COMMUNITY ACTION ON HEALTH SERVICES – Consultation.

Response of the Berkshire Priorities Committee, UK.

Please find below the submission of BERKSHIRE PRIORITIES COMMITTEE and others in connection with consultation on *Community Action on Health Services* (Brussels, 26 September 2006). The Berkshire Priorities Committee advises health authorities (primary care trusts) in the county of Berkshire on matters concerning the use of NHS resources.

The need for consultation arises from the decisions of the European Court of Justice (ECJ), culminating in the case of *Watts v Bedfordshire PCT* (2006). These decisions encourage patients to obtain "normal" health care in other Member States when it cannot be obtained at home without "undue delay."

We are concerned at these developments. The following explains why by discussing: (A) the funding of NHS care, (B) the problems introduced by the ECJ and (C) asking, What is the Solution?

A. FUNDING OF NHS CARE: THE POSITION OF PRIMARY CARE TRUSTS (PCTS) IN ENGLAND

PCTs have two primary statutory duties: (a) not to exceed their annual financial allocations and (b) to promote a "comprehensive health service" in their local communities (sections 97 and 1, National Health Service Act 1977). In common with many health care systems, demand for health care exceeds the supply of resources made available. These twin obligations require a system of "priorities" to be introduced in the NHS, both by central government and local health authorities. Only in this way can limited resources be used to optimum effect for the benefit of the community as a whole.

Resource scarcity affects doctors as well as patients. The British Medical Association says that 10,000 junior doctors will be unemployed in 2006 because hospitals have insufficient funds to employ them.

In the UK today, pressure of resources gives rise to fewer difficulties with respect to waiting times. Modern NHS policy in England is committed to reducing waiting times to 18 weeks (which is unlikely to constitute "undue delay.") Rather, the problem is that some treatments are not offered within the NHS at all. This may happen for two reasons:

1. The Treatment is not recommended by the National Institute for Health and Clinical Excellence (NICE)

NICE is a statutory body established to advise the NHS as to the treatments it should, and should not, support. NICE has an international reputation and its recommendations are used by many jurisdictions outside the UK. Its *Technology*

Appraisal Guidance normally has mandatory force in England and effectively requires PCTs to fund the cost of the treatments it recommends.

By contrast, it may advise that specific treatments may be restricted to carefully selected patient groups. It has done so in the case of eg:

- Inhaled insulin for Treatment of Type 1 and Type 2 Diabetes
- Alzheimers' Disease – donepezil, galantamine, rivastigmine and memantine.

In this case, the treatment may be restricted by PCTs and will not generally be available within the NHS.

2. Treatments that have not been considered by NICE and which are not funded by local PCTs.

The decision whether to fund treatments that have not been considered by NICE remain within the statutory discretion of PCTs. This discretion is closely supervised by the courts for the manner in which it treats patients fairly, equally and consistently, but it means that PCTs may determine that some treatments do not command sufficient priority to be funded except in exceptional circumstances.

This may be important in respect of cosmetic treatments, gender-reassignment surgery, homeopathy and other complimentary therapy, assisted reproduction treatments and high-cost interventions with little additional benefit over existing treatments. In these cases, treatment may be withheld on the basis that, for example, the clinical evidence is inadequate, or incomplete, or its costs cannot be justified by its (sometimes unknown) benefits. Judgment is necessary to avoid diverting finite public resources away from patients with greatest capacity to benefit from treatment.

Of course, there may be disagreement as to whether the treatment will be effective, or the patient has exceptional needs. But the need for decisions of this kind is unavoidable in any system constrained by finite resources.

B. THE PROBLEMS INTRODUCED BY THE ECJ

The interventions of the ECJ cause significant difficulty. Medicine is not a wholly "objective" science and disagreement between doctors is common. Patients denied access to care following the reasonable decisions of NICE may seek doctors elsewhere in the EU with different opinions in order to obtain treatment in a "host" Member State. This is problematic for a number of reasons.

1. Free Movement of *Public* Services Undermines Social Solidarity.

The principle of the free movement of services is intended to encourage *private trade* and commerce between Member States and to reduce trade barriers. It was not intended to extend into *public services*. Art 152(2) specifically excludes this principle in relation to national health systems. It says that:

> Community action in the field of public health shall fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care.

