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The exclusion of health services from the Services Directive

European Parliament resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (2006/2275(INI))

The European Parliament,

- having regard to Articles 16, 49, 50, 95(1) and 152 of the EC Treaty,
- having regard to Article 35 of the Charter of Fundamental Rights of the European Union;
- having regard to the judgments of the Court of Justice of the European Communities ("Court of Justice") of 28 April 1998 in case C-120/95 Decker¹, of 28 April 1998 in case C-158/96 Kohl², of 12 July 2001 in case C-157/99 Geraets-Smits and Peerbooms³, of 12 July 2001 in case C-368/98 Vanbraekel⁴, of 25 February 2003 in case C-326/00 IKA⁵, of 13 May 2003 in case C-385/99 Müller-Fauré and van Riet⁶, of 23 October 2003 in case C-56/01 Inizan⁷, of 18 March 2004 in case C-8/02 Leichtle⁸ and of 16 May 2006 in case C-372/04 Watts⁹,
- having regard to Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market¹⁰, and in particular Article 2(2)(f) thereof and recitals 22 and 23 thereto,
- having regard to the Commission communication of 26 September 2006 entitled 'Consultation regarding Community action on health care services' (SEC(2006)1195/4),
- having regard to its resolution of 9 June 2005 on patient mobility and healthcare developments in the European Union¹¹,
- having regard to the Council Conclusions on Common values and principles in European Union Health Systems¹²,
- having regard to Article 152(5) of the Treaty, enshrining the subsidiarity principle with regard to health care, and having regard to Council Regulation (EEC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-

¹ [1998] ECR I-1831.

² [1998] ECR I-1931.

³ [2001] ECR I-5473.

⁴ [2001] ECR I-5363.

⁵ [2003] ECR I-1703.

⁶ [2003] ECR I-4509.

⁷ [2003] ECR I-12403.

⁸ [2004] ECR I-2641.

⁹ [2006] ECR I-4325.

¹⁰ OJ L 376, 27.12.2006, p. 36.

¹¹ OJ C 124 E, 25.5.2006, p. 543.

¹² OJ C 146, 22.6.2006, p. 1.

employed persons and to members of their families moving within the Community¹³ and to Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems¹⁴,

- having regard to Rule 45 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinions of the Committee on Employment and Social Affairs and the Committee on the Environment, Public Health and Food Safety (A6-0173/2007),
- A. whereas the Member States are responsible for organising, managing, delivering and financing health care systems, which are different in every Member State,
- B. whereas the Court of Justice has handed down a number of judgments, on issues such as access to health care and the settlement of criteria for prior authorisation procedures or for reimbursement of costs, which authorise EU citizens to move freely in order to find health care in another Member State,
- C. whereas, in its above mentioned Conclusions on Common values and principles in European Union Health Systems, the Council adopted a statement by the 25 health Ministers of the European Union about the common values and principles that underpin Europe's health systems,

Principles

1. Considers that cross-border mobility of patients and health professionals will increase in future, thus giving patients more choice; considers that, whatever their level of income or place of residence, all European citizens should be guaranteed equal and affordable access to health care in due time, in accordance with the principles of universality, quality, safety, continuity and solidarity, thus contributing to the social and territorial cohesion of the Union while ensuring the financial sustainability of national health care systems; considers that, in accordance with those principles, the mobility of patients and professionals may contribute to improving accessibility to and quality of health care;
2. Notes that the Member States do not sufficiently promote health care, as a result of which patients' rights are restricted;
3. Recalls that the Member States that have implemented the existing case law of the Court of Justice have not experienced any major increase in health care budgets as a result of patients' increased mobility;
4. Takes into account that Member States may only introduce a system of prior authorisation once it has been proven that cross-border movement of patients has a negative effect on the financial balance of the national health budget; urges Member States to take note of the possibility of making use of a test period during which no prior authorisation is required;
5. Stresses that patient mobility and professional mobility should not be an excuse for a

¹³ OJ L 149, 5.7.1971, p. 2.

