PHARMAC
Pharmaceutical Management Agency

MEMORANDUM FOR BOARD MEETING 30 SEPTEMBER 2016

To: PHARMAC Directors

From: Chief Executive

Date: September 2016

Decision to award sole supply of venlafaxine in the community and DHB hospitals

Recommendations

It is recommended that having regard to the Factors for Consideration set out in PHARMAC's Operating Policies and Procedures you:

resolve to accept the Request For Tenders (RFT) bid from Mylan New Zealand Limited (Mylan) for its Enlafax XR brand of venlafaxine capsules to be the sole subsidised brand of the community pharmaceuticals venlafaxine cap 37.5 mg, 75 mg and 150 mg from 1 September 2017 until 30 June 2020;

resolve to accept the RFT bid from Mylan for its Enlafax XR brand of venlafaxine capsules to be the Hospital Supply Status brand of the hospital pharmaceuticals venlafaxine cap 37.5 mg, 75 mg and 150 mg from 1 June 2017 until 30 June 2020 with a 1% DV Limit;

resolve to list Enlafax XR (venlafaxine 37.5 mg, 75 mg and 150 mg capsules) under the Other Antidepressants subheading of the Nervous System Therapeutic Group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 April 2017 as follows:

Chemical	Presentation	Brand	Pack Size	Subsidy and price (ex-man., ex. GST)
Venlafaxine	Cap 37.5 mg	Enlafax XR	84	$ 6.38
Venlafaxine	Cap 75 mg	Enlafax XR	84	$ 8.11
Venlafaxine	Cap 150 mg	Enlafax XR	84	$11.16

resolve to apply reference pricing to the other listings of venlafaxine tablets and capsules in Section B of the Pharmaceutical Schedule from 1 June 2017 as follows:

Chemical and presentation	Brand	Pack Size	Current subsidy and price (ex-man., ex. GST)	New subsidy (ex-man., ex. GST)
Venlafaxine Tab 37.5 mg	Arrow-Venlafaxine XR	28	$5.06	$2.13
Venlafaxine Tab 75 mg	Arrow-Venlafaxine XR	28	$6.44	$2.70
Venlafaxine Tab 150 mg	Arrow-Venlafaxine XR	28	$8.86	$3.72
Venlafaxine Tab 225 mg	Arrow-Venlafaxine XR	28	$14.34	$8.10

Venlafaxine Cap 37.5 mg	Efexor XR	28	$5.69	$2.13
Venlafaxine Cap 75 mg	Efexor XR	28	$11.40	$2.70
Venlafaxine Cap 150 mg	Efexor XR	28	$13.98	$3.72

resolve to remove the Special Authority and Hospital Restrictions for venlafaxine cap 37.5 mg, 75 mg and 150 mg in Section B and Part II of Section H of the Pharmaceutical Schedule (as applicable) from 1 June 2017;

resolve to apply the stat dispensing rule to venlafaxine in Section B of the Pharmaceutical Schedule from 1 December 2017;

resolve to delist the following venlafaxine brands from Section B of the Pharmaceutical Schedule on 1 September 2017:

Chemical and presentation	Supplier	Brand	Pack Size
Venlafaxine Tab 37.5 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 75 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 150 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 225 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Cap 37.5 mg	Pfizer	Efexor XR	28
Venlafaxine Cap 75 mg	Pfizer	Efexor XR	28
Venlafaxine Cap 150 mg	Pfizer	Efexor XR	28

resolve to delist the following venlafaxine brands from Part II of Section H of the Pharmaceutical Schedule on 1 June 2017:

Chemical and presentation	Supplier	Brand	Pack Size
Venlafaxine Tab 37.5 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 75 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 150 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Tab 225 mg	Actavis	Arrow-Venlafaxine XR	28
Venlafaxine Cap 37.5 mg	Pfizer	Efexor XR	28
Venlafaxine Cap 75 mg	Pfizer	Efexor XR	28
Venlafaxine Cap 150 mg	Pfizer	Efexor XR	28

resolve to list on 1 September 2017 and delist on 1 December 2017 in the Various Section of Section B of the Pharmaceutical Schedule the following brand switch fee:

Chemical and presentation	Brand	Pack Size	Subsidy and price (ex-man., ex. GST)
Pharmacy Services, Brand switch fee (BSF)	BSF Enlafax XR	1 fee	$4.50
May only be claimed once per patient			

resolve to add a note to the following chemical as listed in Section B of the Pharmaceutical Schedule from 1 September 2017 and delist on 1 December 2017 as follows (changes in bold):

VENLAFAXINE **– Brand Switch Fee payable**

Cap 37.5 mg	6.38	84	√ Enlafax XR
Cap 75 mg	8.11	84	√ Enlafax XR
Cap 150 mg	11.16	84	√ Enlafax XR

resolve that the consultation on this proposal was appropriate, and no further consultation is required; and

note that an implementation plan has been developed to manage the specific challenges of the proposed brand switch.

SUMMARY OF PHARMACEUTICAL			
Brand name	Enlafax XR	**Chemical name**	Venlafaxine
Therapeutic Group	Other Antidepressants - Nervous System	**Presentation**	Capsules, Cap 37.5 mg, Cap 75 mg, Cap 150 mg
Supplier	Mylan New Zealand Ltd	**Pharmaceutical type**	Generic
MoH Restriction	Prescription medicine	**Application date**	N/A
Section F	No	**Original pack**	No
Proposed restriction	0		

Brand - Formulation - Packsize	Current subsidy	Proposed subsidy	Price
Efexor XR - Cap 37.5 mg - 28	$8.71	$0.00	$0.00
Efexor XR - Cap 75 mg - 28	$17.42	$0.00	$0.00
Efexor XR - Cap 150 mg - 28	$21.35	$0.00	$0.00
Arrow-Venlafaxine XR - Tab 37.5 mg - 28	$5.06	$0.00	$0.00
Arrow-Venlafaxine XR - Tab 75 mg - 28	$6.44	$0.00	$0.00
Arrow-Venlafaxine XR - Tab 150 mg - 28	$8.86	$0.00	$0.00
Arrow-Venlafaxine XR - Tab 225 mg - 28	$14.34	$0.00	$0.00
Enlafax XR - Cap 37.5 mg - 84	$0.00	$6.38	$6.38
Enlafax XR - Cap 75 mg - 84	$0.00	$8.11	$8.11
Enlafax XR - Cap 150 mg - 84	$0.00	$11.16	$11.16

Market data	Year ending	30 Jun 2017	30 Jun 2018	30 Jun 2019
Number of patients		48,675	51,535	53,835
Number of Maori or PI people		3,894	4,123	4,307
Combined Pharmaceuticals	Subsidy (gross)	$7,230,000	$2,710,000	$2,800,000
	Net cost to Schedule	($440,000)	($5,250,000)	($5,400,000)
	Net present value	($18,350,000)		
	Net distribution costs	($18,000)	($330,000)	($740,000)
	Net cost to DHBs	($460,000)	($5,580,000)	($6,140,000)
	Net present value	($20,460,000)		
Hospital Pharmaceuticals	Expenditure (gross)	$39,000	$15,000	$15,000
	Net cost to DHBs	($2,000)	($26,000)	($26,000)
	Net present value	($89,000)		
Other DHB costs	Net cost to DHBs	$0	$0	$0
Total	Total cost to DHBs	($460,000)	($5,600,000)	($6,160,000)
	Net present value	($20,550,000)		

Notes:
1. Subsidy (gross) and expenditure (gross) = forecast of spending at the proposed price and subsidy.
2. Net cost to DHBs = forecast of change in spending compared with status quo.
3. All pharmaceutical costs are ex-manufacturer.
4. All costs are ex-GST.
5. NPV is calculated over 5 years using an annual discount rate of 8%.
6. Calculations are in A930516.

