

5 March 2010

Updated proposal to fund donepezil hydrochloride

PHARMAC recently sought feedback on a proposal to fund donepezil hydrochloride for the treatment of Alzheimer's disease, subject to Special Authority restrictions.

Following consideration of responses to consultation on that proposal, PHARMAC now proposes to fund donepezil without restrictions. This would mean that donepezil would be funded when prescribed for any indication, and regardless of whether or not patients are in institutional care.

Funding would occur as soon as possible after registration of the Donepezil-Rex brand, but not before 1 July 2010.

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 Friday, 19 March 2010** to:

Geraldine MacGibbon	Email: geraldine.macgibbon@pharmac.govt.nz
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 updated proposal

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 brand of donepezil hydrochloride, and would have Hospital Supply Status, from the date of listing in the Pharmaceutical Schedule until 30 June 2012.

Background information

We initially proposed that, in addition to the “Details of the updated proposal” set out on page 1 of this document, the listing of Donepezil-Rex in Section B of the Pharmaceutical Schedule would be subject to the following Special Authority restrictions:

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).

While responses to the consultation on the initial proposal were largely supportive, many responders expressed concerns about the proposed Special Authority, such as:

- Some prescribers (eg neurologists and general practitioners with expertise in dementia care) would be prevented from applying for funded access to donepezil for their patients.
- Patients who develop Alzheimer’s disease earlier in life would be excluded from access to funded donepezil.
- Patients with other types of dementia (eg vascular dementia and Lewy Body dementia) who benefit from treatment with donepezil would be excluded from access to funded donepezil.
- Patients in rest homes may continue to benefit from treatment with donepezil but the proposed Special Authority criteria would encourage stopping treatment in patients who are institutionalised.
- The requirement for a Special Authority would place an unnecessary administrative burden on prescribers and the processing system, particularly given the low pricing proposed for Donepezil-Rex (which is lower than some other treatments commonly used to manage dementia and which are currently funded without restrictions).

In light of these concerns PHARMAC has reviewed the need for a Special Authority, and now proposes to list donepezil without restriction.

Several responders considered that it was important for patients with dementia to receive specialist assessment and/or be referred to specialist services. The updated proposal for unrestricted access to funded donepezil would not preclude patients receiving specialist assessment, but it would mean that this would not be a requirement to access funding.

We note that the Special Authority criteria were recommended by the Pharmacology and Therapeutics Advisory Committee at a time when the private market cost of donepezil hydrochloride was substantially higher than that proposed for Donepezil-Rex (\$165.19 per 28 x 5 mg tabs and \$169.50 per 28 x 10 mg tabs). PHARMAC considers that, given the proposed pricing of Donepezil-Rex, any financial risk associated with unrestricted access would be low and acceptable.

Finally, we note that issues raised during the initial consultation that were not specifically related to the proposed Special Authority criteria will be also be considered by PHARMAC’s Board (or Chief Executive acting under delegated authority) prior to making a decision on this updated proposal.