In the health care cases, the ECJ has ignored this principle. It has failed to understand the danger of extending free movement principles to public services, ie that they are limited by finite budgets. In a competition for *public* services, "the winners" tend to secure access to scarce resource at the expense of someone else. This undermines social solidarity because the winners tend to be able-bodied, articulate and middle class. The "losers" tend to be poor, disabled, elderly and mentally ill. The ECJ has failed to recognise that principles intended to promote *private* interests (eg freedom to purchase private goods and services) are not automatically relevant to *public interests* (which are concerned with issues of equality of access, and social solidarity). If this latter objective is eroded, public confidence in health care systems will be damaged.

2. The ECJ fails to Accommodate Public Interests

Although the ECJ purports to recognise the problems of financial stability and integrity in public services, its fails to respond to this concern for two reasons.

First, the ECJ considers that it is not possible to deny individuals access to care on the grounds that others have more urgent needs. This is because the justification for treatment in another Member State must be judged according to the needs of each *individual* patient (without regard to public interests). Therefore, legitimate waiting lists, necessitated by the need to give priority to patients, may not prevent others from access to care. In *R (Watts) v Bedfordshire PCT Case* (2006) ECJ, C-372/04, the ECJ said,

> where the delay arising from such waiting lists appears to exceed *in the individual case concerned* an acceptable period having regard to an objective medical assessment of all the circumstances of the situation and the clinical needs of the person concerned, *the competent institution may not refuse the authorisation sought on the grounds of the existence of those waiting lists, [or] an alleged distortion of the normal order of priorities linked to the relative urgency of the cases to be treated* (paras 119-20, emphasis added).

This principle ignores the public interest. Instead, it imposes on national courts a duty to divert care to some patients, without knowing about others, perhaps with more urgent needs, from whom treatment will be withdrawn as a result. It ignores the inescapable fact that rationing may be unavoidable in public health systems.

Second, in *Muller-Faure* and *Van Riet* the ECJ purports to recognise the need for Member States to retain control over health spending and confirmed their right to restrict the circumstances in which public funding would be available. It said:

> it is for the Member States alone to determine the extent of the sickness cover available to insured persons, so that, when the insured go without prior authorisation to [another] Member State to receive treatment there, they can claim reimbursement of the cost of the treatment… only within the limits of the cover provided by the sickness insurance scheme in the Member State of affiliation (para 98).

However, it is a mistake to believe that modern health care systems control health care expenditure by "including", or "excluding" care. Instead, they use generic terms which promise to provide for example, "comprehensive," "medically necessary", or "non-experimental" care. Although it would be conceivable to devise a "white list" of approved treatments (or "black list" of excluded ones), the exercise is impossibly difficult. (Who would decide, how often, on the basis of what evidence?) In practice, these matters are left to clinicians to decide within a broad framework of guidance.

Therefore, the suggestion that Member States should “determine the extent of sickness cover” so as to exclude certain treatments from health care is misconceived and unworkable.

3. The Criteria for Determining Access to Health Services are Unworkable.

The ECJ states that the right to obtain treatment abroad requires two conditions to be satisfied, namely: (i) the treatment is regarded as "*normal* in the professional circles concerned", in the sense that it is "sufficiently tried and tested by international medical science" and (ii) it cannot be obtained at home "without *undue delay.*" Each is incapable of creating enforceable legal rights.

The ECJ wrongly assumes that “illness” and “disease” are objective phenomena. The experience of illness and the clinical response to it are often driven by subjective considerations about which attitudes differ. Is trans-gender surgery “normal” treatment? or bariatric (stomach restricting) surgery for obesity, *in vitro fertilisation* (IVF) and thallasotherapy for high blood-pressure, or arthritis? As with so many illnesses, there are often differences of professional opinion on these matters. The point is made in the following extract:

> Medicine is widely held to be a science, but many medical decisions do not rely on a strong scientific foundation, simply because a strong scientific foundation has yet to be explored. Hence, what often happens in the decision-making process is a complicated interaction of scientific evidence, patient desire, doctor preferences and all sorts of exogenous influences, some of which may be quite irrelevant. (K McPherson, "Why do Variations Occur?", in T. Folmer Anderson and G. Mooney, *The Challenge of Medical Practice Variations* (Macmillan, 1990)).

