



## **Procedural fairness & drug approvals**

By Ivan Hare

In *R (Eisai Ltd) v National Institute for Health and Clinical Excellence* [2008] EWCA Civ 438, the Court of Appeal determined the extent to which the principles of procedural fairness apply to decisions to recommend certain drugs for use in the National Health Service.

The National Institute for Health and Clinical Excellence (NICE) had changed its guidance on the recommended use of certain forms of drug treatment for Alzheimer's disease in 2006; this led to the drugs being restricted to those with moderately severe symptoms of the disease. Eisai Ltd held the UK marketing authorisation for one such drug and sought to challenge the 2006 guidance. NICE's system for recommendations involves commissioning an independent academic centre to carry out an appraisal of the cost-effectiveness of a particular treatment which often includes the use of economic models. The outcome of this assessment is to produce a cost per quality adjusted life year (QALY). The general threshold for approvals is £20,000 per QALY. The cost of Aricept was significantly above this level. After the technological assessment had been made by the academic centre, consultees are permitted to comment on it and their comments are provided to one of NICE's appraisal committees. The appraisal committee then hears evidence from experts nominated by consultees, patients and carers before producing its preliminary conclusions. A further period of consultation then takes place before the committee's final appraisal is issued. Consultees have a right of appeal against the results of the final appraisal.

In the present case, Eisai had been provided with a read-only version of the economic model used to appraise the Alzheimer drugs, but sought disclosure of a fully-executable version. Eisai appealed unsuccessfully to NICE's appeal panel and then sought judicial review.

The Court of Appeal accepted that NICE's procedures were "exceptionally detailed and elaborate, involving extensive consultation and a high degree of disclosure at all relevant stages" (para 11, per Richards LJ). However, NICE's own views of the appropriate limits of disclosure could not be determinative and the high levels of procedural protection served to emphasise the importance of the issues at stake both to the suppliers of drugs to the NHS and to the health of patients. The economic model was central to NICE's ultimate appraisal of the cost-benefit of a particular drug, but the read-only version prevented consultees from testing the reliability of the model themselves by running different figures and assumptions through it. This in turn reduced the value of the responses that consultees could give to NICE. On this point, the Court favoured the expert evidence submitted by Eisai.

NICE sought to defend their position by reference to the confidentiality of the economic models used and Eisai's delay in challenging the refusal to disclose the fully-executable version of it. The Court was not persuaded by these arguments. NICE had failed to identify what additional confidential information would be disclosed by release of the fully-executable version and had released such a version on occasion in the past. As regards delay, Eisai was entitled to await the outcome of the appraisal and its appeal before issuing judicial review proceedings.

The effect of this decision on the availability of drugs to combat Alzheimer's disease will depend on the results of the further and more detailed consultation in which NICE will be required to engage. More generally, this decision is likely to be relied on wherever expert parties are engaged in evidence-based consultation with public authorities.

*David Pannick QC led Thomas de la Mare on behalf of Eisai (instructed by Arnold & Porter LLP). Brian Kennelly appeared for Shire Pharmaceuticals Ltd (instructed by Ashurst LLP) and Ivan Hare acted for the Association of the British Pharmaceutical Industry as Interveners in support of Eisai's claim.*