¹⁴ OJ L 166, 30.4.2004, p.1.

Member State's failure to invest in its own health care system;

6. Stresses that access to cross-border care is required in order to ensure the free movement of citizens within the Community and that it helps to raise employment and competitiveness levels in Member States;
7. Stresses the need for cutting red tape connected with both the use and provision of cross-border health services;
8. Notes that, in order to cut the red tape relating to the use of cross-border health services, it is necessary to improve the electronic systems of patient identification and patient claims for reimbursement;
9. Invites the Commission to encourage the Member States to actively support the introduction of e-health and telemedicine;
10. Points out that, in accordance with the provisions of the Treaty, the Member States retain primary responsibility for providing efficient and high quality health care to their citizens; stresses that, to this end, they should be able to use the appropriate regulatory tools, at EU level as well as at multilateral and bilateral levels, to manage their national health care systems and health authorities and, in exercising that power, that they must always respect the provisions of the Treaties and the principle of subsidiarity;
11. Emphasises that Treaty rules, including the specific provisions on services of general economic interest, as well as the jurisprudence of the Court of Justice, apply to health services and stresses that health service providers are fully entitled to establish themselves and to provide services in any Member State, following national and EU rules; equally emphasises that patients are fully entitled to seek health care in any Member State;
12. Notes that, whilst health care systems are not a competence of the Community, issues relating to health care systems, such as access to medicines and treatments, patient information, and the movement of insurance companies and health professionals, have a cross-border character; notes that those issues need to be addressed by the Union;
13. Points out that in any case patients must be able to have equal access to appropriate treatment as close as possible to their home and in their own language; considers that Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems¹⁵ should be better applied, so that medicines are placed on the market more quickly, innovation in and safety of medicines is promoted and use of a centralised procedure for marketing authorisations is more strongly promoted;
14. Stresses that Member States should treat residents of another Member State on an equal basis with regard to access to health services, regardless of whether they are private or public patients;
15. Points out that patients should have access to information for which the health care provider has obtained international accreditation and that the accredited providers of

¹⁵ OJ L 40, 11.2.1989, p. 8.

health care should, regardless of where they are situated in the EU, ensure that health care is safe, based on measurable international indicators of quality;

16. Maintains that any policy initiative relating to health services should, as far as possible, be the subject of parliamentary law-making, rather than being pursued on an *ad hoc* basis through rulings of the Court of Justice;
17. Is of the opinion that patients' safety and rights are not ensured in the cross-border provision of health care at present and that legal uncertainty exists regarding reimbursement mechanisms, obligations for national authorities to share regulatory information, the duty of care for both the initial and the follow-up treatment and risk management provisions for private patients;

Definitions

18. Requests a clear definition of health services, so as to clarify and clearly demarcate the scope of application of future legislation in this field; requests a clarification of the elements of a health care system which are relevant in this context;
19. Notes that health care services pursue objectives comparable to other social services of general interest in the sense that they are based on the principle of solidarity, are often embedded in national social protection systems, are person-centred, ensure that citizens can benefit from their fundamental rights, ensure a high level of social protection, and strengthen social and territorial cohesion;
20. Is of the opinion that any Community action relating to health care services should be consistent with Community action relating to social services of general interest;
21. Requests that any further clarification of concepts used in the case law of the Court of Justice not alter the balance struck by the Court of Justice between Member States' prerogatives in the field of public health and the rights of the individual patient; in this respect recalls that, as regards the concept of 'reasonable waiting time', the Court of Justice has clearly indicated that it should be defined exclusively in the light of an assessment of each patient's medical situation and that economic considerations should not play any role in that assessment;
22. Requests further clarification of concepts such as "reasonable waiting times" and definitions of in-patient and out-patient treatment;
23. Points out that, as regards hospital services in another Member State, the procedure for granting authorisation must provide a guarantee for patients protecting them from arbitrary decisions taken by their national authorities; points out that, in order to facilitate the free movement of patients without prejudicing Member States' planning objectives, in the light of the case law of the Court of Justice, hospital treatment should be defined narrowly as treatment which can only be provided within hospital infrastructure and may not be provided, for example, in a practitioner's surgery or at the patient's home; points out, in particular, that any refusal to grant an authorisation must be open to challenge in judicial and quasi-judicial proceedings and that, for the purpose of assessing the medical situation of each patient, entirely objective and impartial advice from independent experts should be sought;