The same applies to the clinical evidence surrounding treatment because it is often ambiguous. Therefore, it is often impossible to say that a treatment is “sufficiently tried and tested by international medical science” because clinical trials are still being conducted and their veracity debated.

How do these words apply to “orphan drugs” developed to treat illnesses which occur in not more than 5 in 10,000 people (see the European Regulation on Orphan Medicinal Products, EC 141/2000)? They may obtain European Medicines Evaluation Agency licenses on the basis of limited clinical evidence (because the diseases they treat are so rare) and are often extremely expensive (because demand for them is so low).

For example, *Laronidase* is an enzyme-replacement therapy for Hurler-Schie disease which may cost up to £400,000 per patient per year (since the dose is weight-dependent). Many doctors may wish to try it, but its cost could destabilise a finite local health authority budget. Such an investment for the few (in treatment that may not be effective) would require massive “disinvestment” from much larger numbers of patients. Should orphan drugs be available in “host” Member States under EU law?

C. WHAT IS THE SOLUTION?

Because litigation naturally focuses on the merits of *individual* cases, it is not an appropriate forum in which to weigh and balance sometimes competing *public* interests. Under *Watts*, there is a danger that either (a) national governments will be required to invest larger sums in public health care (which electorates may not

support), or (b) if this does not happen, other patients will have to wait longer for their treatment. Decisions of this complexity are better suited to policy makers subject to public accountability, not national courts. What should be done?

1. Restore Article 22 of Regulation No 1408/71

As previously understood, EU law preserved the right of Member States to regulate patients' access to care abroad under Article 22 of Regulation No 1408/71, which provides:

> 1. An employed or self-employed person who satisfies the conditions of the legislation of the competent State for entitlement to benefits, taking account where appropriate of the provisions of Article 18, and:…(c) who is authorised by the competent institution to go to the territory of another Member State to receive there the treatment appropriate to his condition, shall be entitled: (i) to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the legislation which it administers, as though he were insured with it; the length of the period during which benefits are provided shall be governed however by the legislation of the competent State;…
>
> 2. … The authorisation required under paragraph l(c) may not be refused where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease.

It is essential to clarify how and when this regulation applies. As a general rule, prior authorisation should be required to obtain publicly funded health care elsewhere in the EU and the impact of the ECJ judgments should be limited.

2. Clarify how Member States may Protect Public Health Care

The ECJ's tests for limiting access to care in other Member States are unworkable. The Commission should clarify the nature and extent of Member States' rights to preserve integrity and equality within national health care systems. Inevitably, there must be a limited range of circumstances in which it is in the public interest that the freedom to obtain treatment abroad will not apply.

Failure to do so will put at risk the sense of social "solidarity" and confidence in public health care systems as some patients gain priority simply by their willingness and ability to travel.

Put simply, the Commission must describe the role of *public* interests in the allocation of finite health care resources.

3. Establish Clear Lines of Accountability

Problems of legal accountability for damages arise in "host" Member States. If treatment is obtained elsewhere in the EU, patients will need to know who is responsible and how to recover compensation when things go wrong. Anecdotal evidence reports patients returning from Europe having paid for treatment who experience post-operative complications requiring further treatment or revision by the NHS.

In principle, those at fault should bear responsibility for damage arising from their care. But should patients have to litigate in a foreign country, perhaps in a language they do not speak? Should they receive financial assistance to do so? Or should cases be heard in the patient's "home" State? How would the clinical evidence about medical accidents abroad be obtained? Are EU doctors/hospitals *always* insured for this risk? Who should be responsible for checking safety and quality in EU hospitals are broadly the same? Should the criteria for doing so be common throughout the EU?

Given Art 152, these matters should remain the responsibility of individual Member States to agree between themselves within a framework of OMC (Open Method of Coordination) "guidance" from the Council. An example of this method is: *Modernising social protection for the development of high-quality, accessible and sustainable health and long-term care* (Council of the EU, Brussells, 14 September, 12410/04).

24 January 2007.
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