Executive Summary

- The proposal is to move to a sole supply arrangement for venlafaxine, without restrictions, following a transition commencing from 1 April 2017. The stat dispensing rule would be applied to venlafaxine following a brand change transition settling in period, from 1 December 2017.
- In June 2016, PHARMAC invited tenders for the sole supply of venlafaxine to DHB hospitals and/or community pharmacies. This proposal to award tenders for Sole Subsidised Supply Status and Hospital Supply Status to Mylan for its Enlafax XR brand of venlafaxine capsules is the result of that tender process.
- Venlafaxine is a serotonin noradrenaline reuptake inhibitor (SNRI) indicated for the treatment of major depression, generalised anxiety disorder, social anxiety disorder and panic disorder. Current annual expenditure on venlafaxine is $7.25 million in the community (financial year ending 30 June 2016).
- PHARMAC currently lists and fully subsidises two brands of venlafaxine in Section B and Part II of Section H of the Pharmaceutical Schedule: Efexor XR capsules (supplied by Pfizer) and Arrow-Venlafaxine XR tablets (supplied by Actavis). Efexor XR capsules are only funded via Special Authority for patients with treatment-resistant depression. Arrow-Venlafaxine XR tablets are listed without restriction.
- The proposal is expected to generate savings of approximately $18.4 million to the Combined Pharmaceutical Budget (CPB) and $20.5 million to DHBs overall including hospital savings (5-year NPV, 8% discount rate).
- This proposal would result in a brand switch for the 45,000 people in New Zealand currently receiving venlafaxine, 73% of whom are dispensed venlafaxine over a period greater than four months (chronically). We consider that this brand switch would be potentially challenging but manageable with appropriate communication and implementation resources, as per the implementation activities plan and in combination with a brand switch fee.
- A comprehensive implementation plan has been developed that would ensure patient disruption as a result of the brand switch is well managed should the Board approve this proposal.

[redacted]

The Proposal

It is proposed that:

- Sole Subsidised Supply status in relation to venlafaxine capsules: 37.5 mg, 75 mg and 150 mg is awarded to Mylan for its Enlafax XR brand from 1 September 2017 until 30 June 2020.
- Hospital Supply Status in relation to venlafaxine capsules: 37.5 mg, 75 mg and 150 mg is awarded to Mylan for its Enlafax XR brand from 1 June 2017 until 30 June 2020, with a 1% DV limit.
- Stat dispensing is applied to all three strengths of venlafaxine (Enlafax XR) in Section B of the Pharmaceutical Schedule from 1 December 2017.

Mylan's proposal was selected as the preferred proposal by an Evaluation Committee of PHARMAC staff.

[redacted]

In addition, it was noted by the Evaluation Committee that Mylan's capsule presentation may be more suitable for assisting in a switch from Efexor XR capsules. Venlafaxine is recognised as a difficult brand switch because of the patient group and the disease. Whilst not usually considered to be a major issue in the selection of pharmaceuticals a switch to a more dissimilar product would add an additional burden to a change resistant patient group.

Following recommendations from the Evaluation Committee, PHARMAC staff entered into post tender negotiations with the Mylan for:

- The addition of an Alternative Brand Allowance clause whereby, PHARMAC reserves the right to subsidise an alternative brand (e.g. Efexor XR) for up to 100 patients in the community for a maximum of 12 months. This is a safety net that would allow PHARMAC to extend the transition to Enlafax XR for up to 100 patients with extreme difficulties in switching brands; and
- A change in pack size, from 90 to 84 capsules with the calendar pack foil – as this would be similar to the Efexor XR packaging and may help with transitioning patients. This is discussed further under the Suitability factor.

[redacted]

The tender agreement between Mylan and PHARMAC (dated 15 June 2016) which is conditional on consultation and approval by PHARMAC's Board is attached in Appendix 1, together with an amendment letter, regarding an Alternative Brand Allowance clause.

