

# Health Policy *Matters*

HELPING DECISION MAKERS PUT HEALTH POLICY INTO PRACTICE

**This issue**

## Who is Directing the Traffic to Europe – the European Court of Justice or the Department of Health?

### Introduction

Social Security, which in Europe includes health care, is an area of policy reserved exclusively to the member states. Within existing treaties there are no plans or powers to initiate harmonisation of national systems for organising or delivering health care. So how is it that in the past year NHS patients have apparently been 'given' access to European hospitals as a consequence of judgements from the European Court of Justice (ECJ)?

To the press, causality was clear:

- **12 July 2001:**  
Decision of the European Court of Justice in the cases of Smits and Peerbooms.
- **19 July 2001:**  
Health Service Journal reports 'cataract operations in Calais for those who need them' and 'French leave for Brits who tire of the wait'.
- **31 July 2001:**  
Financial Times reports West Sussex Health Authority confirmed that one of its PCGs was in discussion to send patients needing joint replacements to Germany....but.... The Department of Health said 'we would not condone that, and we wouldn't allow it.'

- **26 August 2001:**  
Financial Times reports Alan Milburn said British Health Authorities would be free to send patients to other countries for treatment.
- **2 September 2001:**  
The Sunday Times reports 'government's U-turn over sending British patients overseas.... The dramatic U-turn follows a decision by the European courts in which ...judges ruled that patients facing "undue delay" could seek treatment in other European Union states at their home country's expense.'

The press reports were misleading. It was not the 12 July judgement and its discussion of waiting times (the Dutch law on 'undue delay') that forced the Department of Health (DH) to recognise the questionable legality of preventing Health Authorities, Trusts or PCTs from contracting with other European hospitals. However, it can be argued that the press coverage had an important effect on public opinion and consequently on the enthusiasm with which the Government appears to have embraced the need to reverse its long standing policy against contracting with hospitals abroad.

### The European Court of Justice

The role of the European Court of Justice is to ensure that community law is interpreted and applied consistently in member states. Core issues have included removing

discrimination based on nationality, enforcing competition law and, since 1992, encouraging the four freedoms of the EU internal market: freedom of movement of people, goods, services and capital. Jurisdiction includes not only law established in Treaties but also secondary legislation such as Regulations and

Directives. The recent high profile health care cases have all dealt with cross-border health care. There are three key groups:

- frontier workers (E106)
- emergency care (E111)
- (prior) authorisation for non-emergency care (E112)

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It examines the background to the recent Department of Health decision to allow NHS contracting with overseas hospitals and directs the attention of Trusts and PCTs to recent information on the use of this scheme for offering patients choice of overseas providers.

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Any UK resident who has taken a holiday in the EU will be familiar with form E111—it is the growth of tourism that has made arrangements for cross-border emergency medical care essential as this type of economic activity has expanded. The recent decisions of the ECJ have centred on the third group of patients, those seeking authorisation for non-emergency or elective treatment in an EU state other than the country of residence (E112). Under the long standing, if often amended, Regulation 1480/71 an individual can seek authorisation for non-emergency medical treatment in another European country, with the cost of treatment paid by the NHS or the patient's equivalent European health insurance scheme. Regulation 1480 says that authorisation for cross-border treatment cannot be refused

“when the treatment is covered by the legislation of the residence state but cannot be given within the time normally necessary for obtaining the treatment, taking account of the current state of health of the patient and the expected course of the disease”

All the highly publicised health care judgements of the ECJ have been on the question of whether national requirements that the patient obtain authorisation for treatment abroad were consistent with Treaty obligations on the free movement of goods and services.<sup>1</sup> A key issue is who pays. Under existing law, there is nothing to stop an individual travelling to another country for medical care but, unless ‘authorised’, it is the patient who must pay, not the NHS.

## The 12 July 2001 ECJ decision

The 12 July ECJ decision concerned two Dutch patients who had requested and been denied authorisation for treatment outside the Netherlands. Mr. Peerbooms was in a coma after a traffic accident and his neurologist wanted him sent to

Austria for treatment. Mrs Gerats-Smits wished to go to Germany for treatment for Parkinson's disease. The Dutch Court referred the cases to the ECJ for a preliminary ruling on whether the requirement of authorisation contravened Treaty obligations on the free movement of services. Dutch law provided for refusal of authorisation if ‘normal’ medical treatment could be obtained without ‘undue delay’ from hospitals with which the sickness funds had service agreements (contracts). Was this Dutch legislation precluded by Treaty obligations?

