

11 October 2006



**National Institute for  
Health and Clinical Excellence**

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Ref: 2006/048

## **PRESS RELEASE**

### **NICE announces Alzheimer's disease drug appeal outcome and NHS guideline to support patients and carers**

NICE has today (Wednesday 11 October) announced that the appeals lodged by stakeholders against draft guidance on the use of drugs to treat Alzheimer's Disease have not been upheld. NICE will recommend to the NHS in November that donepezil, galantamine and rivastigmine should only be considered as options in the treatment of people with moderate Alzheimer's disease. Memantine is only recommended as part of clinical studies for people with moderately-severe to severe Alzheimer's disease.

**Andrew Dillon, NICE Chief Executive, said:** "Alzheimer's is a cruel and devastating illness and we realise that today's announcement will be disappointing to people with Alzheimer's and those who treat and care for them. But we have to be honest and say that based on all the evidence, including data presented by the drug companies themselves, our experts have concluded that these drugs do not make enough of a difference for us to recommend their use for treating all stages of Alzheimer's disease. We have recommended the use of these drugs where they have the potential to make a real difference, which is at the moderate stage of the illness."

Under normal circumstances, guidance to the NHS would be published at the same time as the decision of the Appeal Panel. However NICE is also developing a clinical guideline on the management of all types of dementia, including Alzheimer's disease, jointly with the Social Care Institute for Excellence. It is in the interests of patients and those who care for them that both pieces of advice are published at the same time. The publication date for the appraisal and the dementia guideline will be 22 November 2006.

**Andrew Dillon continued:** "Next month NICE will also publish, jointly with the Social Care Institute for Excellence, a clinical guideline on the treatment and care of people with dementia. It will complement the guidance on drugs by making it clear what care and support should be provided to people in all stages of Alzheimer's disease."

## Ends

For more information call Sarita Tamber on 020 7067 5915. Press office 020 7067 5900, out of hours press office 07775 583 813.

## Notes to Editors

### About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
2. NICE produces guidance in three areas of health:
  - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
  - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
  - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

### About this appraisal

3. Background information:
  - The original and current NICE guidance on the use of donepezil, galantamine and rivastigmine for Alzheimer's disease issued in 2001 recommends the use of these drugs for all patients, with treatment stopping as soon as they no longer had an effect.
  - NICE's review of this guidance initially concluded that there was not enough evidence to support the use of these drugs for all patients as recommended in the original guidance. However, responses received from stakeholders during consultation on this first draft suggested that the drugs may be more effective for certain groups of people. NICE therefore asked the pharmaceutical companies involved in the appraisal to look for evidence to support this in data from their clinical trials.
  - The Appraisal Committee met on the 20 December 2005 to review this additional data. This new evidence, taken with data already seen by the Committee enabled the Committee to reach the conclusion that donepezil, galantamine and rivastigmine are both clinically and cost effective in patients with moderate Alzheimer's disease (approximately 40% of all patients).
  - The appraisal committee met again on 27 April 2006 to consider comments on the draft document. The Final Appraisal Determination can be found on the website at: <http://www.nice.org.uk/page.aspx?o=appraisals.inprogress.alzheimersdisease#keydocs>.
  - Consultees with a right to appeal could appeal against the Final Appraisal Determination. The Institute received five appeals from Alzheimer's Society, Age Concern, Counsel and Care, Dementia Care Trust and Royal College of Nursing (joint appeal), Eisai Ltd, Lundbeck Ltd, Royal College of Psychiatrists and British Geriatrics Society (joint appeal) and Shire Pharmaceuticals Ltd. An appeal hearing was held on 13-14 July 2006.
  - The outcome of this appeal hearing and Appeal Panel's conclusions can be found at <http://www.nice.org.uk/page.aspx?o=appraisals.inprogress.alzheimersdisease>.
4. The stakeholders involved in the appraisal are:  
**Consultee organisations (these organisations have a right of appeal)**  
Manufacturers/sponsors
  - Eisai Ltd
  - Lundbeck
  - Novartis Pharmaceuticals Ltd

- Shire Pharmaceuticals Ltd

#### Patient/carer groups

- Age Concern England
- Alzheimer's Society
- Counsel and Care for the Elderly
- Dementia Care Trust
- Mental Health Foundation

#### Professional groups

- Association of British Neurologists
- British Geriatrics Society
- British Neuropsychiatry Association For Dementia
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal Pharmaceutical Society

#### Others

- Cheshire West PCT
- Department of Health
- Leeds West PCT
- Rugby PCT
- Welsh Assembly Government

#### **Commentators (no right of appeal)**

##### General

- British National Formulary
- National Collaborating Centre for Chronic Conditions
- NHS Purchasing and Supplies Agency
- NHS Quality Improvement Scotland

##### Research groups

- Alzheimer's Research Trust
- Dementia Research Group and Department of Old Age Psychiatry, Institute of Psychiatry
- Institute for Ageing and Health
- Research Institute for the Care of the Elderly

##### Associated Guidelines

- National Collaborating Centre for Mental Health – Guideline Development Group for Dementia

4. Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:
  - Medicines (for example, drugs)
  - Medical devices (for example, hearing aids or inhalers)
  - Diagnostic techniques (test used to identify diseases)
  - Surgical procedures (for example, repairing hernias)
  - Health promotion activities (for example, patient education models for diabetes).
5. Our technology appraisal recommendations are prepared by an independent Committee, who include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The Committee considers the evidence on the clinical and cost effectiveness of the technology – this includes hearing the views of, and evidence from, clinical health professionals, experts and patients.
6. NHS organisations in England and Wales have to make the resources and facilities available to enable NICE guidance to be implemented. In January 2002 the Government announced a legal obligation for the NHS to provide funding for treatments and drugs recommended by NICE as a part of its technology appraisals work programme.
7. NICE is currently in the process of developing a clinical guideline on the management of dementia, including use of antipsychotic medication in older people. This will address the wider issue of care of patients with dementia (including Alzheimer's disease). This guideline is expected to be published in November 2006. More details can be found at <http://www.nice.org.uk/page.aspx?o=guidelines.inprogress.dementia>.