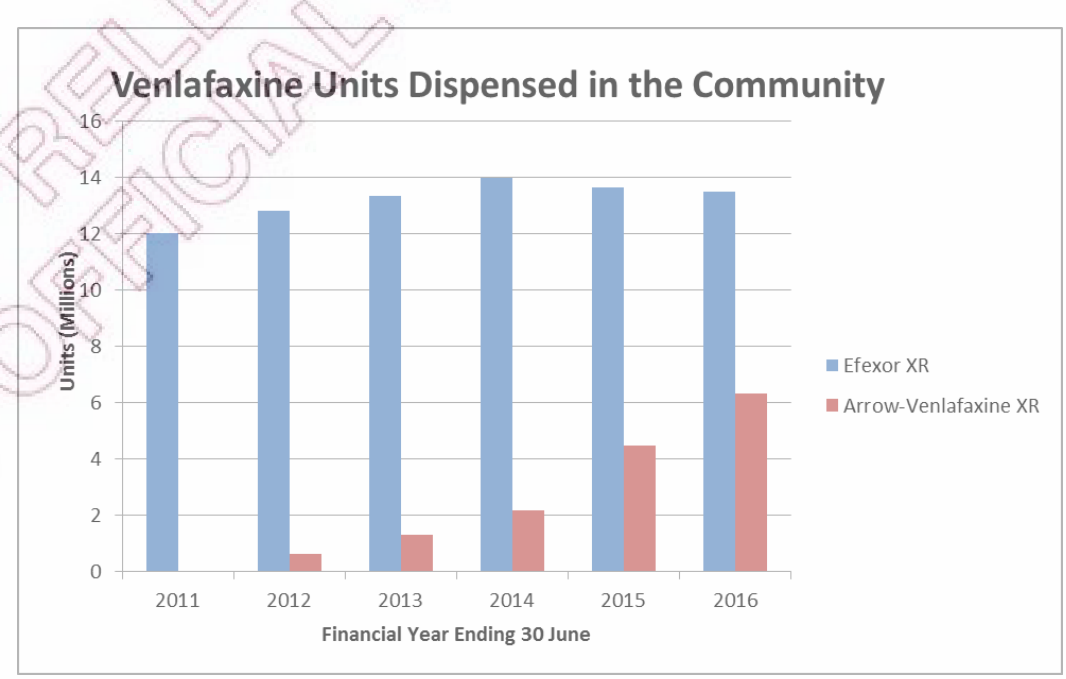
Background

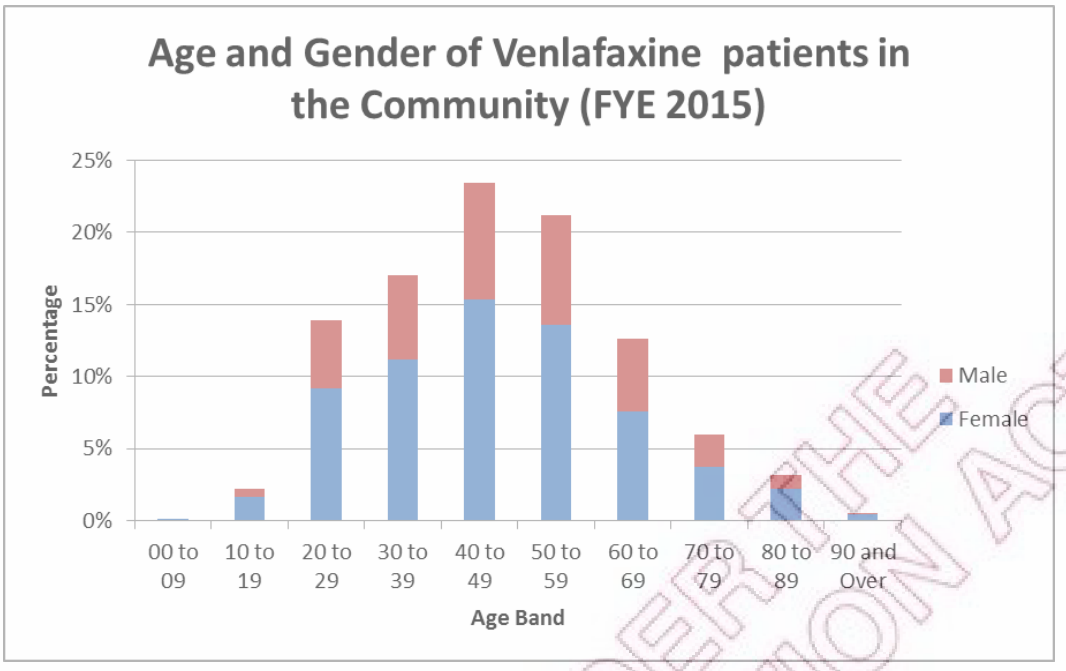
Commercial and Legal History

- The Efexor XR brand of venlafaxine capsules was originally listed on the Pharmaceutical Schedule in January 2004, subject to Special Authority.
- Venlafaxine was included in the December 2006 Invitation to Tender, which was the first time a competitive process had been run for the supply of this pharmaceutical. In July 2007 the Board declined to award a Tender for venlafaxine [redacted]
- In July 2007 PHARMAC issued an RFP for the supply of venlafaxine. [redacted]
- [redacted]
- [redacted]
- PHARMAC later listed the Arrow-Venlafaxine XR brand of venlafaxine tablets, [redacted]
- Arrow-Venlafaxine XR tablets are listed without any restriction, whereas Efexor XR capsules are only funded for patients with treatment-resistant depression via Special Authority.

Current Market Overview – Usage and Expenditure

- In the financial year ending 30 June 2016, the annual expenditure on venlafaxine was $7.25 million in the community and more than 70% of the 45,000 patients were dispensed venlafaxine over a period greater than four months (chronically).
- Despite being restricted via Special Authority, Efexor XR has retained 68% of the market (units dispensed) since Arrow was listed. We attribute this to an aggressive marketing campaign by Pfizer along with significant brand loyalty which is common with antidepressant treatments. Efexor-XR accounted for $5.59 million (77%) of the $7.25 million spent in the community.
- The majority of patients are aged between 20 and 70 and there is an approximate 2:1 ratio of female to male patients across all age bands.





RFT Process

- In June 2016 PHARMAC issued an RFT seeking responses for community Sole Subsidised Supply status and Hospital Supply Status, with a discretionary variance (DV) limit of 1% in DHB hospitals, to commence after the current subsidy and delisting protections expire on 31 March 2017 and to run until 30 June 2020, for the currently listed strengths of venlafaxine. The RFT was limited to extended-release formulations.
- The RFT noted that PHARMAC may award sole supply for venlafaxine capsules and/or tablets with a range made up of just the 37.5, 75 and 150 mg presentations. If that was the case, this would result in the 225 mg presentation being delisted.

Summary of proposals received

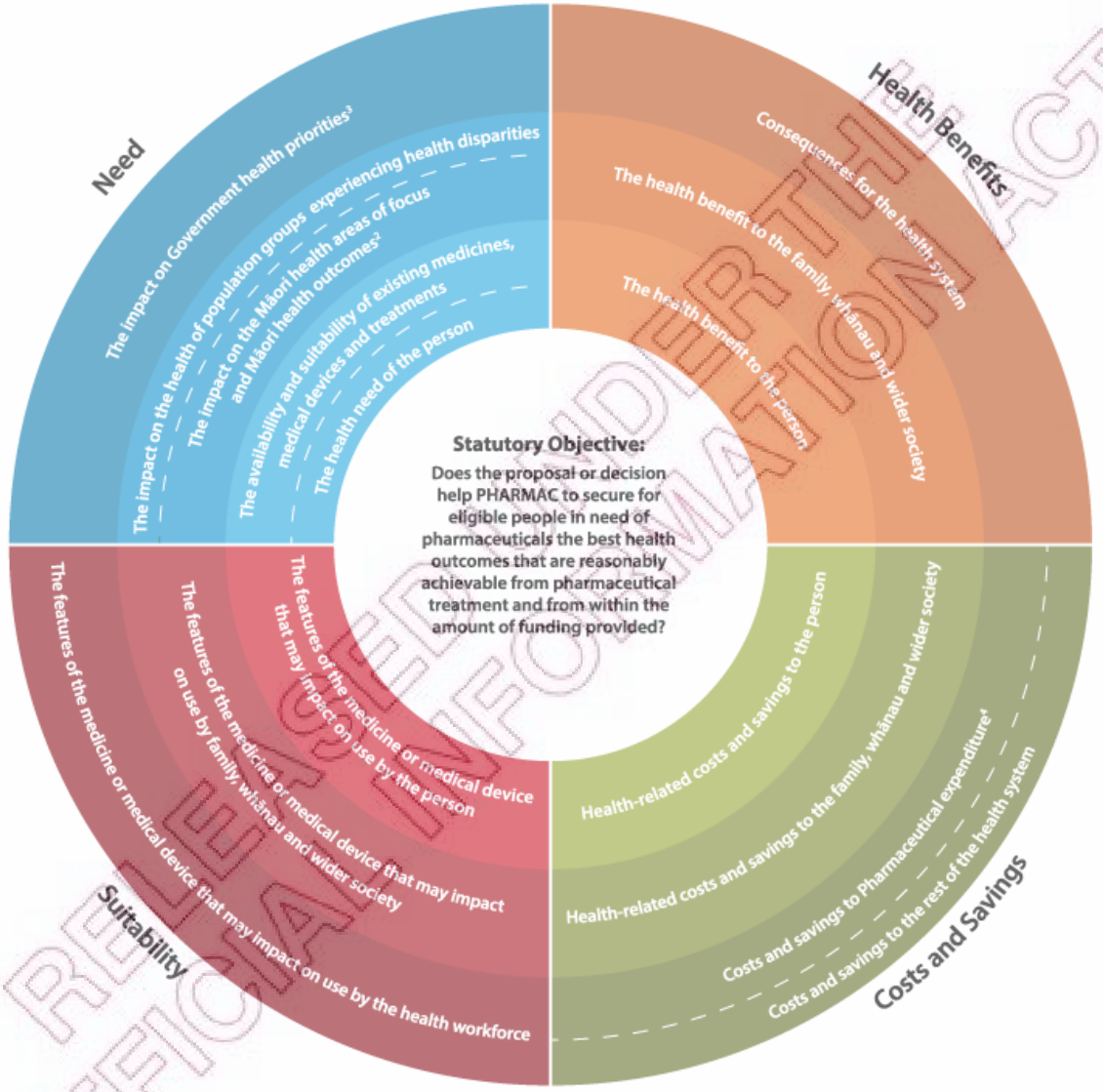
- [redacted]

