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**NOTE**

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| from : | General Secretariat of the Council |
| to : | Working Party on Competitiveness and Growth |
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| Subject : | Proposal for a Directive of the European Parliament and of the Council on services in the internal market<br>- Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs incurred in another Member State with a particular emphasis on the relationship with Regulation N° 1408/71 |

Delegations will find in the Annex to this Note an explanatory note from the Commission Services on the provisions of the proposal for a Directive on services in the internal market relating to the assumption of healthcare costs incurred in another Member State with a particular emphasis on the relationship with Regulation N° 1408/71.

Article 23 codifies and complements the well-established case law of the Court relating to the free movement of services: judgements *Kohll* and *Decker (1998), Smits and Peerbooms* and *Vanbraekel (2001), Müller-Fauré/vanRiet*, *Inizan (2003)* and *Leichtle (2004)*[1]. This jurisprudence is reflected in Article 23 and ensures that patients can take advantage of the benefits of the Internal Market when it comes to accessing the treatments required by their state of health. Article 23 seeks to ensure, that subject to the conditions set out by the Court, patients retain their rights to assumption of costs when the healthcare is provided in another Member State.

This jurisprudence reflected in Article 23 does not call into question the competence of Member States for organising and financing their social security systems: it is up to each Member State to determine the rules governing the rights or duties under their social security system, the healthcare cover and the conditions under which benefits provided by their sickness insurance scheme are granted.

Article 23 is complementary to Regulation n° 1408/71 on the coordination of social security systems, which deals with various scenarios of assumption of costs for cross-border care. In comparison with Regulation n°1408/71, the Services Proposal only deals with a limited number of cross-border healthcare situations.

Article 23 is also fully coherent with the work undertaken within the High Level Group on Health Services and Medical Care which aims at facilitating cooperation among Member States on health services and medical care to contribute to ensuring a high level of health protection for citizens throughout the Union.

## I. Why does the Proposal address the issue of the assumption of health care costs?

The objective of dealing with this issue in the Proposal is threefold: strengthening the rights of patients with respect to the freedom to receive, under certain conditions, health care in another Member State; increasing legal certainty and transparency for patients and for Member States and their social security systems by clarifying a certain number of issues which to date are not sufficiently clear in the jurisprudence of the Court; and giving the opportunity to the European legislator to deal with practical issues left open by the jurisprudence.

With respect to the first objective, Article 23 is an essential component of a section in the Proposal dedicated to strengthening the rights of European citizens as recipients of services. To bring the EU closer to European citizens, it is vital to ensure that they can fully benefit from a better functioning Internal Market for services. The Proposal therefore addresses a number of issues of concern to individuals as recipients of services and aims, for example, to remove discrimination, increase information on cross-border services and improve assistance for recipients of services in case of disputes.

The assumption of costs for medical treatment received in another Member State is among the issues of major concern for European citizens, as is reflected in a steadily increasing number of,

[1] Kohll Judgment, Case C-155/96 of 28 April 1998, ECR 1998 p. I-1931, Decker Judgment, Case C-120/95 of 28 April 1998, ECR 1998 p. I-1831, Smits and Peerbooms Judgment, Case C-157/99 of 12 July 2001, ECR 2001 p. I-05473, Vanbraekel Judgment, Case C-368/98 of 12 July 2001, ECR 2001 p. I-05363; Müller-Fauré/van Riet Judgement, Case C-385/99 of 13 May 2003, ECR 2003 p. I-04509; Inizan Judgement, Case C-56/01 of 23 October 2003 (not yet published); Leichtle Judgement, Case C-8/02 of 18 March 2004 (not yet published);

Questions and Petitions from the European Parliament and cases brought before national Courts[1]. As the Commission services pointed out in a Staff Working Paper of 28 July 2003[2], very few Member States have actually taken steps to implement the Court's jurisprudence. In consequence, the situation faced by patients varies depending on their Member State of affiliation; very often they are still encountering unjustified or disproportionate obstacles when it comes to exercising their right to reimbursement as recognised by the Court.

The Commission, as guardian of the Treaty, must deal with patients' complaints that Member States are not fully complying with the jurisprudence. However, pursuing complaints on a case-by-case basis and bringing infringement procedures against individual Member States is not an efficient way to ensure that all citizens throughout the European Union can benefit from their Internal Market rights.

