COURT OF JUSTICE
OF THE EUROPEAN UNION

THE COURT OF JUSTICE
AND HEALTHCARE

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INTRODUCTION

Since 1952, the Court of Justice of the European Union (CJEU) has ensured that European Union law is observed and properly applied in the Member States. Over time, it has delivered judgments which have strengthened European integration while granting citizens increasingly extensive rights, in particular in the healthcare sector. The following pages present some leading judgments of the Court of Justice in that field.

THE LEGAL SITUATION UNTIL 1998

Since 1971, the issue of cross-border healthcare has been governed, at European Union level, by 'Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community'.

Broadly, that legislation enables patients to travel to another Member State to receive treatment after they have obtained the prior authorisation of their health insurance fund (form S2). Where such authorisation is granted, the treatment costs are generally paid for or reimbursed to the patient in accordance with the tariffs applied in the country of treatment, even if those tariffs are higher than the tariffs in the patient's country.

At the beginning of the 1990s the European Union became an area without internal frontiers, which facilitated the free movement of persons. Increasing numbers of patients then sought to receive treatment from doctors established in another Member State, and the key issue was whether they systematically required prior authorisation from their health insurance fund to do so. In 1998, the Court of Justice adjudicated on two cases in which the patients did not request, or did not obtain, prior authorisation, but nevertheless wished to be reimbursed by their health insurance fund.

THE JUDGMENTS OF 1998 IN KOHLL AND DECKER

The judgment in *Kohll* : no prior authorisation required for scheduled outpatient care in another Member State

In 1994, Mr Kohll, a Luxembourg national, wanted his daughter (a minor) to receive treatment from an orthodontist established in Germany and he requested the relevant authorisation from the Luxembourg health insurance fund. That fund refused authorisation on the ground that the treatment was not urgent and could be provided in Luxembourg. Relying on the freedom to provide services (and not Regulation No 1408/71), Mr Kohll took the view that he had the right to seek treatment for his daughter in Germany without prior authorisation and to claim reimbursement of his costs from his health insurance fund, not in accordance with the tariffs of the country of treatment (Germany) but in accordance with the tariffs applied for that type of treatment in his country of insurance (Luxembourg).

The Court of Justice held that treatment performed by a healthcare professional should be regarded as a service. In those circumstances, rendering payment for scheduled outpatient treatment, at the tariffs applied in the patient's country, subject to prior authorisation constitutes a barrier to freedom to provide services, since such authorisation deters insured persons from approaching providers of medical services established in another Member State. The Court furthermore observed that such rules are not justified either by a risk of seriously undermining the financial balance of the social security system or on grounds of public health (28 April 1998, Kohll, C-158/96).

THE JUDGMENTS OF 1998 IN KOHLL AND DECKER

The judgment in *Decker* : no prior authorisation required for the purchase, in another Member State, of medical devices or medical products on prescription

A patient may be prescribed medicines or medical devices by a doctor established in a Member State and decide to purchase the products in a pharmacy located in another Member State (whether by going there in person or by mail order). That was true in the case of Mr Decker, who, in 1992, purchased a pair of glasses for himself in Belgium prescribed by an ophthalmologist established in Luxembourg. The Luxembourg health insurance fund refused reimbursement of those glasses on the ground that the purchase had taken place abroad without prior authorisation.

The Court of Justice held that the refusal to reimburse medical products purchased without prior authorisation in another Member State constitutes an unjustified barrier to the free movement of goods, inasmuch as such a requirement is not justified on grounds of public health in order to ensure the quality of medical products supplied in other Member States. Since then, patients have been able to buy their medical devices or medical products in another Member State without prior authorisation and to claim reimbursement from their health insurance fund in accordance with the tariffs applied in their own country (28 April 1998, Decker, C-120/95).