Evaluation of proposals

- The Evaluation Committee assessed the proposals 28 July August 2016 (minutes attached in Appendix 2).

Factors for Consideration

This paper sets out PHARMAC staff's assessment of the proposal using the Factors for Consideration in the Operating Policies and Procedures. Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. The Board is not bound to accept PHARMAC staff's assessment of the proposal under the Factors for Consideration and may attribute different significance to each of the Factors from that attributed by PHARMAC staff.



Footnotes

[1] The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000.

[2] The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy.

[3] Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

[4] Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate).

[5] Please note PHARMAC's Factors for Consideration schematic currently does not explicitly refer to the health needs of family, whānau and wider society, but this factor should be considered alongside those depicted in the schematic.

Factors for Consideration

Health need

Disease/illness

Venlafaxine is a serotonin-noradrenaline reuptake inhibitor (SNRI) indicated for the treatment of major depression, generalised anxiety disorder, social anxiety disorder and panic disorder.

Availability and suitability of existing treatments

PHARMAC currently lists and fully funds 17 pharmaceuticals for the treatment of depression and related indications, including venlafaxine:

Antidepressants subheading	Chemical
Cyclic and Related Agents	amitriptyline, clomipramine, dothiepin, doxepin, imipramine, maprotiline, nortriptyline
Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective	phenelzine, tranylcypromine
Monoamine-Oxidase Type A Inhibitors	moclobemide
Selective Serotonin Reuptake Inhibitors (SSRIs)	citalopram, fluoxetine, escitalopram, sertraline, paroxetine
Other Antidepressants	venlafaxine, mirtazapine

As previously noted, PHARMAC currently lists and fully subsidises two brands of venlafaxine. Arrow-Venlafaxine XR tablets are listed without any restriction, whereas Efexor XR capsules are only funded for patients with treatment-resistant depression via Special Authority.

Should the proposal be approved this would result in:

- Continued funding of venlafaxine;
- An open listing of venlafaxine for the Enlafax XR brand with no restrictions; and
- The delisting of the Arrow-Venlafaxine XR 225 mg tablet presentation, which is currently received by approximately 1,500 patients. These patients would need to change to a dose of two or more Enlafax XR capsules (3 x 75 mg or 1 x 150 mg + 1 x 75 mg) in order to remain on funded venlafaxine treatment.

Health need of others

The health need of others would be unchanged as a result of this proposal.

Impact on Māori health areas of focus and health outcomes

Mental health is a Māori health area of focus (as outlined in the Te Whaioranga Strategy). Usage of venlafaxine by Māori is about 8%, which is 50% below the proportion of Māori in the general population. We consider that this proposal is unlikely to have a significant clinical impact on Māori, as patients would continue to have access to a fully funded brand.

Any other populations experiencing health disparities

We are not aware of any particular population among the various indications for venlafaxine that would be experiencing health disparities and who might be impacted by this proposal.

Government health priorities

In the Minister of Health's 2016/17 letter of expectations to PHARMAC, it was outlined that the Minister expects PHARMAC to manage brand switches and high profile decisions carefully. Other current Government priorities appear to be not directly relevant to this proposal. A description of how PHARMAC would plan to manage this brand switch is provided later in this paper.

Health Benefit

Clinical advice

Advice was sought from the Mental Health Subcommittee of PTAC by email on 2 August 2016 with regard to implementation activities, the transition period and stat dispensing.

In summary, the five responses were supportive of the actions PHARMAC staff proposed with regard to the potential brand switch.

- The Subcommittee did not have any further implementation advice for the potential brand switch beyond the activities that PHARMAC staff had suggested.
- The majority of responses from Subcommittee members did not see any benefit in extending the second transition period out to 6 months, from the usual 3 months.
    - One member noted that some patients may only have an appointment with their prescriber every three months and there was a risk that the prescriber may miss the opportunity to discuss a brand switch. However they noted that strong pharmacy input would be key to assisting the patients' transition.
- The Subcommittee supported a change to stat dispensing – noting that overdose safety concerns would need to be managed by clinicians, as they are currently for many other pharmaceuticals on stat dispensing.

A full copy of the request for advice and all responses can be found in Appendix 3.

Health benefit to others

The health benefit to others would be unchanged as a result of this proposal.

Consequences for the health system

The removal of Special Authority from venlafaxine capsules would result in a reduction of Special Authority requests needing to be processed by Sector Services. There are approximately 27,550 patients with a Special Authority approval for Efexor-XR and the applications are required to be initiated by a relevant specialist or vocationally registered general practitioner and renewed after two years, as required, by any medical practitioner.

Suitability

Registration Status

Enlafax XR was registered with Medsafe on 12 March 2009. The reference product used in the registration application was Efexor-XR capsules.

PHARMAC staff note that the 84 blister pack of Enlafax XR is not currently registered with Medsafe. The registered pack size is a 28 blister pack. Should the proposal be approved then Mylan would register the additional pack size with Medsafe. It is not expected that this would impact on the proposed timelines.

Indications

Enlafax XR is registered for the same indications as the currently funded brands of venlafaxine.

Appearance

Our understanding is that patients have a strong brand loyalty to the Efexor XR brand of venlafaxine, which has been listed on the Pharmaceutical Schedule since 2004. Pfizer has actively marketed Efexor-XR directly to patients through various media including television.

Arrow-Venlafaxine was listed in 2011 without a Special Authority, which was intended to reduce the administrative burden for prescribers and widen access to new prescriber and patient groups. Despite this, Pfizer's Efexor-XR still accounted for 68% of the total amount of units dispensed in the financial year ending 30 June 2016.