With respect to the second objective of the Proposal, i.e. to provide greater legal certainty, it should be noted that the High Level Reflection Process on Patient Mobility and Healthcare Developments in the EU emphasised the need for greater legal certainty concerning the right of patients to reimbursement for medical treatment in another Member State. This was also emphasised by the EPSCO Council on 1- 2 June 2004.

Thus far, certain important questions such as the precise distinction between hospital care and non-hospital care - including in cases when a treatment is considered as hospital care in some Member States but non-hospital care in other Member States - have not been clarified in the jurisprudence. Other issues, such as the level of assumption of costs, which in principle have been addressed in the jurisprudence, nevertheless raise further questions.

Last but not least, by addressing the issue of assumption of costs, the Proposal gives the European legislator the opportunity to deal with certain practical issues for their social security systems. This will result in greater legal certainty than would be the case if these questions were left to further development of jurisprudence by the Court.

## II. What are the main elements of the jurisprudence on which the Proposal is based?

As indicated above, the Proposal is based on well-established case law of the Court relating to the free movement of services under Article 49 EC Treaty.

In brief, the Court has confirmed that:

1. health services including hospital services are services within the meaning of the Treaty: *"It is settled case-law that medical activities fall within the scope of Article 60 of the Treaty, there being no need to distinguish in that regard between care provided in a hospital environment and care provided outside such an environment*" (*Smits and Peerbooms*, para 53);

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[1] For instance, in the United Kingdom, High Court of Justice, Queens Bench Division, Administrative Court, Judgement of 1.10.03 between Yvonne Watts and Bedford Primary Care Trust and Secretary of State for Health; in Sweden, Regjeringsrätten (the Swedish Supreme Administrative Court), the Supreme Administrative Court delivered three judgements on 30.01.04 in *Jelinek* case (Case 5595–99), in the *Stigell* case (case 6790-01) and in the *Wistrand* case; in France, Cour de Cassation, decision n° 758 of 25.05.04; in Germany, two cases are pending: Eva-Maria Weller v. Deutsche Angestellten-Krankenkasse in Sozialgericht Augsburg; and Karin Bautz v. AOK Baden Wurttemberg in the Bundessozialgericht Stuttgart (this case is referred to the European Court of Justice under the number C-454/02-1).

[2] SEC(2003)900

2. health services are services within the meaning of the Treaty irrespective of the way Member States organise and finance their social security systems: "*a medical service does not cease to be a provision of services because it is paid for by a national health service or by a system providing benefits in kind. (...) there is no need, from the perspective of the freedom to provide services, to draw a distinction by reference to whether the patient pays the costs incurred and subsequently applies for reimbursement thereof or whatever the sickness fund or the national budget pays the provider directly*". (*Müller-Fauré/van Riet*, para 103)

3. the requirement of an authorisation for the reimbursement of medical costs incurred in another Member State is an obstacle to the free provision of services for both patients and providers of medical services: *"Consequently, such rules deter insured persons from approaching providers of medical services established in another Member State and constitute, for them and their patients, a barrier to the freedom to provide services" (Kohll*, para 34 and 35*)*.

4. an authorisation requirement may be justified for hospital services but not for non-hospital services

   – as regards hospital services, the Court indicated that in view of the necessary planning in order to ensure sufficient and permanent access to a balanced range of high quality hospital treatment as well to control costs and prevent as far as possible any wastage of financial, technical and human resources, *"a requirement that the assumption of costs, under a national social security system, of hospital treatment provided in a Member State other than that of affiliation must be subject to prior authorisation appears to be a measure which is both necessary and reasonable."* (*Smits and Peerbooms,* para 76 to 80*; Müller-Fauré/van Riet* para 76 to 92*)*

   – by contrast, as regards non-hospital services, the Court indicated that such a requirement is not justified in so far as the reimbursement of costs for non-hospital care, made within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation, would not seriously affect the financial balance of social security systems. (*Müller-Fauré/van Riet,* para 93 to 98)

**III. What is the value added of the Directive with respect to the jurisprudence?**

1. The Proposal codifies the jurisprudence as regards the distinction between non-hospital and hospital care. It confirms that Member States may maintain a prior authorisation requirement for the assumption of costs of hospital care and demands that Member States remove such a requirement for non-hospital care. At the same time, the Proposal incorporates all the conditions, as regards the reimbursement of non-hospital care and hospital care respectively, which the Court accepted as justified in order not to disrupt the financial equilibrium of social security budgets and to ensure a high level of public health.

