

27 January 2010

## Proposal to fund donepezil hydrochloride and to decline funding for memantine hydrochloride

PHARMAC is seeking feedback on a proposal to fund donepezil hydrochloride for the treatment of Alzheimer's disease, subject to Special Authority restrictions (outlined on page 2 of this consultation document). Funding would occur as soon as possible after registration of the Donepezil-Rex brand, but not before 1 July 2010.

In addition, as a separate but related matter, PHARMAC proposes to decline the current funding applications for memantine hydrochloride (Ebixa) for the treatment of Alzheimer's disease and for the treatment of severe behavioural disturbance in patients with moderate-to-severe dementia.

Further details of this proposal can be found below and on the following pages.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **4 pm on Thursday, 25 February 2010** to:

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Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

### Details of the proposal

#### *Funding of donepezil hydrochloride*

Donepezil-Rex would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule as soon as possible following registration, but not before 1 July 2010, at the following prices and subsidies (as applicable, ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Donepezil hydrochloride	5 mg tablet	Donepezil-Rex	90	\$7.71
Donepezil hydrochloride	10 mg tablet	Donepezil-Rex	90	\$14.06

Donepezil hydrochloride would be required to be dispensed 'stat' from the date of listing in the Pharmaceutical Schedule, meaning that prescriptions would need to be dispensed all-at-once.

Donepezil-Rex would be the sole subsidised supply brand of donepezil hydrochloride, and would have Hospital Supply Status, from the date of listing in the Pharmaceutical Schedule until 30 June 2012.

The funding of Donepezil-Rex would be subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule:

**SAXXX Special Authority for Subsidy**

**Initial application** from any relevant practitioner. Applications valid for six months for applications meeting the following criteria:

All of:

- 1 Applicant works in a DHB specialist health service for older people; and
- 2 Patient has mild-to-moderate Dementia of the Alzheimer's type; and
- 3 Patient is living in the community (not in institutional care) and has adequate social support.

**Renewal** from any relevant practitioner. Applications valid for six months for applications meeting the following criteria:

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment (applicants are encouraged to consider stopping therapy where the patient has been institutionalised, as this could indicate disease progression to the extent that the treatment could no longer be considered effective).

We note that the cost of Donepezil-Rex for patients who did not meet the proposed Special Authority criteria would be at the discretion of the pharmacy.

***Decline of memantine hydrochloride***

PHARMAC also proposes to decline the current funding applications for memantine hydrochloride (Ebixa) for the treatment of Alzheimer's disease and for the treatment of severe behavioural disturbance in patients with moderate-to-severe dementia. Any decision to decline these funding applications would not prevent PHARMAC from considering future proposals or applications for memantine hydrochloride; however, it would clearly indicate that no active work on funding this treatment through the Pharmaceutical Schedule would be occurring at this time.

**Background information**

***Donepezil hydrochloride***

Donepezil hydrochloride is an acetylcholinesterase inhibitor registered for use in the treatment of mild, moderate and severe Alzheimer's disease and the treatment of vascular dementia (dementia associated with cerebrovascular disease). Other acetylcholinesterase inhibitors include galantamine hydrobromide and rivastigmine tartrate. There are currently no funded acetylcholinesterase inhibitors in New Zealand.

In 2003 PHARMAC completed an economic analysis on acetylcholinesterase inhibitors, which indicated that these medicines were not good value for money compared with other pharmaceuticals that could be funded. These medicines were not, therefore, considered to be a high priority for investment at that time compared to other pharmaceuticals awaiting funding and in 2004 PHARMAC's Board resolved not to fund acetylcholinesterase inhibitors.

In 2008 the Pharmacology and Therapeutics Advisory Committee (PTAC) provided updated advice for acetylcholinesterase inhibitors. A full copy of the relevant minutes from the February 2008 and July 2008 meetings at which these treatments were discussed can be found on PHARMAC's website at [www.pharmac.govt.nz/PTACminutes](http://www.pharmac.govt.nz/PTACminutes).

In summary, PTAC recommended listing acetylcholinesterase inhibitors in the Pharmaceutical Schedule with a low priority under Special Authority criteria similar to those proposed in this consultation document. The Committee considered that all the acetylcholinesterase inhibitors (donepezil hydrochloride, galantamine hydrobromide and rivastigmine tartrate) were similar to the extent that it would be reasonable to choose to fund one over the others based on price.

We note that the cost effectiveness of acetylcholinesterase inhibitors is heavily dependent on price. Having become aware of significant competition within the donepezil hydrochloride market, PHARMAC ran a request for proposals (RFP) in an attempt to obtain the best possible pricing. We have determined that the pricing offered for Donepezil-Rex would allow the funding of donepezil hydrochloride from within the available budget, and that at these prices the cost-effectiveness of donepezil hydrochloride is favourable compared with other possible funding options at this time.

Please note that if this proposal for donepezil hydrochloride is approved, it would not preclude the listing of other acetylcholinesterase inhibitors in the future.

### ***Memantine hydrochloride***

We are also proposing to decline the funding applications for memantine hydrochloride (Ebixa). Memantine hydrochloride is an NMDA glutamate receptor antagonist indicated for treatment of the symptoms of moderate-to-severe Alzheimer's disease.

PHARMAC received an application from Lundbeck to fund memantine hydrochloride for Alzheimer's disease which was reviewed by PTAC in 2004; PTAC recommended that the application be declined. A copy of the relevant minute from this meeting can be found on PHARMAC's website at [www.pharmac.govt.nz](http://www.pharmac.govt.nz), by searching for "memantine".

In May 2005 PTAC reviewed memantine hydrochloride for the treatment of severe behavioural disturbance in patients with moderate-to-severe dementia following an application from the Faculty of Psychiatry of Old Age New Zealand Branch on behalf of the Royal Australian and New Zealand College of Psychiatrists. The Committee deferred making a recommendation pending receipt and review of additional information.

PTAC again reviewed memantine hydrochloride for the treatment of severe behavioural disturbance in patients with moderate-to-severe dementia at its meeting in February 2008 and recommended that the application be declined, on the basis of limited evidence of efficacy, and poor cost-effectiveness. A full copy of the relevant minute from this meeting can be found on PHARMAC's website at [www.pharmac.govt.nz/PTACminutes](http://www.pharmac.govt.nz/PTACminutes).

Please note that if this proposal to decline these funding applications is approved it does not mean that proposals or applications for the funding of memantine hydrochloride could not be considered in the future. Rather, it indicates that PHARMAC would do no further work on the applications that it currently has at this time.