The appearance of the proposed Enlafax XR capsules is similar to the Efexor-XR capsules. There is a slight difference in appearance with the 37.5 mg presentation where the proposed Enlafax XR capsule is larger and a single colour. Key comparisons between Enlafax XR and the currently funded brands are detailed below:

Strength	Variations	Currently listed Arrow-Venlafaxine XR	Currently listed Efexor XR	Proposed Enlafax XR
37.5 mg	Size Capsule contents Colour Marking	Round tablet Φ 7 mm N/A White None	Capsule 6mm x 16mm Small pellets Grey cap / Peach body "W" on cap "37.5" on body	Capsule 8mm x 22mm One 37.5 mg tablet White "VEN" on cap "37.5" on body
75 mg	Size Capsule contents Colour Marking	Round tablet Φ 8 mm N/A White None	Capsule 7mm x 19mm Small pellets Peach "W" on cap "75" on body	Capsule 8mm x 22mm Two 37.5 mg tablets Flesh "VEN" on cap "75" on body
150 mg	Size Capsule contents Colour Marking	Round tablet Φ 10 mm N/A White None	Capsule 9mm x 23mm Small pellets Dark Orange "W" on cap "150" on body	Capsule 9mm x 23mm Three 50 mg tablets Scarlet "VEN" on cap "150" on body

Inside the proposed Enlafax XR capsules are one, two or three, small tablets (details above). This differs from the contents of the Efexor-XR brand capsule which contains small pellet.

We note that the appearance of Enlafax XR capsules is noticeably different from Arrow-Venlafaxine XR tablets. However, we consider that this is less of an issue than for Efexor XR due to Arrow-Venlafaxine XR comprising a smaller proportion of the market and we consider it likely to have less strong brand loyalty.

PHARMAC staff have worked with Mylan to minimise the differences in appearance of packaging between the proposed brand, Enlafax XR, and the dominant Efexor-XR. If the proposal is approved Enlafax XR will be packaged in calendar packs (blister foils with the days of the week printed on the reverse) similar to the Efexor-XR brand (see right).

PHARMAC staff note that the reason for a calendar style foil is to increase patient acceptance of the brand change by minimising differences in packaging not because we consider that calendar packaging offers additional benefits. The impact of the proposal to keep the calendar style foil is that an 84 capsule pack size is required, rather than the original 90 capsule pack, which Mylan bid with. [redacted]

We note that requesting an 84 capsule calendar pack rather than a standard 90 pack is not consistent with the latest draft Invitation to Tender 20016/17 which does state a preference for a "*30 or 90 day pack"* and was included after discussions with the pharmacy sector in an effort to reduce administration in pharmacies. However, the Pharmacy Guild and New Zealand Hospital Pharmacists' Association did not raise concerns over the 84 pack size in their consultation feedback.

On balance PHARMAC staff believe that maintaining the calendar pack and keeping the proposed brand packaging as similar to the dominant incumbent brand as possible would improve patient acceptability of the brand change. There would also be the possibility of agreeing a change in pack size in future years once the brand switch was well established.

Delisting of the 225 mg tablet

As previously noted, after 1 September 2017, patients would no longer be able to receive the Arrow-Venlafaxine 225 mg tablet presentation. Approximately 700 patients take this strength chronically. These patients would need to change to a dose of two or more Enlafax XR capsules (3x75 mg or 1x150 mg + 1x75 mg) in order to remain on funded treatment, noting that the latter combination would incur an additional co-payment so is unlikely to be used. PHARMAC staff note the additional pill burden for what is a small number of patients.

Other

From consultation feedback, PHARMAC staff were made aware of an off-label use practice whereby some patients prescribed Efexor-XR, remove a small number of pellets from the capsules in stages to slowly titrate their dose. This was mainly used for patients with severe withdrawal symptoms when titrated at the recommended pace and who were able to remove the pellets every day. This off-label titration practice would not be possible with Enlafax-XR.

Consultation feedback also questioned whether there was data on crushing the tablets contained in the Enlafax-XR capsules for the purpose of administration to acute hospital admission patients via nasogastric tubes. Mylan has confirmed that crushing, chewing or dissolving the tablets contained in the proposed Enlafax-XR capsules would be an off-label use of the product and could lead to rapid release and absorption of the venlafaxine and is not recommended. We consider that this would also apply to the currently listed brands.

Costs and Savings

Health related costs and savings to the person.

Should the proposal be approved, the 225 mg tablet presentation would be delisted from the Pharmaceutical Schedule on 1 September 2017. As described above, if patients were prescribed 1 x 150 mg cap and 1 x 75 mg cap, those patients would be required to pay two patient co-payments. Patients prescribed 3 x 75 mg would not see an increase in co-payment fees but would have an additional pill burden. PHARMAC staff note that should the proposal be approved and stat dispensing be applied, there would be a potential benefit to patients both in terms of suitability and reduced transaction costs – such as travel.

Health related costs and savings to the family, whānau and wider community.

Health related costs and savings to the family, whānau and wider community would remain unchanged as a result of this proposal.

Cost and savings to Pharmaceutical expenditure

This proposal would be cost saving to the CPB and to DHB hospitals:

- Estimated savings to the CPB would be approximately $5.4 million per annum or $18.3 million over five years (5 year NPV, 8%).
- Estimated savings to DHB hospitals would be approximately $26,000 per annum or $90,000 over five years (5 year NPV, 8%).

Costs and savings to the rest of the health system

Net distribution saving

There would be estimated savings of approximately $500,000 per annum or $1.9 million over five years (5 year NPV, 8%) as a result of reduced pharmacy mark-up.

Brand switch fee

PHARMAC staff have considered the change of funded brand for venlafaxine under the criteria agreed with the DHBs and consider a brand switch fee should be applied to venlafaxine 37.5 mg, 75 mg and 150 mg capsules if the tender is awarded.

Venlafaxine is recognised as a difficult brand switch because of the nature of the relatively large (45,000) vulnerable and change resistant patient group size, and a large proportion of these patients (>50%) have been taking the current brands on a long term basis. Paying the brand switch fee would be in the best interests of all parties to ensure a smooth transition and recognises the additional support patients would require from their pharmacy.

PHARMAC staff note that there would be a financial impact to DHBs in the financial year ending 30 June 2018, as a one off cost of approximately $220,000 (which is not part of the Combined Pharmaceutical Budget), as a result of the brand switch fee, payable to pharmacists for assisting the transition of ~49,000 patients after 1 September 2017.

Cost-Effectiveness

Cost effectiveness would be improved substantially as result of the reduced price, given price is the sole change (benefits, other health sector costs remaining unchanged).

PTAC View

PTAC's view has not been sought. Except for pharmaceuticals with a narrow therapeutic index, PHARMAC staff do not usually consult with PTAC about the listing and reference pricing of generic pharmaceuticals. Venlafaxine does not have a narrow therapeutic index. In this case we did not consider PTAC advice to be necessary for a proposed tender between bioequivalent products. Given the likely implementation challenges, we did consider it necessary to seek further advice on such matters and as noted above, the Mental Health Subcommittee was consulted via email regarding implementation of the proposal.

