

27 August 2008

Proposal for Strattera (atomoxetine), Humalog Mix 25 and Humalog Mix 50 (insulin lispro with insulin lispro protamine suspension), Zyprexa and Zyprexa Zydis (olanzapine), and Actos (pioglitazone)

Proposal summary

PHARMAC and Eli Lilly have entered into a provisional agreement that would result in funding of a new treatment for Attention Deficit Hyperactivity Disorder (ADHD) and a new insulin treatment for diabetes mellitus, as well as amending the terms of listing of two currently funded pharmaceuticals. The agreement includes the following components:

- Funding atomoxetine (Strattera) as a second-line treatment for ADHD under Special Authority criteria, subject to Medsafe approval of two higher strength tablets.
- Funding insulin lispro with insulin lispro protamine suspension (Humalog Mix 25 and Humalog Mix 50) for the treatment of diabetes mellitus.
- Amending the terms of listing of olanzapine (Zyprexa and Zyprexa Zydis) and pioglitazone (Actos), without changing access criteria.

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

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **5 pm, Thursday 11 September 2008** to:

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All feedback received before the closing date will be considered when a decision is made on this proposal by PHARMAC's Board.

The details of the proposal

We have entered into a provisional agreement with Eli Lilly and Company (NZ) Limited to list atomoxetine (Strattera) and insulin lispro with insulin lispro protamine suspension (Humalog Mix 25 and Humalog Mix 50) in Section B and in Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

| Pharmaceutical | Brand | Form and Strength | Pack Size | Proposed price & subsidy |
|---|----------------|--|------------------|-------------------------------------|
| Atomoxetine | Strattera | Capsule 10 mg | 28 | \$107.03 |
| Atomoxetine | Strattera | Capsule 18 mg | 28 | \$107.03 |
| Atomoxetine | Strattera | Capsule 25 mg | 28 | \$107.03 |
| Atomoxetine | Strattera | Capsule 40 mg | 28 | \$107.03 |
| Atomoxetine | Strattera | Capsule 60 mg | 28 | \$107.03 |
| Atomoxetine | Strattera | Capsule 80 mg | 28 | \$139.11 |
| Atomoxetine | Strattera | Capsule 100 mg | 28 | \$139.11 |
| 25% insulin lispro with 75% insulin lispro protamine suspension | Humalog Mix 25 | Solution for injection, 100 u per ml, 3 ml | 5 cartridges | \$52.15 |
| 50% insulin lispro with 50% insulin lispro protamine suspension | Humalog Mix 50 | Solution for injection, 100 u per ml, 3 ml | 5 cartridges | \$52.15 |

- The listing of Strattera would occur as soon as is practicable subject to Medsafe approval of the 80 mg and 100 mg strengths, but not before 1 November 2008.
- The listing of Humalog Mix 25 and Humalog Mix 50 would occur on 1 November 2008.
- Strattera would be subject to the following Special Authority for subsidy:

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Once-daily dosing; and
- 2 Any of:
 - 2.1 Treatment with a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of stimulant treatment with another agent would pose an unacceptable medical risk; or
 - 2.2 Treatment with a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with stimulant therapy; or
 - 2.3 An effective dose of a stimulant has been trialled and has been discontinued because of inadequate clinical response; and
- 3 The patient will not be receiving treatment with atomoxetine in combination with a stimulant.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

- Humalog Mix 25 and Humalog Mix 50 would be funded without Special Authority restriction.
- Confidential rebates would apply to Humalog Mix 25, Humalog Mix 50 and Strattera, reducing the net subsidy paid for these products.
- New, confidential, rebates would apply to Zyprexa and Zyprexa Zydis (olanzapine) and Actos (pioglitazone), while the listings of these two pharmaceuticals in the Pharmaceutical Schedule would remain unchanged.
- Humalog Mix 25, Humalog Mix 50 and Strattera would have protection from subsidy reduction and delisting until 1 July 2013.
- Actos would have protection from delisting and subsidy reduction until 1 July 2009 (as is the case currently).

Background information

Strattera

The Pharmacology and Therapeutics Advisory Committee (PTAC) has reviewed an application to fund atomoxetine (Strattera) for the treatment of ADHD. The Committee recommended that atomoxetine be listed in the Pharmaceutical Schedule with a medium priority subject to the Special Authority criteria outlined earlier in this consultation letter.

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

Humalog Mix 25 and Humalog Mix 50

PTAC has reviewed an application to fund insulin lispro 25% with 75% insulin lispro protamine suspension (Humalog Mix 25) for the treatment of diabetes mellitus. The Committee recommended that Humalog Mix 25 be listed in the Pharmaceutical Schedule only if cost-neutral to the Pharmaceutical Budget (in particular, cost-neutral against human insulin 30/70).

In addition, PTAC considered that Humalog Mix 50 may be useful for patients with significant postprandial blood glucose peaks whose diabetes is not controlled by human insulin 30/70 or Humalog Mix 25.

PHARMAC has taken the above factors and others into account in developing this multiproduct proposal.