2. The Proposal complements the jurisprudence in providing a definition of hospital care in order to provide greater legal certainty. The Court in *Müller-Fauré/van Riet* para 75 admitted that the distinction between the two categories of care is not easy to draw and provided some guidelines to facilitate this. Building on this point, Article 4(10) proposes objective criteria to help determine the type of care for which the requirement of a prior authorisation can be justified.

3. The Court made clear that the reasons of general interest justifying an authorisation requirement are intrinsically linked to the need to plan healthcare provided within a hospital infrastructure; the criterion is not therefore that the treatment is provided within a hospital but that it cannot be provided outside this environment. The clearest criterion for assessing this principle is that the healthcare concerned requires overnight accommodation. Some Member States have questioned this definition. They feel that the need for accommodation is not the only reason for which certain types of medical treatment are reserved to hospitals. This matter could be explored further with Member States with a view to fine tuning the definition.

   Questions have, in particular, arisen as regards how to determine whether the medical care concerned is hospital or non-hospital care within the meaning of the Proposed Directive in the case where one Member State provides the care in a hospital and the other does not. In the light of the case law of the Court, the Member State of reference is the Member State of affiliation of the patient as it is this Member State which has got responsibility for the planning of hospital services on its territory. In consequence, an authorisation may be required for the assumption of costs of what is considered to be hospital care in his Member State of affiliation, even though this treatment is considered non-hospital care in the Member State where the treatment is obtained. This could be clarified in the text of the definition of hospital care in Article 4(10). This definition is without prejudice to the competence of Member States to determine on public health grounds, which treatments are to be provided within or outside a hospital infrastructure. It has no other meaning than allowing a proper application of the distinction made in Article 23 between hospital and non-hospital care. This could be clarified in moving the definition now appearing under Article 4(10) to Article 23.

4. The Proposal provides that the transparency requirements applying to all authorisation schemes (as set out in Articles 9, 10, 11 and 12 of the Directive), apply equally to authorisation schemes which Member States may have concerning the assumption of healthcare costs. The Court made clear in *Smits and Peerbooms* (para 90), *Müller-Fauré/van Riet* (para 85) and *Inizan* (para 48 and 57) that, in order to be justified, an authorisation scheme must be based on transparent criteria in such a way as to circumscribe the exercise of the national authorities' discretion.

## IV. What is the relationship between Regulation 1408/71 and the Proposed Directive?

Regulation 1408/71 organises the coordination of national social security legal schemes in order to ensure that the application of the different national legislation does not adversely affect persons exercising their right to free movement within the European Union. It deals with situations where citizens, for professional or personal reasons, are staying temporarily in a Member State other than the Member State in which they are affiliated to social security system and they happen to need healthcare during their stay. By virtue of this Regulation such treatment will be delivered on the same basis as for persons insured in that country and the costs will be reimbursed according to the tariffs in force in the Member state where the care was received. Regulation 1408/71 also deals with patient mobility, where the purpose of the travel is to obtain medical treatment. Regulation 1408/71 provides in this case for authorisation to be given by the social security institution to the patient in order to get the assumption of costs of the treatment on the basis of the tariff in force in the Member state where the treatment is provided.

1. Regulation 1408/71 applies in the case of hospital care for which an authorisation is necessary or, in the case of non-hospital care, when a patient requests an authorisation in order to benefit from the mechanisms established by this Regulation. It has to be recalled that, even though a patient does not need an authorisation for the reimbursement of costs of non-hospital care, he nevertheless may ask for an authorisation in order to benefit from the provisions of the Regulation, in particular as regards the level of assumption of costs provided by the Regulation, which may be higher than the level of assumption of costs without authorisation. This means that in comparison with Regulation 1408/71, the proposed services Directive deals only with cases where a patient claims reimbursement without authorisation for non-hospital care obtained in another Member State. This relationship with Regulation 1408/71 could be explained in a recital.