Comments from Interested Parties

Section 49(a) of the New Zealand Public Health and Disability Act 2000 (the Act) requires PHARMAC to consult, when it considers appropriate to do so, on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by decisions on those matters.

A consultation letter was posted on PHARMAC's website and circulated on 10 August 2016 to: all suppliers, Mental Health Subcommittee of PTAC, Nervous System Therapeutic Group distribution list, General Practice NZ, NZ Medical Association, Royal New Zealand College of General Practitioners and NZ Rural General Practice Network, which in the view of PHARMAC staff, may be affected by the recommendations contained in this paper.

We note that the web version of the consultation letter, dated 10 August 2016, was amended on 18 August 2016 to make it consistent with the pdf that was emailed to interested parties on 10 August 2016. The revised web version amended the pack size from 90 to an 84 pack. In consideration, the period to submit feedback was extended by one week.

The consultation letter and all responses received by 1 September 2016 are attached as Appendix 4. Summaries of what PHARMAC staff believe are the significant matters raised in these responses are provided below. For the full response, please refer to Appendix 4.

Responder	Theme	PHARMAC Staff Response
Pharmacy Guild Mental Health Special Interest Group, NZHPA Clinical Practice Education Committee, Pegasus Health	**Removal of the 225 mg strength** Patients currently taking the 225 mg strength of venlafaxine will require extra support from pharmacists as the proposal would result in a more complicated medication regimen, an increase in the patient's pill burden and potentially cost to the patient (i.e. 2 prescription charges rather than one depending on what combination of strengths is used). All of which are likely to impact on patient compliance and therefore health outcomes. Some DHB pharmacies have changed their hospital supply to the Arrow-Venlafaxine XR brand as there was the 225mg strength – the loss of this would be unfortunate.	Approximately 700 patients were dispensed the 225 mg strength of venlafaxine on a long term basis in the 12 months ending 30 June 2015. We consider the savings of the proposal outweigh the inconvenience to a small group of long term use patients. We note that there would be two ways of making up the same strength – 3 x 75 mg or 1 x 150 mg and 1 x 75 mg. We acknowledge that the latter would result in an additional prescription charge.
Mental Health Special Interest Group, NZHPA	**Appearance/Dosage/Titration** 1. The capsule actually contains extended release tablet(s). 2. Is there data on crushing those tablets for the purpose of administration to acute hospital admission patients with nasogastric tubes who will otherwise have significant withdrawal issues? 3. Are the strengths easy to differentiate? 4. There are currently people using Efexor XR caps to slowly titrate down (i.e.: having a few pellets less at each dose reduction) – mainly those whose withdrawal symptoms were awful when they went at a "usual" pace and where they can actually manage fiddling about with the pellets every day.	1. We confirm that Enlafax XR capsules contain the following: 37.5 mg: one 37.5 mg tablet; 75 mg: two 37.5 mg tablets; 150 mg: three 50 mg tablets; each of venlafaxine (as hydrochloride). 2. To our knowledge there is no data on crushing the tablets contained in the Enlafax XR capsules. Dividing, crushing, chewing or dissolving the tablets contained in the capsules would be an off-label use of the product and could lead to rapid release and absorption of the venlafaxine and is not recommended. We note that a 1% DV limit applies to DHB hospitals and this could be used for patients with nasogastric tubes; however, these same issues would apply to any extended-release formulation of venlafaxine. 3. We consider that the three strengths are easy to differentiate with clear colour coded outer packaging and blister pack foils. The capsules themselves are also different colours with "37.5", "75" or "150" printed on the appropriate capsule. 4. The recommendation for Efexor XR is that the capsules must be swallowed whole; titrating in this way is not recommended for Efexor XR. Likewise dividing, crushing, chewing or dissolving the tablets contained in the Enlafax XR capsules would be an off-label use of the product and is not recommended.
Dr Asteriadis, Psychiatrist Mental Health Special Interest Group, NZHPA Clinical Practice Education Committee, Pegasus	**Stat Dispensing** 1. Three responders commented on the proposal to implement stat prescribing given the risks associated with overdose. They considered that: a) If the proposal is approved, venlafaxine should be made a safety medicine so prescribers have the discretion to adjust supply where they know risk is higher.	1. PHARMAC has received advice from the Mental Health Subcommittee of PTAC that stat dispensing would be appropriate for venlafaxine. We note that the risk of overdose is inherent in depression and that with all medications there are safety concerns of overdose but this needs to be managed by clinicians. We note that, under normal supply conditions, seven out of the seventeen currently funded antidepressant medicines are able to be stat dispensed. a) We do not consider that venlafaxine meets the Safety Medicine criteria. We note that prescribers are able to modify the dispensing frequency on a

Health Actavis NZ Limited	b) The new brand of venlafaxine continue as monthly dispensing for a transition period past 1 September 2017 until all patients have transitioned and are stable. c) Encouraging this patient group to interact less with health professionals doesn't appear to be in the patient's best interests. 2. A fourth responder considered that the proposal would result in additional dispensing time and expense in pharmacies due to the perceived need for pharmacies to split blister packs and add six capsules to the proposed 84 capsule pack to make up a 90 pack, with the potential for errors, wastage and spoilage.	prescription if they deem a particular patient would be at risk of receiving three months' of medication at a time. A Pharmacist may also dispense medication in monthly lots without prescriber approval. b) The proposal is for stat dispensing to be introduced after the transition period i.e. 1 December 2017. This is a change from the consultation letter, which stated that stat dispensing would commence on 1 September 2017 and would allow patients transitioning at the end of the transition period to stabilise on the new brand prior to receiving three months' supply at once. c) We note the concern. Please see 1.a above. 2. We note that all incumbent strengths are packaged as 28 tabs/caps and that in just over half of the dispensings they are dispensed as 30s. Therefore there would be no additional work for pharmacists.
Pharmacy Guild Dr Asteriadis, Psychiatrist Pfizer New Zealand Limited SigJaws Charitable Trust	**Patient Group Concerns** Four responders raised safety concerns for what is perceived as a vulnerable patient group, who find changes from original versions to generics very difficult. Noting negative experiences, adverse reactions – potential for increased hospitalisations and one specific patient experience of a similar previous brand switch (fluoxetine).	Enlafax XR demonstrates bioequivalence to Efexor XR, meaning that patients could expect to get the same clinical benefit from Enlafax XR as from their current brand. We understand that changing brands can be challenging for some patients and we will develop a range of resources to support health professionals and patients during the brand change. In addition PHARMAC entered into post tender negotiations with Mylan to add an Alternative Brand Allowance clause – whereby, PHARMAC reserves the right to subsidise an alternative brand (e.g. Efexor XR) for up to 100 patients in the community for a maximum of 12 months. This is a safety net that would allow PHARMAC to extend the transition to Enlafax XR for up to 100 patients with extreme difficulties in switching brands.
Pharmacy Guild	**Implementation & Brand Switch Fee** One responder thought that: 1. Patients would need additional information and support from their prescriber and pharmacist. 2. It would be important for written and online information to be prepared for prescribers and pharmacists well in advance to prepare these patients for the future brand change. 3. It would be essential that a brand switch fee be applied to all strengths of Enlafax XR from 1 September 2017.	We would develop patient information that can be utilised by healthcare professionals to help support patients with a change in brand. Information would be able to be viewed and downloaded from the PHARMAC website. We would develop an online education module focusing on pharmacy and other healthcare professionals, equipping them with the skills they need to positively influence patients through a change of medicine and convey confidence in generics to patients We propose a brand switch fee is paid to community pharmacy in recognition of the additional support patients would require. For more information please see the Implementation section and Implementation Plan (Appendix 6).

