Hampshire International Business Park
Chineham, Basingstoke
Hampshire RG24 8EP
United Kingdom
Tel +44 (0)1256 894000
Fax +44 (0)1256 894709

www.shire.com

Shire

Kate Moore
Technical Appraisal Project Manager
National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BD

25 October 2010

Dear Kate

Re: Appraisal Consultation Document: Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (Review of TA 111)

Shire supports the recommendations of the draft ACD for the treatment of Alzheimer's disease (AD) with the AChEI drugs, namely that both mild and moderate AD patients be treated on the NHS, consistent with the licensed indications. We believe that this sound guidance is well supported by the clinical and cost effectiveness data collected over the last 20 years. In particular we note that the appraisal committee has recognised that AChEI treatment results in a delay in time to institutionalisation.

We have only one comment to make on the content of the draft guidance. In paragraph 3.4, the drug regimen for galantamine mentions only the older twice daily treatment (tablets), which is now used only to a minor extent. The once daily (capsule) treatment now predominates and its omission from 3.4 is serious. Therefore the once daily regimen must be emphasised in paragraph 3.4. We suggest the following amended wording:

3.4 Galantamine (Reminyl, Shire) is an AChE inhibitor, which works by increasing the concentration of acetylcholine at sites of neurotransmission and also modulates activity at nicotinic receptors. Galantamine has a marketing authorisation in the UK for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer's type. The formulation most frequently prescribed is the once daily capsules (Reminyl XL), given initially at 8 mg once daily for 4 weeks and then increased to 16 mg once daily for at least 4 weeks. Maintenance treatment is 16-24 mg once daily depending on assessment of clinical benefit and tolerability.

Regarding the specific questions which you pose, our answers are as follows:

- Has all of the relevant evidence been taken into account? Yes
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Yes
- Are the provisional recommendations sound and a suitable basis for guidance to the NHS? Yes
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief? No

Yours sincerely,