THE INFLUENCE OF THE JUDGMENTS OF THE COURT OF JUSTICE ON THE EU LEGISLATION ON HEALTHCARE

In delivering the judgments in Kohll and Decker on 28 April 1998 (see the previous pages), the Court of Justice initiated a long series of judgments, on the basis of which the European Union legislature has substantially altered the EU legislation on healthcare.

The judgments in Kohll and Decker demonstrated that, in parallel to the system put in place by Regulation No 1408/71 and its implementing regulation (Regulation No 574/72), which provide for a prior authorisation scheme governing cover for medical treatment scheduled in another Member State in accordance with the tariffs applied by that Member State, the fundamental freedoms enshrined in the Treaties (the freedom to provide services in Kohll and the free movement of goods in Decker) may be relied upon in order to obtain, without the prior authorisation of the health insurance fund, payment for outpatient care or purchases of medical products in another Member State in accordance with the tariffs applied by the patient's country.

The Court of Justice has thus, through its case-law, progressively contributed to the establishment of criteria to be taken into account in order to safeguard the rights of citizens in this field. That case-law has moreover been codified by the European Union legislature in the adoption of Regulations No 883/04 and No 987/09 and Directive 2011/24, which today offer citizens detailed rules on cover for medical treatment and medical purchases which take place in another Member State.

THE CASE-LAW OF THE COURT OF JUSTICE ON THE 1971 REGULATION (CODIFIED IN THE 2004 AND 2009 REGULATIONS)

After the judgments in Kohll and Decker, the Court of Justice had the opportunity on several occasions to interpret the 1971 Regulation. It did so in two main fields: scheduled hospital treatment and non-scheduled hospital treatment.

THE CASE-LAW OF THE COURT OF JUSTICE ON THE 1971 REGULATION (CODIFIED IN THE 2004 AND 2009 REGULATIONS)

Scheduled hospital treatment

Where the authorisation necessary for hospital treatment scheduled in another Member State has been incorrectly refused and it is, for whatever reason, granted after that hospital treatment, the patient is entitled to reimbursement of the costs incurred in the same way as if the authorisation had been granted in due time (12 July 2001, Vanbraekel and Others, C-368/98).

To be allowed to refuse a patient's request for authorisation to receive treatment in hospital abroad on the ground that he could be treated, after a certain waiting time, in a hospital in his country, the national authorities must ensure that the waiting time set does not exceed a medically acceptable period in the light of the patient's state of health and clinical needs (16 May 2006, Watts, C-372/04). In addition, prior authorisation may not be refused where a lack of basic medical commodities prevents the patient from receiving hospital treatment in good time in his country (9 October 2014, Petru, C-268/13).

On the other hand, prior authorisation may be refused if the medical benefits provided abroad are not covered under the patient's social security system. However, if the treatment method applied abroad corresponds to benefits covered in the patient's Member State, it is not permissible to refuse prior authorisation on the ground that such a method is not practised in that Member State (5 October 2010, Elchinov, C-173/09).

Where a patient has obtained authorisation for treatment in a hospital in another Member State and he bears part of the hospital treatment costs, he can request his health insurance fund to reimburse all or part of those costs in accordance with the cost of the equivalent treatment in his country (16 May 2006, Watts, C-372/04).

THE CASE-LAW OF THE COURT OF JUSTICE ON THE 1971 REGULATION (CODIFIED IN THE 2004 AND 2009 REGULATIONS)

Non-scheduled hospital treatment

The 1971 Regulation, replaced by Regulation No 883/2004, provides that an employed or self-employed person whose state of health immediately requires healthcare during a stay in another Member State (emergency medical care) is entitled to have that care covered by his health insurance fund, without obtaining its prior authorisation, in accordance with the tariffs applied in the country of treatment.

Where a pensioner travels to another Member State and must receive emergency hospital treatment there, his health insurance fund cannot render its provision of cover for the medical costs dependant on the grant of prior authorisation or on the requirement that the illness from which that person suffers manifested itself suddenly, even if that requirement is applicable to employed and self-employed persons. The difference in treatment between pensioners and workers can be explained by the legislature's desire to promote effective mobility of pensioners having regard to their greater vulnerability and dependence in health terms (25 February 2003, IKA, C-326/00).