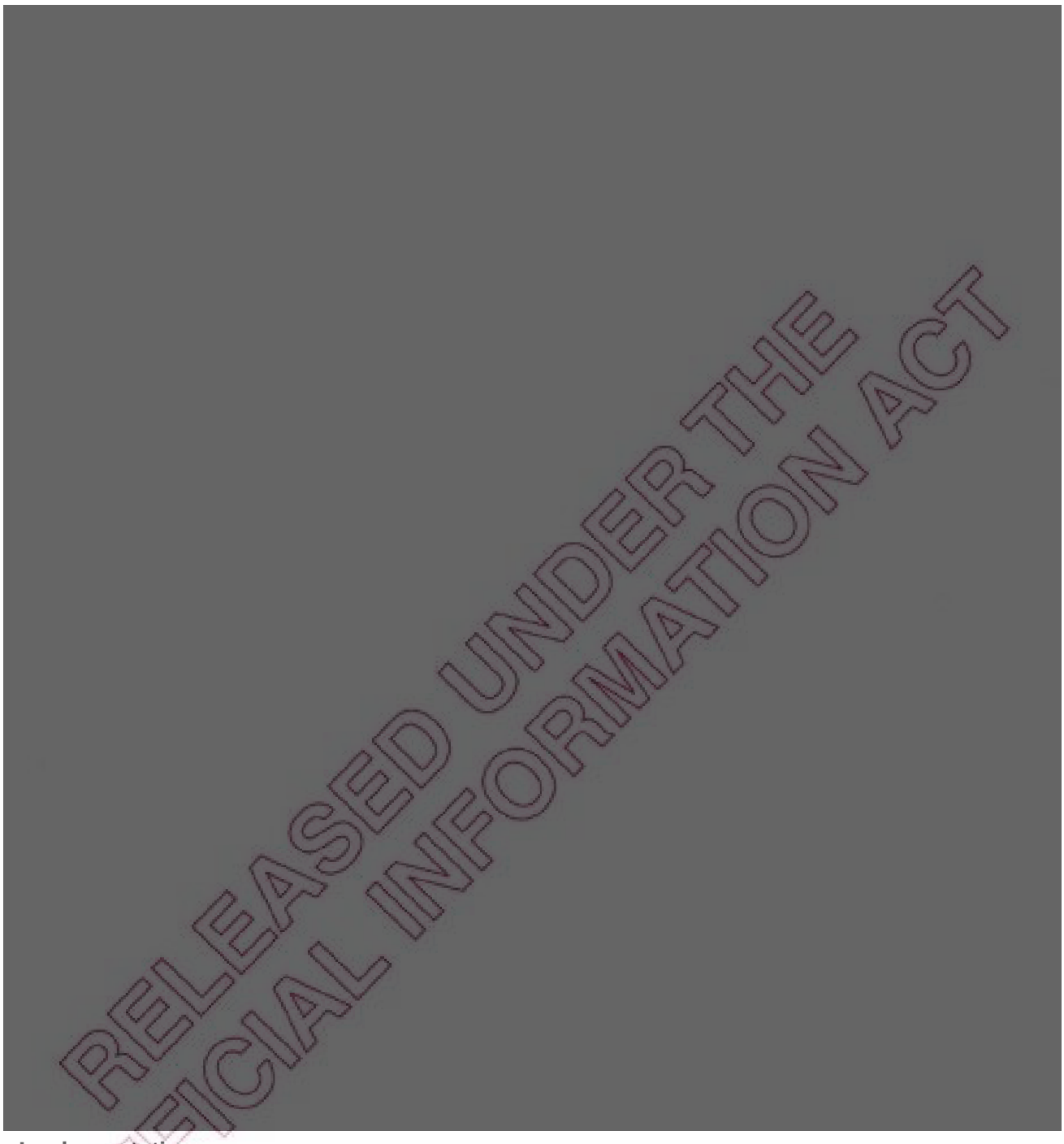
Pfizer New Zealand Limited Actavis NZ Limited Chemo SA (Manufacturer of ArrowVenlafaxine)	**Incumbent Supplier & Manufacturer Feedback** **Pfizer:** 1. [redacted] 2. Questions whether the savings from this proposal warrant the significant disruption to this group of patients and the additional costs to the healthcare system outside of PHARMAC's budget of implementing this change. **Actavis:** 3. [redacted] 6. Notes that it is unaware of any data on comparative bioequivalence between Enlafax XR and Arrow-Venlafaxine XR. 7. Notes that a specific packaging requirements for 'days of the week' on the reverse of blister packaging' was not outlined in the RFT. 8. Notes that the original consultation letter PHARMAC published on its website differed from the consultation letter pdf forwarded to interested parties. 9. Believes that Board approval would give the impression of a disregard for taxpayer funds and will also raise very serious questions for those companies providing generic medicines within New Zealand.	1. PHARMAC staff considered all of the Factors For Consideration in recommending the tender be awarded to Mylan. 2. We note that there will be disruption to patients, prescribers and pharmacists but consider the disruption will be worth the overall gain to the proposed savings. [redacted] 3. Throughout the process, PHARMAC staff have acted to ensure compliance with the NZ Government Rules of Sourcing. 4. [redacted] 5. A clarification of PHARMAC's RFT and consultation process has been sent to Actavis (in the letter dated 30 August 2016). This has clarified that the purpose of the consultation process is to seek feedback from interested parties on the possible effects of the proposed amendment to the Schedule – in this case the proposal to list Enlafax XR with sole supply until 30 June 2020, not to seek to re-litigate or review the evaluation component of the procurement process that has led to the proposal. 6. We note that Efexor XR is Enlafax XR has met Medsafe's standards for registration in New Zealand, including a requirement that Enlafax XR demonstrates bioequivalence to Efexor XR. While it is true that bioequivalence of Enlafax XR to Arrow-Venlafaxine XR has not been established, as is usual for a generic to generic switch, both brands have demonstrated bioequivalence against the innovator. We maintain our view that patients could expect to get the same clinical benefit from Enlafax XR as from their current brand.