Patient mobility

24. Notes the great diversity in mobility and the different reasons for mobility among patients sent abroad by their national health system and among patients looking for medical treatment abroad of their own volition – tourists who fall ill, migrant workers, students, retired people and anyone living in a Member State other than their country of origin, or living in border regions – and stresses that those differences should be taken into account when formulating policy;
25. Stresses that it is desirable to distinguish between, on the one hand, cross-border health services, meaning those which are situated on either side of a border common to two Member States, in order to maintain and offer patients a high standard of access and care, and, on the other hand, international health services within the European Union, which offer health care for the treatment of rare or orphan diseases or diseases which require rare and very expensive technologies (care reference centres) or provide access to care which the Member State or state of residence cannot at present offer patients;
26. Calls on the Commission to provide annual statistics for each Member State on patient mobility and on the number of cases of reimbursements being refused, and the reasons therefor;
27. Whilst recognising that health care policy is primarily a competence of the Member States and emphasising the need for high-quality health care provision in the country of origin of the patient, nevertheless welcomes the Commission's initiative to launch a consultation on the best form of Community action with a view to improving the access of patients, within a reasonable timeframe, to a safe, high-quality and efficient framework for cross-border aspects of health care, and calls on the Commission to come up with concrete proposals to encourage and monitor progress in this area;
28. Notes that considerable numbers of patients from several Member States are not able to receive the necessary medical treatment in their own country within a reasonable timeframe because of the length of waiting lists and notes that these patients are, therefore, dependent on medical treatment abroad;

Improving information for patients

29. Notes how difficult it is for patients to obtain clear and precise information on health care, especially on cross-border health care, and the complexity of the procedures that have to be followed; notes that this difficulty, which is not created only by language barriers, potentially increases risks to patient safety;
30. Considers that the EU has an important role to play when it comes to improving patients' access to information on access to cross-border health care;
31. Notes that effective and transparent sharing and exchange of information on health is a vital requirement in ensuring consistency and maintaining a high quality of health care between health care services across different Member States;
32. Considers that it is important to give patients the right to choose health care in another Member State when this allows them to receive appropriate treatment, having been informed fully of both the terms and prior conditions for access to and the implications of

that choice, considers that, according to the above mentioned case law of the Court of Justice, prior authorisation for hospital care should be easily obtainable, dealt with immediately and evaluated on the basis of objective and neutral criteria; is of the opinion that refusal of authorisation should be justified on the basis of objective criteria which must be verified in a transparent way and that reasons should be given therefor, and that any refusal should be reasoned with reference to an opinion given by independent experts;

33. Calls for the adoption of a European charter of patients' rights on the basis of existing charters in the Member States and of work carried out by non-governmental organisations;