Furthermore, where a person with a prior authorisation is treated in another Member State and the doctors of that State decide to transfer him, on grounds of a medical emergency, to a hospital located in a State which does not form part of the EU (Switzerland, for example), the patient can retain their entitlement to cover in respect of the medical costs. The patient's health insurance fund must trust the doctors in the Member State of treatment, who are the best placed to assess the treatment required by the patient (12 April 2005, Keller, C-145/03).

Lastly, where emergency hospital treatment is administered during a trip in another Member State, it is permissible for the patient's health insurance fund to refuse to reimburse the costs which, in the State of treatment, are borne by patients (such as, for example, a patient co-payment) (15 June 2010, Commission v Spain, C-211/08).

THE CASE-LAW OF THE COURT OF JUSTICE IN RESPECT OF THE FREEDOM TO PROVIDE SERVICES (CODIFIED IN THE 2011 DIRECTIVE)

After the 1998 judgment in Kohll, the Court of Justice clarified its case-law in the case where a person decides to receive treatment in aanother Member State under the freedom to provide services instead of on the basis of the 1971 Regulation. Such clarification concerns only scheduled medical treatment (outpatient or hospital treatment), and not emergency medical treatment (unexpected treatment).

THE CASE-LAW OF THE COURT OF JUSTICE IN RESPECT OF THE FREEDOM TO PROVIDE SERVICES (CODIFIED IN THE 2011 DIRECTIVE)

Scheduled outpatient treatment not provided in hospital

Following on from the judgment in Kohll, the Court of Justice held that prior authorisation was not required for outpatient treatment not provided in hospital and administered in another Member State by non-approved providers (13 May 2003, Müller-Fauré and Van Riet, C-385/99). Furthermore, the Member States may not render the provision of cover for expenses in relation to a spa cure abroad conditional on the fact that such a spa cure must have much greater prospects of success (18 March 2004, Leichtle, C-8/02).

Member States must also provide, in their national legislation, that insured persons have the possibility to be reimbursed for the costs of medical analyses and laboratory tests carried out in another Member State (27 January 2011, Commission v Luxembourg, C-490/09). Moreover, it is not permissible for Member States to restrict cover for outpatient treatment administered abroad to the sole exceptional circumstance where the national healthcare system cannot provide the treatment needed for the patient affiliated to that system (27 October 2011, Commission v Portugal, C-255/09).

However, the Court of Justice has acknowledged that the Member States may provide that the reimbursement of outpatient treatment provided in another Member State is conditional on the grant of prior authorisation where such treatment requires use of major medical equipment (for example an MRI or PET-SCAN). In the light of the particularly onerous nature of such equipment, it must be possible for it, like hospital services, to be the subject of planning policy in order to be able to ensure, throughout national territory, a rationalised, stable, balanced and accessible supply of treatment and in order to avoid any waste of financial, technical and human resources. A prior authorisation requirement for that type of treatment therefore constitutes a justified restriction on the freedom to provide services (5 October 2010, Commission v France, C-512/08).

THE CASE-LAW OF THE COURT OF JUSTICE IN RESPECT OF THE FREEDOM TO PROVIDE SERVICES (CODIFIED IN THE 2011 DIRECTIVE)

Scheduled hospital treatment

The Court of Justice has held that, in contrast to outpatient treatment not performed in a hospital (see the previous page), the requirement of prior authorisation for hospital treatment can be justified by the need to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State in question, to control costs and to prevent any waste of financial, technical and human resources. At the same time, the Court has held that the conditions for obtaining such prior authorisation must be justified, non-discriminatory and proportionate (12 July 2001, Smits and Peerboms, C-157/99). It follows that, for scheduled hospital treatment, prior authorisation is always required, be it to obtain cover for such treatment in accordance with the tariffs applied in the country of treatment (the 2004 and 2009 Regulations) or in accordance with the tariffs applied in the patient's country (the 2011 Directive).

