

THE IMPLICATIONS OF COST-BENEFIT ANALYSIS FOR DRUGS FOR ALZHEIMER'S DISEASE

P. Feldschreiber

Barrister Four New Square, Lincolns' Inn, London and Medicines and Healthcare Products Regulatory Agency, Department of Health, London, UK

This paper will compare and contrast the evaluation of risk/benefit of anti-cholinesterase inhibitors with the cost/benefit analyses carried out by the National Institute for Health and Clinical Excellence (N.I.C.E) in the UK. N.I.C.E. first evaluated a range of cholinesterase inhibitors (donepezil, galantamine and rivastigmine) during the period 2001 to 2007. Their first guidance on the use of these drugs recommended that they should be prescribed in 'patients with 'mild-to- moderate Alzheimer's disease, with the restriction that treatment should only be continued 'if global , functional and behavioural condition remains at a level where the drug is considered to have a worthwhile effect' after approximately 2 – 4 months.

After reviews in 2003 and 2005, NICE currently recommends against the use of cholinesterase inhibitors altogether. This recommendation was based on a pharmaco-economic model adapted from the AHEAD template (Assessment of Health economics in Alzheimer's disease) published in 2001. This paper reviews the robustness and cogency of decisions made using this model and the legal challenges that have been mounted in the UK in consequence of the loss of availability of these drugs. In particular we discuss the use of legal challenge against scientific and economic decision making by NICE.