Reimbursement

34. Acknowledges the existing differences between health care systems in Member States and the complex legal frameworks which regulate reimbursements; calls for a codification of existing case law on the reimbursement of cross-border health care in order to ensure the proper application of that case law by all Member States and to improve the information available to patients, national insurance schemes and health care providers without creating additional cumbersome bureaucratic burdens for Member States;
35. Calls on the Commission to encourage all Member States to apply the existing procedures for reimbursement of cross-border health care; considers that it should be possible for the Commission to start proceedings against Member States that fail to do so;
36. Calls for a European reference scheme to be put in place concerning reimbursement in order to allow citizens to make comparisons and to make a choice as to which treatment is most suitable for them;
37. Calls for examination of ways of actively supporting and promoting work aimed at making use of the European Health Insurance Card ("EHIC"), containing a standardised set of electronic patient data, common practice, in order to simplify procedures for European citizens to obtain health care in other Member States; considers that the holders of an EHIC must determine themselves the data which will appear on it; in order to make the most effective use of this system, calls for the adoption of European health indicators; considers that it is crucial, for reasons of patient safety, to encourage national authorities to exchange information on registration and disciplinary matters relating to health care providers operating across borders; believes that it is appropriate to expand the EHIC scheme to include a system of international exchange of data concerning the insurance status of patients;
38. Calls on the Member States to ensure that health service providers post a clearly visible symbol demonstrating, in a way similar to that used in the case of credit cards in hotels and restaurants and so on, that a patient's EHIC can be accepted in a given Member State, in line with Regulation (EC) No 883/2004; calls for a high level of data protection for patients as regards cross-border cooperation in health services in order to ensure confidentiality of sensitive medical data;

Mobility of health professionals

39. Notes that Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications¹⁶ does not remedy all the current regulatory shortcomings at EU level concerning the free movement of health professionals, particularly with regard to continuing training, the right of establishment and providing assurances as to the competence of health professionals; stresses that any future legislation in this field should strongly facilitate the provision of cross-border health services and the establishment of service providers from other Member States;
40. Notes that, although mutual recognition of professional qualifications exists in the EU, there remains insufficient uniformity in the quality of the content of professional training and of the ways in which professions are pursued, or insufficient provision for such uniformity;
41. Stresses that Article 35 of the Charter of fundamental Rights provides that the Union shall ensure a high level of health protection and in this regard points out that the quality of health services and the ability of the sector to retain staff are conditioned by the quality of work and the working conditions of health service workers, including with reference to rest times and training opportunities; points out further that accompanying measures such as quality control, supervision and the use of new information technologies should ensure the best possible medical care for patients;
42. Considers it important for health care providers directly in contact with patients to have a sufficient command of the language spoken in the host Member State;
43. Calls on the Commission to set up a system for collecting data and exchanging information between the various national authorities on health care providers, and to set up a European card to provide access to information on the skills of health care professionals and to make that information available to patients, as well as to develop a reliable health information system for service providers, with an obligation for national authorities to share that information;
44. Calls on the Commission, in the context of increased professional mobility in Europe, to establish a legal duty for national authorities to exchange registration and disciplinary information about health care professionals in order to ensure patient safety;
45. Welcomes the work carried out by Health Professionals Crossing Borders as a good example of close multilateral cooperation between Member States' health care authorities;
46. Stresses the need better to inform health care professionals of their right of mobility within the EU by using existing tools established by the Commission, such as EURES (European Employment Services);

Legal liability

47. Insists that patient mobility needs the safeguards of concurrent and clear rules governing liability for the provision of cross-border health services and the resultant need for ease of

¹⁶ OJ L 255, 30.9.2005, p. 22.

access to redress and judicial mechanisms, particularly if the various stages of treatment have taken place in more than one Member State;

48. Notes that the combination of current rules of private international law on jurisdiction and applicable law with various Community law instruments, leads to a complex and difficult web of regimes on legal liability which does not promote ease of access to justice; stresses that this is a matter of particular concern in relation to health services which are, by their nature, both personal and individual; moreover, notes that a patient who seeks redress is likely to be both vulnerable and proceeding alone against either an institution or a professional body;
49. Stresses therefore the need to guarantee the legal security of patients and professionals; calls for clarification of liabilities in the event of injury and for an obligation for all health professionals to have compulsory third-party liability insurance at reasonable cost;
50. Stresses the need to strengthen the protection of patients by requiring health professionals to take out professional indemnity insurance; notes, however, that both the means of guaranteeing this, and the definition of a health professional, will be determined by the relevant insurance or other financial security arrangements in place in each Member State;
51. Points out that health care often requires follow-up medical checks; calls for clarification of the rules on the division of responsibilities between health care providers during the various stages of treatment in order to ensure continuity in care; points out that telemedicine and e-health are developing on such a scale that new rules of play need to be agreed in the areas of social protection, funding and access to such care;