It is permissible to refuse prior authorisation if treatment which is the same or equally effective as that envisaged abroad exists in the patient's country and if that treatment can be administered without undue delay in the patient's country. In this connection, the national authorities must take into account the patient's medical condition and history, the probable course of the disease and the degree of pain or the nature of the disability (13 May 2003, Müller-Fauré and Van Riet, C-385/99).

A Member State cannot restrict the reimbursement of the costs of hospitalisation either to certain categories of persons (children for example) or according to the public or private nature of the hospital which administers the treatment. Such a broad exclusion of reimbursement of the costs of hospital treatment would be contrary to EU law, since it would deter or even prevent patients from being admitted to hospital in other Member States (19 April 2007, Stamatelaki, C-444/05).

Lastly, if the tariffs in force in the country of treatment are lower, in respect of the hospital treatment at issue, than those applicable in the patient's country, the patient is entitled to an additional reimbursement corresponding to the difference between those two tariffs ('the differential additional amount') (12 July 2001, Vanbraekel and Others, C-368/98).

REIMBURSEMENT OF TRAVEL, ACCOMMODATION AND SUBSISTENCE COSTS

When a patient travels to another Member State to receive treatment there, he necessarily incurs travel costs and, in some cases, accommodation and subsistence costs. The issue has thus arisen of whether the patient's health insurance fund must also reimburse those costs.

A patient who is authorised by his health insurance fund to travel to another Member State to receive treatment there under the 1971 Regulation (or the 2004 and 2009 Regulations) cannot claim the reimbursement of his travel costs or, in the case of outpatient treatment, of his accommodation and subsistence costs. On the other hand, in respect of scheduled hospital treatment, the accommodation and subsistence costs will be reimbursed. The obligation to reimburse covers exclusively the expenses linked to the healthcare treatment received by the patient in the Member State of treatment (15 June 2006, Herrera, C-466/04).

The same applies where the authorisation is granted by virtue of the freedom to provide services (the 2011 Directive). However, if the travel, accommodation and subsistence costs are covered by the patient's health insurance fund for treatments provided within national territory, those costs must then be reimbursed when the patient travels to another Member State to receive treatment there (16 May 2006, Watts, C-372/04).

The Member States are at liberty in all cases (whether under the regulations or the directive) to reimburse travel, accommodation and subsistence costs if they choose to do so.

PURCHASE OF MEDICAL PRODUCTS OR DEVICES BY MAIL ORDER

Following the 1998 judgment in Decker, the Court of Justice has had the opportunity to clarify its case-law, inter alia in the field of the purchase by mail order of medical products and devices.

A Member State may not prohibit the sale by mail order of medicinal products authorised on its market and not subject to prescription. By contrast, a national prohibition on the sale by mail order of medicinal products subject to prescription can be justified. Allowing those medicinal products to be supplied by mail order and without any control could increase the risk of prescriptions being abused or inappropriately used. Furthermore, the possibility that the label of a medicinal product may be in a different language may have more harmful consequences in the case of prescription medicines (11 December 2003, Deutscher Apothekerverband, C-322/01).

Lastly, it is not open to a Member State to set fixed prices for prescription-only medicinal products, since setting such prices could impede the access of foreign pharmacies and mail order pharmacies to the market (19 October 2016, Deutsche Parkinson Vereinigung, C-148/15).

FOR FURTHER INFORMATION

In every Member State, 'national contact points' with expert knowledge of EU legislation on cross-border healthcare have been established to answer questions on practical issues from people who wish to be treated in a Member State other than their own. The updated list of those national contact points may be consulted on the internet at the following address: https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/cbhc_ncp_en.pdf

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