

## R (Eisai Ltd) (Alzheimer's Society & Shire Ltd) v. the National Institute for Health and Clinical Excellence ~ The Wider Implications

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A challenge to the rules for NHS funding of drugs to treat Alzheimer's disease has **important wider implications**

In *R (Eisai Ltd) (Alzheimer's Society & Shire Ltd, Interested Parties) v. the National Institute for Health and Clinical Excellence*<sup>2</sup> ('NICE') the Court upheld in part a challenge to the decision of the Appeal Panel of NICE and their consequent guidance on the cost-effectiveness of drugs, known as inhibitors, for the treatment of patients suffering from Alzheimer's disease. NICE is a statutory body<sup>3</sup> whose role is to provide guidance to the NHS. The challenge was mounted on three grounds, namely: (i) procedural unfairness; (ii) discrimination; and (iii) irrationality.

Mrs Justice Dobbs upheld the challenge by the Alzheimer's Society and EISAI, a drug manufacturer, that NICE had failed in its duty to ensure that its guidance was not discriminatory. The Appeal Panel had failed to give any proper consideration "*to NICE's duties as a public authority to promote equal opportunities and to have due regard to the need to eliminate discrimination.*"<sup>4</sup> Similarly, there was no evidence that NICE had considered or complied with its "due diligence" equality duties or its present and imminent obligations under anti-discriminatory law, before issuing the guidance.

The Court dismissed EISAI's argument that the decision-making process was unfair because NICE's cost effectiveness model was not made public (only a partly-executable version of the model was disclosed), as well as certain irrationality challenges raised by EISAI and the Alzheimer's Society.

There are, however, **two key points** of wider importance beyond the subject matter of this case, concerning the Court's approach to disclosure of the economic model, and its approach to NICE's equality duties.

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<sup>2</sup> [2007] EWHC 1941 (Admin)

<sup>3</sup> Established by the National Institute for Clinical Excellence (Establishment and Constitution) Order SI 1999/220

<sup>4</sup> See paragraph 96 of the judgment

## **Fairness: disclosure of the economic model**

EISAI argued that the lack of access to the fully-executable model hampered it in contesting the appropriateness of the model to assess the cost-effectiveness of the inhibitors.

In considering whether fairness required NICE to disclose the fully-executable version of the model, Mrs Justice Dobbs noted that the answer would depend on the particular facts and circumstances of the case. The Court took into account that the Claimant was a consultee, citing the principles set out in *R v North and East Devon HA ex.p. Coughlan per Lord Woolf*<sup>5</sup> and *R v Secretary of State for Social Services ex.p. Association of Metropolitan Authorities*<sup>6</sup>, to the effect that consultees should be provided with sufficient information in order to enable them to make a sufficiently informed and considered response.

The Court held that *on the particular facts of the case*, EISAI had more than sufficient information to make an intelligent response and to give proper advice. Although EISAI had not been able to test the model as it wished, it had been able to advance suggestions and concerns which had actually led to NICE making alterations. EISAI had also been able to advise on the need to check figures and run sensitivity analyses.

It is clear that the claim regarding disclosure of the executable version of the model did not fail as a matter of principle, but rather on its facts. In another case, such a challenge might succeed.

## **Discrimination**

The Alzheimer's Society and EISAI successfully argued that the guidance would result in discrimination against "atypical groups", such as those from a non-English speaking background and those with learning disabilities because (in essence) the Guidance was excessively rigid.

The Court also upheld the argument of the Alzheimer's Society and EISAI that NICE had failed to have regard to its positive duty to promote equality of opportunities. Section 71(1) of the Race Relations Act 1976 places public bodies, including NICE, under a duty to carry out its functions with "*due regard to the need (a) to eliminate unlawful racial discrimination; and (b) to promote equality of opportunity and good relations between persons of different racial groups*". Section 49A of the Disability Discrimination Act (DDA 1995) imposes a similar duty with respect to disability discrimination. It was argued that, although the amendment to the DDA 1995 did not come into force until 4 December 2006 and the guidance was published in November 2006, it would have been wholly unreasonable for NICE to formulate guidelines for the future without regard to these imminent duties.

In ordering NICE to amend its guidance, Mrs Justice Dobbs made strong criticisms of NICE's failure to comply with its present and imminent statutory equality duties. The transcripts of the Appeal Panel demonstrated that there had been no discussion about the legal duties and obligations placed on NICE and that no consideration had been given as to how NICE could promote equal opportunity.

This case leaves no room for doubt that the compliance of a public authority with its statutory duties to promote equality is truly justifiable and capable of giving rise to a public law challenge. It is necessary for public bodies to give "proper consideration" to their "due regard" duties to promote equality. Thus, anti-discrimination law requires that a particular *process* be followed by decision makers, as well as seeking to ensure that no substantive discrimination occurs.

*Tim Ward and Gerry Facenna acted for the Alzheimer's Society*

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<sup>5</sup> [2001] QB 213 at 259

<sup>6</sup> [1986] 1 WLR 1 at 4