The Court ruled that the requirement of authorisation did place restrictions on the freedom to provide services but that the restriction was justified by the need to ensure financial stability of the national health care system and the need to plan hospital capacity through agreements (contracts) with providers. The Court refined the concept of ‘normal’ medical treatment (see below) but offered no comment on the interpretation of ‘undue delay’ or what waiting time constituted ‘undue delay’.

## The messages for the NHS

The 12 July judgement of the ECJ dealt with a specific piece of Dutch legislation and its compatibility with EU law. However, the impact of case law is cumulative and elements of this decision could be of relevance to future legal actions that concern the NHS.

### Normal treatment

The Dutch health care system, like the NHS, offers comprehensive health care with benefits in kind. There is no list of treatments to which a patient is entitled. Legislation simply states that patients are entitled to normal, medically necessary treatment. In considering whether adequate treatment was available from the country of residence, the ECJ, in the Smits-Peerbooms case, put forward a definition of ‘normal’ treatment as a treatment ‘sufficiently tried and tested by international

medical science’. The Court determined that what constitutes ‘normal’ treatment should not be solely dependent on the views of the Dutch medical establishment. Note the absence of ‘cost-effectiveness’ in this definition. What happens if NICE recommends the NHS not provide some patients with a ‘tried and tested treatment’? Under European law every country has the power to restrict the range of treatments available under its health care system but the basis of the restriction must satisfy criteria of transparency.<sup>2</sup> It remains to be seen whether NICE procedures are sufficiently transparent to meet legal criteria.

### Waiting times

‘Undue delay’ is a term that appears in Dutch legislation. There is no equivalent in English law. The NHS waiting time targets have no legal force – they are administrative statements of intent. In the Smits-Peerbooms case, the court did not seek to interpret or define ‘undue delay’. However, there is a case pending judgement of the ECJ that is directly concerned with waiting time (Case C-385/99, Van Riet). The judgement in this case may give important indication of the extent to which differences in national practice as to what constitutes acceptable waiting times will be subject to European wide criteria. It is possible to speculate. One commentator has suggested that ‘significant deterioration’ of the medical condition may emerge as the legal definition of ‘undue delay’. But how will ‘significant’ be defined? We must wait for pending judgements.

## The Department of Health

.....  
If the 12 July ECJ decision said nothing that might imply rights to shorter waiting times for NHS patients, why did the Department of Health reverse its earlier position and, after 28 August 2001, allow NHS organisations to contract with non-UK hospitals? The immediate

explanation centres on the publicity given to the signing of the 'Concordat' with the UK private sector in October 2000. NHS purchasers and Trusts were encouraged to contract with UK private sector hospitals and make use of private sector excess capacity to reduce NHS waiting times. Some Health Authorities and Trusts had always made use of the private sector to deal with waiting list problems but it was ad hoc and not publicised. To encourage contracting with the UK private sector, and at the same time to forbid contracting with French or German private sector hospitals wanting to bid for this work, was in direct contravention of EU competition law and the more general prohibition in Article 12 of the Treaty against 'discrimination on grounds of nationality'. The illegality of such discrimination has routinely been pointed out in UK Treasury guidance on public sector purchasing.<sup>3</sup>

Given the priority the Department of Health has given to reducing waiting times, it was announced that some overseas hospitals would be identified and contracted to treat groups of NHS patients suffering long waits for 'low risk' procedures such as major joint replacement and cataracts. Five Health Authorities were selected for a pilot of arrangements for sending NHS patients to hospitals in France and Germany. To date fewer than 200 patients have received overseas treatment as part of this project. The pilot has been evaluated by the York Health Economics Consortium (YHEC) and the report is now available.<sup>4</sup>

It is important to note that NHS patients sent abroad as part of this pilot have not applied for 'authorisation', the subject of the ECJ decisions referred to above. There has been no change in the way the UK deals with requests of individual patients for authorisation of treatment abroad (E112). The existing pilot, and plans to expand arrangements for NHS patients to be treated overseas, are being

developed through bilateral contract negotiations independent of the established EU co-ordinating mechanisms of Regulation 1480/71. This distinction is important if we are concerned with equity in access to NHS care.

