CONSULTATION

PHARMAC
Pharmaceutical Management Agency

**7 August 2014**

## Rivastigmine transdermal patches (Exelon)

PHARMAC is proposing to list rivastigmine transdermal patches (Exelon) on the Pharmaceutical Schedule as a second-line treatment for patients with dementia.

- Rivastigmine transdermal patches (Exelon) would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 November 2014 at the following prices and subsidies (ex-manufacturer, excluding GST):

| Chemical | Presentation | Brand | Strength | Pack size | Price and subsidy |
|---|---|---|---|---|---|
| Rivastigmine | Transdermal patch | Exelon | 4.6 mg per 24 hour | 30 | $90.00 |
| Rivastigmine | Transdermal patch | Exelon | 9.5 mg per 24 hour | 30 | $90.00 |

- A confidential rebate would apply to Exelon which would reduce the net price of the treatment.
- Exelon would have subsidy and delisting protection until 31 October 2017.
- Rivastigmine transdermal patches would be listed subject to the following restrictions in Section B and Part II of Section H of the Pharmaceutical Schedule:

### Section B

**Special Authority for Subsidy**
**Initial application** from any relevant practitioner. Applications valid for 6 months for applications meeting the following criteria:
Both:
1 The patient has been diagnosed with dementia; and
2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

**Renewal** from any relevant practitioner. Applications valid for 12 months for applications meeting the following criteria:
Both:
1 The treatment remains appropriate; and
2 The patient has demonstrated a significant and sustained benefit from treatment.

### Part II of Section H

**Initiation**
Re-assessment required after 6 months
Both:
1 The patient has been diagnosed with dementia; and
2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

**Continuation**
Re-assessment required after 12 months



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Both:
1 The treatment remains appropriate; and
2 The patient has demonstrated a significant and sustained benefit from treatment.

***About rivastigmine***

Rivastigmine is an acetylcholinesterase inhibitor used to treat dementia. It is available in capsule and patch form. Rivastigmine patches are registered in New Zealand for the treatment of mild, moderate and severe dementia of the Alzheimer's type (also termed Alzheimer's disease).

Other medicines in the same therapeutic class as rivastigmine include donepezil, which is funded without restrictions, and galantamine, which is not currently funded. Our clinical advice has been that the three treatments provide broadly similar efficacy.

PTAC has advised that approximately 20% of patients are unable to tolerate the gastrointestinal side effects of donepezil tablets and that this can lead to treatment discontinuation. The Committee noted that patients who are unable to tolerate therapeutic doses of donepezil tablets are unlikely to be able to tolerate any acetylcholinesterase inhibitor taken orally. The Committee considered that there was an unmet clinical need for a different presentation of an acetylcholinesterase inhibitor in these patients and, therefore, recommended that rivastigmine patches be funded subject to the funding criteria outlined in this proposal, with a low priority.

PHARMAC has also received a funding application for rivastigmine capsules, which PTAC has recommended funding only if they were no more expensive than donepezil. Although we are not proposing to fund rivastigmine capsules at this time, this is something we could consider if we were to receive an acceptable commercial proposal or the clinical advice changed.

The minutes for the relevant reviews, and details of the funding applications for rivastigmine, can be found on the PHARMAC website at the following links:

- www.pharmac.govt.nz/ApplicationTracker?ProposalId=180
- www.pharmac.govt.nz/ApplicationTracker?ProposalId=374