according to several MS, these fields of cooperation might not be ready yet for a joint approach. Therefore, respective comitology measures were adapted accordingly and non-binding guidelines were proposed.

In spite of the amendments made, over half of MS still doubt the use of comitology to be the only possible solution for fulfilling the aim of Chapter IV. These doubts are related to the yet unfinished debate about the primary objective of provisions in this Chapter: whether they provide for cooperation in the context of cross-border healthcare or whether they foster cooperation in the area of quality and safety of healthcare independently of any cross-border element. There are some MS who expressed fundamental doubts about the concept of non-binding comitology. Nevertheless, there is a number of MS that expressed their support for the approach given by the revised compromise.

Despite only a small number of reservations on the actual provision concerning the principle of mutual recognition of prescriptions, its substance needs to be further discussed, in particular as regards its implementation in practice and reimbursement procedures. Following the orientations provided by the FR Presidency, the scope of the article was extended to medical devices.

The Commission's proposal on Chapter IV also contained a provision on data collection for statistical and monitoring purposes (Article18). As the majority of MS agreed that this would be duplication of activities falling under Regulation (EC) No. 1338/2008 on Community statistics on public health and health and safety at work[8], this article was deleted.

19. Reports

In addition to the Commission's original provision on drawing up a report on the operation of this Directive, the respective article of the revised compromise also specifies what kind of information this report should include (patient flows, financial dimension of patient mobility, functioning of NCPs and ERNs) and, at the same time, that the MS should provide the Commission with all the necessary assistance and information for carrying out the assessment and preparing the reports. No reservations were raised against this article or its wording.

[8] OJ L 354, 31. 12. 2008, p.70.

20. Transposition

As a significant majority of MS expressed their concerns about the original one-year period for transposition of such a complex legislative proposal, the transposition period was extended to three years.

III. ISSUES FOR FURTHER DISCUSSION

21. In addition to the above, the Presidency has identified a number of substantive issues which still need to be discussed in depth by the WP, in particular:

(i) Clarification of the actual content of key terms used

One of the difficulties identified during the discussions was the difference in understanding of several key terms related to the different organisation of health systems across Europe. On the one hand, there are MS with a system of health insurance (either in benefits in a kind system or reimbursement based system); on the other hand, there are MS which have introduced a national health system (NHS).

In its March compromise, the Presidency attempted at creating a joint definition of "assumption of costs" taking into account the specifics of various health systems applied in the MS. However, the discussion at the WP showed that this term is understood differently and, therefore, in the end, the Presidency returned to the use of both terms "reimbursement" and "assumption of costs" in the revised compromise text, with respect to the content of each individual provision.

For the same reason, i.e. to facilitate further discussion, more clarification is needed – or a better term, suitable for all existing systems, needs to be found – on the content of the terms "statutory social security/ public health system" and "contracted" / "non-contracted" vs. "public" / "private" healthcare provider.

Besides the above, i.e. irrespective of the particular nature of a health system, a disagreement remains on "long-term care", or, to be more specific, what types of care are understood under this term. The definition of "healthcare" needs to be finalised.

(ii) scope of the Directive and exclusion of certain types of care

Requests of the MS to exclude certain types of care, as described above in points 7 and 13, need to be discussed further, particularly in the light of subsequent possible impacts of such specific exclusions;

(iii) reasons for refusal to grant a prior authorisation and provisions concerning the relation to Regulation (EC) No. 883/2004, particularly, its implementation in practice;

(iv) reimbursement of prescriptions following the application of the principle of mutual recognition of prescriptions issued in another MS;

(v) provisions on cooperation on healthcare

The aim of provisions contained in Chapter IV needs to be determined, also in relation to the legal basis of the proposal. The use of comitology and other possible alternatives which could fulfil this aim should be discussed as well;

(vi) the legal basis

The legal basis of the proposal should be debated in depth, scrutinised and adjusted, depending on the final wording of the Directive, taking into account the fact that Article 152 of TEC was not proposed by the Commission as legal basis of the Directive.

22. With respect to the Resolution of the European Parliament of 23 April 2009 on the proposal, the amendments proposed by the European Parliament need to be discussed.

23. The Commission was also requested by MS to clarify and further explain the following issues:

- relation between the proposal on a Directive of the application of patients' rights in cross-border healthcare and the proposal on a Directive on standards of quality and safety of human organs intended for transplantation[9], in particular as regards the relation between organ donation/transplantation and organ allocation;

- detailed explanation of the reasoning behind the proposed use of comitology for respective articles in Chapter IV, description of expected outcomes from comitology and other possible alternatives to the comitology procedure, which could help achieve the Commission's stated objectives, in particular that of ensuring sustainable funding;

- details on implementation in practice of the principle of mutual recognition of prescriptions issued in another MS, in order to understand better the impacts of Article 12.

IV. CONCLUSIONS

The Council takes note of the progress achieved so far, confirms that the revised compromise, as described above and reflected in document no. 10231/09, where remaining reservations presented so far are set out in footnotes, provide a good basis for future discussions, and invites the incoming Presidency to build on the progress made and examine all outstanding issues, and the recitals of the Commission's proposal which have not been examined so far.

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[9] 16521/08 SAN 306 CODEC 1691 (COM(2008) 818 final)