Data on the characteristics of patients who successfully apply for authorisation for overseas treatment are not available. However, there is an expectation that they tend to be the relatively articulate, independent and financially well off. A patient applying to the DH for authorisation of treatment abroad must, with his or her consultant, locate an appropriate hospital abroad, deal with the bureaucracy of applying for treatment and have sufficient financial resources to pay for travel and any accompanying relatives. If it approves the application, the NHS only pays for the treatment. The traditional arrangements under which, with prior authorisation, the NHS pays for treatment overseas is likely to favour the highly motivated and relatively well off.

The new arrangements for sending NHS patients overseas, to be rolled out from the present pilot, may prove more equitable. The NHS, through the DH appointed commissioners, will seek out, vet and contract with the overseas hospitals to which NHS patients will be sent. The patient and consultant no longer need take the initiative in locating a provider. Patients waiting beyond current NHS waiting time targets will, if thought appropriate, be asked if they would like the option of treatment overseas. Transport costs and, in some cases, those of an accompanying relative will be paid by the NHS.<sup>5</sup> The final selection of patients via this route could be expected to reflect more equitable access to the overseas option for reducing waiting times than the traditional route via prior authorisation examined by the ECJ.

While we speculate about the future, it is useful to keep numbers in perspective.

## Authorisation under EU Regulation 1408/71:

- For the year 2000: 1,100 British patients were granted authorisation for treatment abroad.
- For the period 1 January 2001 – 16 October 2001: 920 patients were granted authorisation for treatment abroad.<sup>6</sup>

## NHS patients treated overseas under the new DH programme:

- Less than 200 during the pilot running from January-April 2002.
- Forecast (by an enthusiastic commissioner involved in the pilot) that 'as many as 10-20,000 patients could be treated abroad annually'.<sup>7</sup>

## Against a background of:

- Between 60-70,000 operations a year carried out by the UK private sector for NHS patients.<sup>7</sup>
- In the year 2000, approximately 4.5 million non-emergency operations were carried out in the NHS.

The DH has made clear that it prefers to bring overseas clinicians to the UK rather than send NHS patients for treatment overseas.<sup>8</sup> There is no published explanation of why this is the preferred government policy. Now that the option of overseas treatment with NHS contracted providers is embedded in all documents on Patient Choice, it would be timely to produce some evidence on the extent to which patients may prefer to go to established continental providers as opposed to treatment in England by overseas visiting clinical teams. The DH is inviting international investors to establish Diagnostic Treatment Centres (DTCs) in England to be staffed by overseas doctors.<sup>9</sup> This may be one way around the recent difficulties encountered by the DH in securing Trust participation in the programme to have visiting overseas surgeons work in English hospitals.<sup>10,11</sup>

The future balance of (1) treatment overseas, (2) treatment in England by overseas clinical teams, (3) treatment in English-based overseas DTCs and (4) treatment by the UK private sector is likely to be struck by tough negotiation between all parties and the DH.

## The uncertain future

In spite of Treaty undertakings that the organisation of health services remains an area reserved for member states, many directives relating to general economic activity have impinged on the management of the NHS. A current example is the working time directive with its continuing impact on junior doctors

hours.<sup>12,13</sup> There will no doubt be future examples. The purely domestic policy decision to open the English provider market to a richer mix of non public sector for-profit and not-for-profit companies will force the NHS to pay more attention to EU competition law. Now that the ECJ has noted 'undue delay' and there is a pending case on waiting time, future court decisions may well have an impact on NHS management of waiting time.

## Action now

For the moment PCTs and Trusts have to focus on how they implement the new DH programme for giving patients with long waits the choice of

going overseas. The DH has published draft guidance on this topic.<sup>5</sup> The YHEC evaluation of the overseas patient treatment pilot contains information on the patient experience that will be of interest to both clinicians and patients considering the overseas option. It also alerts Trusts and PCTs to potential problems and offers advice on how to deal with them.<sup>4</sup> For doctors and patients interested in pursuing the traditional route of seeking prior authorisation to be treated in an overseas hospital with which the NHS does not have a contract, there is much less information available from the DH but at least a contact number is provided.<sup>14</sup>

## References & resources

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- For an example of the importance of transparency when restricting available NHS services see Regina v. Secretary of State for health ex parte Pfizer Ltd, Case No: C/4934/98, 26 May 1999. One of several grounds for the successful legal challenge of the Secretary of State's instruction to forbid prescribing of Viagra was the lack of transparency in the criteria used to arrive at this decision.
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