

6 May 2009

Proposal to fund mirtazapine for depression

Proposal summary

PHARMAC is seeking feedback on a proposal to fund the antidepressant mirtazapine (Avanza) as soon as possible following receipt of the necessary Medsafe consents, through a provisional agreement with Schering-Plough.

Mirtazapine would be funded subject to Special Authority criteria for patients with major depressive disorder who have tried, but not responded to, at least two previous antidepressants, or who have not responded to one previous antidepressant and have been hospitalised as a result of an acute depressive episode.

Avanza would have protection from delisting and subsidy reduction until 1 July 2012.

Further details of the proposal can be found on the following page.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Friday 22 May 2009** to:

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Therapeutic Group Manager Fax: (04) 460 4995
PHARMAC
PO Box 10-254
Wellington 6143

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

We note that in June 2008 we consulted on the proposed Special Authority criteria for mirtazapine in the context of potentially funding mirtazapine through PHARMAC's annual tender. The tender for mirtazapine was subsequently declined. Relevant responses to that consultation received at the time will be taken into consideration when a decision is made on this current proposal. Relevant responses to the September 2007 consultation on the potential inclusion of mirtazapine in the 2007/08 tender will also be taken into consideration when a decision is made on this proposal.

Further details of the Proposal

Mirtazapine (Avanza) tablets would be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule as soon as possible following receipt of the necessary Medsafe consents at the following prices and subsidies (expressed ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Mirtazapine	Avanza	Tablet 30 mg	30	\$22.00
Mirtazapine	Avanza	Tablet 45 mg	30	\$35.00

Schering-Plough does not intend to register a 15 mg tablet strength of Avanza in New Zealand; however, we note that the 30 mg tablet is scored.

Proposed Special Authority criteria that would apply to the funding of mirtazapine are as follows:

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has a severe major depressive episode; and
- 2 Either:
 - 2.1 The patient must have had a trial of two different antidepressants and failed to respond to an adequate dose over an adequate period of time (usually at least four weeks); or
 - 2.2 Both:
 - 2.2.1 The patient is currently a hospital in-patient as a result of an acute depressive episode; and
 - 2.2.2 The patient must have had a trial of one other antidepressant and failed to respond to an adequate dose over an adequate period of time.

Renewal from any relevant practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

Mirtazapine has been reviewed by the Mental Health Subcommittee of PTAC. The Subcommittee considered that there was an unmet clinical need in patients with severe depression who had not responded adequately to currently funded treatments, and recommended that mirtazapine be listed on the Pharmaceutical Schedule with a medium-to-high priority for this group of patients.

If the Board approves this proposal there would be no other current funding applications under consideration by PHARMAC with regards to mirtazapine; however, we would remain open to receiving future applications for changes to the access criteria or otherwise.