Cooperation between Member States

52. Considers that closer cooperation between health systems on the local, regional, intergovernmental and European levels should make it possible to obtain appropriate treatment in other Member States, improve the quality of services and thus increase citizens' confidence;
53. Points out that cross-border cooperation between those concerned can result in finding appropriate solutions, as shown by the example of Euroregis;
54. Expects Member States to pursue cross-border cooperation in offering health services, so as to be able to run their respective health systems more cost-effectively;
55. Calls on the Commission to draw up technical standards, and calls on the governments of the Member States to actively support the introduction of interoperable transparent information systems allowing effective exchange and sharing of information on health between health care providers in different Member States,
56. Encourages the development of networks of reference centres, including electronic reference centres that deal with rare, specific and chronic diseases, and the exchange of knowledge between Member States on best practices with regard to treatment and the organisation of health care systems; calls on the Commission to optimise cross-border administrative cooperation;

57. Considers that the EU can play an important role in improving the availability of information for patients on cross-border mobility, including through the promotion of European health indicators;
58. Recognises that there is a demand for properly regulated, high-quality health and pharmaceutical cross-border services and for cooperation and the exchange of scientific and technological experience between highly specialised medical centres; points out, however, that surveys show that most people would prefer to receive high quality treatment near to where they live; considers that, in order to provide the most appropriate legislative response, the Commission should first conduct an exhaustive study firstly of the real need for patient mobility and secondly of the patients to which such mobility could apply, while assessing the impact of that mobility on health systems;
59. Expects, given the existing differences, Member States to resolve issues such as access to and quality of care and cost control among themselves;
60. Believes that the open method of coordination is one of the appropriate instruments by which to organise closer cooperation among Member States;
61. Hopes that bilateral or multilateral agreements between Member States, regions or local authorities and between the players in the health care sector will develop, and is of the opinion that this would stimulate the sharing of material and human resources in cross-border areas, in particular in areas with high numbers of short-term visitors, and would stimulate also exchanges of skills and knowledge;
62. Calls for the creation and use of a point of single contact, on the basis of existing Community instruments, in accordance with the organisational peculiarities of each health care system, to guarantee access to objective and independent information for patients, health professionals, health care institutions and competent authorities; considers that health professionals can assist patients to find this information;
63. Encourages the Commission to make use of all existing instruments, such as SOLVIT and infringement procedures, in order to assist patients who have been refused reimbursement (for non-hospital care) or authorisation (for hospital care), even though the conditions laid down in the case law were fulfilled;
64. Encourages the Commission to continue collecting data from the Member States and to further analyse trends and challenges facing the cross-border mobility of patients and health professionals;

Conclusions

65. Calls on the Commission to strengthen its policy of pursuing violations of EU law with a view to ensuring that all Member States comply with the case law of the Court of Justice and that all European patients, irrespective of their country of origin, benefit from the rights conferred on them by the Treaty;
66. Invites the Commission to submit to Parliament and the Council a proposal for an appropriate instrument with a view, in particular, to codifying the case law of the Court of Justice;

67. Invites the Commission to come forward with a proposal taking into account this resolution and ECJ rulings on patients' rights; calls for a guarantee for patients of the greatest possible access to health care services all over Europe as well as a guarantee for health service providers of the freedom to provide services and the freedom of establishment;
68. Given that the Commission proposal to deal with health issues in Directive 2006/123/EC was not accepted by the European Parliament and the Council, insists that further action is now required to preserve existing rights; consequently, calls on the Commission, as the guardian of the Treaties, to guarantee the safeguarding of those rights;
69. Believes that, above all, a new European regulatory framework for cross-border health care should improve access to high-quality health care in the event of illness, contribute to patient safety and increase the number of choices available to all patients in the European Union, without increasing inequality in health care outcomes;

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70. Instructs its President to forward this resolution to the Council and Commission.