CONSULTATION

PHARMAC
Pharmaceutical Management Agency

14 June 2013

Proposal involving diazepam, gabapentin, naltrexone and venlafaxine

PHARMAC is seeking feedback on provisional agreements with Arrow Pharmaceuticals (NZ) Limited for the supply of its brands of diazepam, gabapentin, naltrexone and venlafaxine in Section B and in Part II of Section H of the Pharmaceutical Schedule, and to apply reference pricing to the Nupentin brand of gabapentin. In summary, this proposal would result in:

- the subsidy and delisting protection for diazepam 2 mg and 5 mg tablets (Arrow-Diazepam) being extended from 30 June 2014 (the current protection date) to 30 June 2017;
- Arrow-Gabapentin (gabapentin 100 mg, 300 mg and 400 mg capsules) being listed in the Pharmaceutical Schedule from 1 December 2013 subject to the same restrictions that apply to the Nupentin brand of gabapentin;
- the subsidy for the Nupentin brand of gabapentin 300 mg and 400 mg capsules in Section B of the Pharmaceutical Schedule being reduced to the level of the Arrow-Gabapentin subsidies via the application of reference pricing from 1 March 2014. This would mean that if the supplier of Nupentin did not reduce its price to match the new subsidy, patients would need to switch brands to remain on a fully funded brand of gabapentin;
- access to naltrexone 50 mg tablets (Naltraccord) being widened in Section B of the Pharmaceutical Schedule from 1 August 2013 via extension of the Special Authority approval periods from 3 to 6 months, in conjunction with a price decrease;
- the restrictions being removed from the Arrow-Venlafaxine XR brand of venlafaxine 37.5 mg, 75 mg, 150 mg and 225 mg tablets from 1 August 2013, in conjunction with a price decrease. The Efexor XR brand of venlafaxine 37.5 mg, 75 mg and 150 mg capsules would remain subject to the same restrictions that currently apply to it.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm on Friday, 28 June 2013** to:

Geraldine MacGibbon
Therapeutic Group Manager
PHARMAC

Email: geraldine.macgibbon@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143

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

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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

Diazepam

- There would be no change to the listing of diazepam 2 mg and 5 mg tablets (Arrow-Diazepam) in the Pharmaceutical Schedule. Subsidy and delisting protection for Arrow-Diazepam would be extended from 30 June 2014 (the current protection date) to 30 June 2017.

Gabapentin

- Arrow-Gabapentin would be listed in Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 December 2013 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Gabapentin	Cap100 mg	Arrow-Gabapentin	100	$7.16
Gabapentin	Cap 300 mg	Arrow-Gabapentin	100	$11.00
Gabapentin	Cap 400 mg	Arrow-Gabapentin	100	$13.75

- Arrow-Gabapentin would be listed in the Pharmaceutical Schedule subject to the same restrictions that apply to the Nupentin brand of gabapentin (Special Authority in Section B, prescribing restrictions in Part II of Section H).

- From 1 March 2014 the subsidies for the Nupentin brand of gabapentin would be reduced in Section B of the Pharmaceutical Schedule to the level of the subsidies for the Arrow-Gabapentin brand through the application of reference pricing as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed subsidy (and price, where different*)
Gabapentin	Cap 100 mg	Nupentin	100	$7.16	$7.16
Gabapentin	Cap 300 mg	Nupentin	100	$11.50	$11.00 ($11.50)

Gabapentin	Cap 400 mg	Nupentin	100	$14.75	$13.75 ($14.75)

*If the supplier of Nupentin did not reduce its price to match the new subsidy, it would result in a manufacturer's surcharge applying to Nupentin cap 300 mg and 400 mg.

Naltrexone

- The price and subsidy for Naltraccord would be reduced in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 August 2013 as follows (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Naltrexone	Tab 50 mg	Naltraccord	30	$79.00*	$76.00

*currently listed at $123.00 but due to reduce to $79.00 from 1 July 2013 as a result of a tender decision which has been notified separately (www.pharmac.health.nz/news/item/tender-results-february-2013)

- Access to Naltraccord would be widened in Section B of the Pharmaceutical Schedule from 1 August 2013 by amending the Special Authority criteria as follows (deletions in ~~strikethrough~~, additions in **bold**):

> Initial application from any medical practitioner. Approvals valid for ~~3~~ **6** months for applications meeting the following criteria:
> Both:
> 1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
> 2 Applicant works in or with a community Alcohol and Drug Service contracted to one of the District Health Boards or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard.
>
> Renewal from any medical practitioner. Approvals valid for ~~3~~ **6** months for applications meeting the following criteria:
> Both:
> 1 Compliance with the medication (prescriber determined); and
> 2 Any of the following:
> 2.1 Patient is still unstable and requires further treatment; or
> 2.2 Patient achieved significant improvement but requires further treatment; or
> 2.3 Patient is well controlled but requires maintenance therapy.
>
> ~~The patient must not have had more than 1 prior approval in the last 12 months.~~

- Naltraccord would retain its Sole Subsidised Supply Status and Hospital Supply Status until 30 June 2016 as previously notified.

Venlafaxine

- The price and subsidy for Arrow-Venlafaxine XR would be reduced in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 August 2013 as follows:(ex-manufacturer, excluding GST):

Brand of venlafaxine	Presentation	Pack size	Current price and	Price and subsidy	Proposed price and subsidy

			subsidy	from 1 July 2013*	from 1 August 2013
Arrow-Venlafaxine XR	Tab 37.5 mg	28	$12.67	$7.84	$5.06
Arrow-Venlafaxine XR	Tab 75 mg	28	$19.00	$13.94	$6.44
Arrow-Venlafaxine XR	Tab 150 mg	28	$23.41	$17.08	$8.86
Arrow-Venlafaxine XR	Tab 225 mg	28	$35.12	$27.14	$14.34

*scheduled price reductions in the current agreement with Arrow.

- The Special Authority that currently applies to the Arrow-Venlafaxine XR brand of venlafaxine tablets listed in Section B of the Pharmaceutical Schedule would be removed from 1 August 2013. The hospital restrictions would also be removed from the Arrow-Venlafaxine XR brand of venlafaxine tablets from 1 August 2013.

- The Special Authority (and hospital restrictions from 1 July 2013) that currently applies to the Efexor XR brand of venlafaxine capsules would remain in place.

Background

The proposals in this consultation letter are essentially commercial transactions involving pharmaceuticals that are already funded. Two of the proposals (naltrexone and venlafaxine) would result in widening of access and one would result in reference pricing (gabapentin).

We note that in 2008 the Pharmacology and Therapeutics Advisory Committee (PTAC) reviewed an application to widen access to naltrexone as proposed, and recommended that the application be declined on the basis of lack of compelling evidence (minutes available at www.pharmac.govt.nz/2008/08/27/2008-05%20PTAC%20Minutes.pdf). Since then we have received advice from addiction specialists that there is a small proportion of patients who would receive significant benefit from extended treatment with naltrexone, which would be addressed by this proposal. We consider that, in addition to the stated clinical benefit, the proposal is commercially acceptable in the context of recent and proposed price reductions for naltrexone.

We are aware that clinicians would like to see access to naltrexone widened further than proposed in this letter and we intend to take advice from the relevant advisory committees about this in the coming months.