2. If a patient asks for an authorisation (i.e. either for hospital care, where an authorisation is necessary, or for non-hospital care, where a patient wishes to obtain one in order to benefit from Regulation 1408/71) the Regulation establishes the conditions under which an authorisation to undergo medical treatment in another Member State cannot be refused. In that respect, Article 22 (2) of Regulation 1408/71, provides that an authorisation cannot be refused when the two following conditions are met: the treatment would be available under the legislation of the Member State on whose territory the insured person resides; and the treatment which the patient intends to undergo in a Member State other than that in which he is affiliated could not be given to him within the time normally necessary for obtaining the treatment in question in the Member State of affiliation, taking account of his current state of health and the probable course of the disease. In *Smits and Peerbooms* (para. 103 et 104) and *Müller-Fauré/vanRiet* (para. 90 to 92), the Court has indicated that this second condition should be interpreted exclusively on medical grounds and not economic ones. Regulation 1408/71, as simplified and modernised (as Regulation 883/2004), has made this last condition clearer in specifying in its Article 20(2) that a strictly medical criterion has to be applied in order to assess whether the treatment is available without undue delay in the country of affiliation of the patient. In that respect, Article 20(2) implements the jurisprudence of the Court. The same two substantive conditions under which an authorisation may not be refused have been incorporated in Article 23(2) of the Proposed Directive in order to ensure full coherence with the Regulation. This relationship could be clarified by a cross-reference to the relevant provision of Regulation 1408/71 within Article 23(2).

## V. What is the level of assumption of costs under Article 23 and Regulation 1408/71?

The two following scenarios have to be distinguished:

1. **for non-hospital care when a patient receives treatment in another Member State without authorisation**: in that case, in order to avoid any significant impact on the social security budget of the Member State of affiliation of the patient, reimbursement of the costs should be made in accordance with the tariff applicable for the same treatment in the Member State of affiliation of the patient and within the limit of the costs assumed for the same treatment in the Member State of affiliation of the patient. (*Kohll*, para 42, *Müller-Fauré/van Riet para 98 and 106*). Moreover, as emphasised by the Court, apart from the issue of the level of reimbursement as such, reimbursement of medical costs without authorisation can only be required within the limit of the cover provided by the health system of the Member State of

affiliation of the patient. This means that the treatment in question must appear amongst the benefits provided for by the Member State of affiliation of the patient and the conditions for the granting of this treatment in this Member State must be fulfilled. The reimbursement of healthcare costs incurred in another Member State without authorisation should not impose any significant financial burden on the social security budget of the Member State of affiliation of the patient. Furthermore, in para 107 of *Müller-Fauré/van Riet,* the Court offers Member States operating a system of benefits-in-kind the possibility of fixing the amounts of reimbursement which patients who have received care in another Member State can claim, provided that those amounts are based on objective, non-discriminatory and transparent criteria. It should also be noted that Article 23 does not oblige Member States to cover travel and accommodation costs. This issue is dealt with at national level. Those points could be clarified in a recital.

2. **for hospital care, when a patient has been granted an authorisation**[1]. That situation falls within Regulation 1408/71, which provides that reimbursement is made on the basis of the legislation of the Member State where the treatment is obtained. This applies also for non-hospital care when a patient has asked for and has been granted an authorisation. In those cases, the amount reimbursable under the legislation of the Member State where the treatment is received may be more beneficial than that reimbursable under the legislation of the Member State of affiliation of the patient. It may also be the case, as in *Vanbraekel,* that this amount is lower. In the latter case, the Court indicated in *Vanbraekel* (para 53 in fine) that Article 49 of the Treaty requires the Member State of affiliation to pay the patient an additional reimbursement covering the difference with the amount he would have been entitled to if the hospital care had been provided in their own Member State. The Court made clear

3. (*Vanbraekel* para 51 and 52) that such an additional reimbursement does not impose an additional financial burden on the social security system of the Member State of affiliation of the patient as it would have had to assume the same amount if the treatment had been provided on its territory. In consequence, this is not likely to jeopardise the maintenance in this Member State of a balanced medical and hospital service open to all or the maintenance of treatment capacity or medical competence on national territory. It is worth noting that, in any event, the assumption of costs is limited to the costs actually incurred by the patient and that the patient can never claim an amount which would be higher than the actual costs of treatment. This could be further explained in a recital.

