

12 October 2015

Levetiracetam and lamotrigine proposal with REX Medical Ltd

PHARMAC is seeking feedback on a proposal involving levetiracetam and lamotrigine, resulting from a provisional agreement with REX Medical Ltd. Both medicines are already listed in the Pharmaceutical Schedule in the Nervous System, Antiepilepsy Drugs, Therapeutic Group.

The proposal would result in:

- a reduction in expenditure for levetiracetam tablets;
- a new brand name for Levetiracetam-Rex (the brand name Levetiracetam-Rex will change to Everet);
- listing a new 1000 mg strength of levetiracetam tablet; and
- listing a new brand of lamotrigine dispersible tablets: 25 mg, 50 mg, and 100 mg (Motrig).

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 26 October 2015** to:

Adrienne Martin
Senior Therapeutic Group Manager/Team
Leader
PHARMAC
PO Box 10 254
Wellington 6143

Email: adrienne.martin@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposal

Levetiracetam-Rex

- Levetiracetam-Rex would remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule until 1 August 2016 at the following prices (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Levetiracetam	Tab 250 mg	Levetiracetam-Rex	60 tablets	\$24.03	\$24.03*
Levetiracetam	Tab 500 mg	Levetiracetam-Rex	60 tablets	\$28.71	\$28.71*
Levetiracetam	Tab 750 mg	Levetiracetam-Rex	60 tablets	\$45.23	\$45.23*

- *From 1 February 2016, a confidential rebate would apply to Levetiracetam-Rex, reducing the net price paid by the Funder.
- From 1 August 2016, Levetiracetam-Rex would be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule.

Everet

- Everet, including a 1000 mg tablet strength, would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 February 2016 at the following prices (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Levetiracetam	Tab 250 mg	Everet	60 tablets	\$24.03*
Levetiracetam	Tab 500 mg	Everet	60 tablets	\$28.71*
Levetiracetam	Tab 750 mg	Everet	60 tablets	\$45.23*
Levetiracetam	Tab 1,000 mg	Everet	60 tablets	\$59.12*

- * A confidential rebate would apply to Everet, reducing the net price paid by the Funder.
- Everet would have subsidy and delisting protection until 31 January 2019.

- The net price of Everet would be published in the Pharmaceutical Schedule from 1 November 2018.
- The proposed listing of Everet reflects a brand name change for Levetiracetam-Rex, there would be no changes to the formulation or manufacturing of the product.

Motrig

- Motrig would be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 July 2016 at the following prices (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Current and proposed price and subsidy
Lamotrigine	Tab dispersible 25 mg	Motrig	56 tablets	\$14.74
Lamotrigine	Tab dispersible 50 mg	Motrig	56 tablets	\$24.73
Lamotrigine	Tab dispersible 100 mg	Motrig	56 tablets	\$42.34

Background

In response to PHARMAC's consultation on the 2015/16 Invitation to Tender product list, REX Medical Ltd submitted an alternative commercial proposal (ACP) involving Levetiracetam-Rex, Everet, and Motrig.

Levetiracetam and lamotrigine are both listed in the Pharmaceutical Schedule in the Antiepilepsy Drugs, Control of Epilepsy area of the Nervous System Therapeutic Group. Levetiracetam is indicated, as an add-on therapy, in the treatment of epilepsy. Lamotrigine is indicated, as adjunctive therapy, in the treatment of epilepsy and for the prevention of mood disorders in patients with bipolar disorder.

This ACP forms the basis of PHARMAC's provisional agreement with REX Medical Ltd and, if approved, would result in Levetiracetam-Rex, Everet, and Motrig being fully funded, subject to the provisional agreement's terms.