## VI. What are the socio-economic implications of patient mobility?

The Working Paper of 28 July 2004[2] included socio-economic data related to patient mobility. Judging from the figures provided by the Member States, patient mobility is currently negligible. The majority of medical treatments undergone in another Member State are covered by the authorisation forms provided for by Regulation 1408/71 and, in the case of treatment voluntarily undergone in another Member State, the E-112[3] form. The largest number of patients from other EU Member States treated in a single Member State under the E-112 form was 14,061, in 2000 and cost € 25,907,697. There are generally few requests for authorisation for treatment in another Member State, with only two countries receiving more than 10,000. In the Member States which

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1 It should be noted that this applies also when an authorisation has been refused and it is subsequently established that the refusal was unfounded (*Vanbraekel*, para 34)

2 See footnote 4

3 In the framework of regulation 1408/71, the so called E 112 is a form currently given by their sickness institution to persons in order to get the assumption of the cost of treatment obtained in another Member state according to the tariff of that Member State.

have modified their legislation in order to reimburse non-hospital care without prior authorisation and collect relevant data, the amounts mentioned were insignificant: in the country with the highest number of insured persons to benefit from non-hospital treatment abroad, 58,030 persons per year were concerned - equivalent to just over 1% of the total number of persons insured. This Member State spends €3,445,470 - or 0.03% of its social security budget - on such care.

Although patients are becoming more aware of healthcare possibilities in other Member States, mobility is likely to remain limited. There may be some specific situations where mobility may be useful for both patients and for systems as a whole in providing care more quickly, efficiently and effectively, but the overwhelming majority of care will continue to be provided within national systems

The Court in *Müller-Fauré/van Riet* (para 95) indicated various factors likely to limit patient's mobility: linguistic barriers, geographic distance, the cost of staying abroad and the lack of information about the kind of care provided. The Court emphasised that if emergencies are disregarded, the most obvious cases of patients travelling abroad are in border areas or where specific conditions are to be treated.

## VII. What is the relationship with the follow-up of the work of the High Level Reflection Group on Patient Mobility?

In addition to the legal framework set out by Regulation 1408/71 and the Proposed Directive, there is a need for strengthened cooperation between Member States to bring benefits to individual patients and to improve the effectiveness and efficiency of health systems overall. This need is increasingly recognised by Member States and by health sector stakeholders, but must be met while fully respecting the competence of Member States for the organisation and financing of their social security systems. Following the work carried out within the High Level Reflection Process on Patient Mobility and Healthcare Development in the EU, the Commission adopted in April 2004 a Communication setting out practical cooperation initiatives on patient mobility and healthcare, supported by a new High Level Group on Health Services and Medical Care.
This initiative complements the legislative initiatives for the assumption of healthcare costs by helping patients to have high-quality health care and helping health systems to improve their effectiveness and efficiency through greater cooperation at European level.

**VIII. Conclusion**

1. **The definition of hospital care in Article 4(10) could be reworded on the basis of discussions with Member States. In particular, it could be made clearer that the Member State of affiliation of the patient is to determine what is considered as hospital care regardless of whether this treatment is hospital care in the Member State where the treatment is obtained. It could also be made clearer, by moving the definition now appearing under Article 4(10) to Article 23, that the definition has no other meaning than allowing a proper application of the distinction made in Article 23 between hospital and non-hospital care.**
2. **It could be specified that Regulation 1408/71 will apply in cases where an authorisation is either necessary or asked for by patients. It could be made clearer that the Proposed Directive incorporates the conditions laid down by Regulation 1408/71 under which an authorisation cannot be refused. A cross-reference to this Regulation could be made in Article 23(2).**
3. **It could be made clearer in Article 23 (3) that a patient cannot make a profit when receiving treatment abroad and that his right to assumption of costs is always limited by the actual costs incurred.**
4. **It could be specified that Article 23 does not require Member States to reimburse travel and accommodation costs and that this issue is dealt with at national level.**
5. **The level of assumption of healthcare costs incurred in another Member State without authorisation could be further clarified. In particular,**
   a) **It could be explained that the extent of the sickness cover is entirely determined by the Member State of affiliation of the patient as regards the limits of the costs assumed, the medical treatments covered and the conditions for granting those medical treatments including the need to consult a generalist or a specialist prior to certain types of tests or treatments.**
   b) **It could be explained that Member States which do not operate a reimbursement system but a system of benefits-in-kind may establish reimbursement tariffs i.e. they may calculate the nominal cost of the treatment which they would normally assume for a certain treatment provided in kind and, on the basis of this, fix thresholds for reimbursement of costs for that treatment in another Member State.**