	[redacted]	7. Noted – As stated in the RFT document Schedule 3, clause 1.6. (a) ii - PHARMAC may initiate limited negotiations in relation to proposed packaging or pack size of a tender item 8. We acknowledge that the web version of the consultation letter dated 10 August 2016 was amended, 18 August 2016, to make it consistent with the consultation letter pdf that was emailed to interested parties on 10 August 2016. The revised web version of the consultation document amended the pack size from a 90 pack to a 84 pack. In consideration of this amendment, PHARMAC extended the period to submit feedback on this proposal by one week, until Thursday 01 September 2016. However, we disagree with the assertion that the difference was 'material' to consideration of the proposal as a whole. 9. See point 4 above. 10. We have acknowledged Chemo SA's letter as a formal complaint. In response, we have noted that the venlafaxine procurement process is ongoing and that its letter will be considered as part of the Board's decision.
Clinical Practice Education Committee, Pegasus Health	**Sole Supply** One respondent did not think a sole supply agreement for venlafaxine was appropriate, noting several issues common to abrupt supply disruptions with any sole supply agreement.	PHARMAC considers that having multiple brands of a product in a market does not necessarily improve security of supply. When there is one supplier, our experience is that supplier forecasting is typically more accurate which helps prevent out-of-stock situations. Further, in exchange for market exclusivity, the supply contracts we have in place require suppliers to agree to rigorous conditions to prevent and manage potential out-of-stocks. Further, we note that prior to the listing of Arrow-Venlafaxine XR there was only one supplier in the market for at least six years which did not present significant issues.
SigJaws Charitable Trust	**Registration Status** One respondent raised a concern regarding the registration status of Enlafax XR with Medsafe.	Enlafax XR was registered with Medsafe on 12 March 2009. PHARMAC staff note that the 84 blister pack of Enlafax XR is not currently registered with Medsafe. Should the proposal be approved then Mylan would register the additional pack size with Medsafe. It is not expected that this would impact on the proposed timelines.
Dr Asteriadis, Psychiatrist	**Other Antidepressants** There are many new antidepressants overseas with novel actions eg agomelatine, which we do not had access to in NZ.	PHARMAC has not received an application to fund agomelatine. The status and further details of all applications reviewed by PTAC and/or the Mental Health Subcommittee of PTAC; can be viewed via the Application Tracker on PHARMAC's webpage. We consider that this response is not relevant to consideration of the proposal.
Ministry of Health	**Miscellaneous** There are no technical or resource impacts anticipated as a result of the proposal.	PHARMAC staff note the response.

Legal Advice

Where necessary, management will obtain legal advice on issues such as whether any proposal is consistent with PHARMAC's legislative and public law obligations, including those which may have specific relevance to the particular proposal eg human rights implications of a proposal. If the Board considers that further legal advice is required on any issue, this should be communicated to management in advance of the Board meeting. Management will then obtain the required advice.

Legal Advisors' View – Legally Privileged Advice from PHARMAC's Legal Counsel



Implementation

Section 49(b) of the Act requires PHARMAC to take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the pharmaceutical schedule. Accordingly, if the Board adopts the recommendations contained in this paper PHARMAC staff will take the following measures to inform the public, groups and individuals of that decision:

- Notify health professionals, suppliers and public through a notification letter sent directly to those who were consulted with and upload to the PHARMAC website;
- Ensure prescribing and pharmacy IT systems are provided with information about the change for providing updates to their systems;

- Notify the Senior Schedule Analyst for inclusion in the Pharmaceutical Schedule; and
- Notify the Contract Management Team for ongoing contract management

We have extensive experience in managing difficult brand changes. We have drawn on our experience to develop a programme we are confident will manage the challenges and improve the patient acceptance of the new brand. In particular:

- The long lead time from notification to implementation would ensure ample time to prepare a range of patient support materials and education resources for health professionals. These would include:
    - Developing patient information for the primary health care team and patient support groups about the change in brand;
    - A dedicated PHARMAC 0800 line, support by a pharmacist, for patient and health professional enquires;
    - Develop web-based interactive training programme for pharmacy and other healthcare professionals, equipping them with the skills they need to positively influence patients through a change of medicine and convey confidence in generics to patients;
    - During the transition period, engaging the University of Auckland to further their research the influences of branding on patient experience of a brand change with a specific focus on the impact of direct to consumer advertising. This research would reassure patients that PHARMAC is committed to improving their experience during brand changes and give patients additional avenue to share their experience; and
    - Communications, including email updates, items for newsletters and potentially paid media opportunities, to provide information to healthcare professionals about the change of brand;
- We propose a brand switch fee is paid to community pharmacy in recognition of the additional support patients would require; and
- Based on similar changes in brand, it is possible that some patients would not tolerate this change in brand and would need to switch to a different treatment. There are 16 other funded antidepressant medications available and we would provide information to health professionals about these alternative treatments.

Full details of the proposed activities and approach to support any changes can be found in the Engagement and Implementation plan in Appendix 6.

Appendices

Appendix 1: Agreement with Mylan (RFT & Letter of Amendment – Alternative Brand Allowance)

Appendix 2: RFT Evaluation Committee Minutes

Appendix 3: Clinical Advice Summary – Venlafaxine Implementation and Stat Dispensing

Appendix 4: Consultation Letter and Responses

Appendix 5: Letters of Correspondence with Actavis

Appendix 6: Implementation Plan

PHARMAC
Pharmaceutical Management Agency

Engagement and implementation plan to support a potential change in brands of venlafaxine

Purpose

The purpose of this implementation plan is to set out how PHARMAC would address the identified risks and challenges that may arise from changing funded brands of venlafaxine from Efexor-XR and Arrow Venlafaxine XR to Enlafax XR.

Summary of the challenges and activities

The main challenges arising from this proposal are:

- Approximately 45,000 people will need to change brands and some people may find changing brands challenging;
- Some healthcare professionals may find it challenging to communicate and support people taking the medicine to change brands; and
- The 225 mg tablet would no longer be funded: approximately 700 people take this strength long term and would need to take two or three pills to make up this strength (or take a different strength on the advice of a Doctor). (Depending on choice, an additional co-payment may also apply.)

We have extensive experience in managing difficult brand changes. We have drawn on our experience to develop a programme of activities we are confident will manage the challenges and improve patient acceptance of the new brand. In particular:

- The long lead time from notification to implementation would ensure ample time to prepare a range of patient support materials and education resources for health professionals. These would include:
    - Developing patient information for the primary health care team and patient support groups about the change in brand.
    - A dedicated PHARMAC 0800 line, supported by a pharmacist, for patient and health professional enquires.
    - Developing a web-based interactive training programme for primary healthcare professionals.
    - During the transition period, engaging the Department of Psychological Medicine at the University of Auckland to further their research into the influences of branding on patient experience of a brand change.
    - Communications, including email updates, items for newsletters and potentially paid media opportunities, to provide information to healthcare professionals about the change of brand.
- Proposed implementation of a brand switch fee to community pharmacy.
- The availability of an ‘alternative brand allowance’ for people who have particular difficulty in changing brands.
- Consideration of the appearance and packaging of the proposed brand to help minimise sector and consumer disruption.

The programme of support activities

The programme of support activities would focus on two areas:

- Supporting health professionals to feel knowledgeable about the importance and value of brand changes, the change of brand and strategies that can be used to positively influence patients; and
- Improve patient acceptability of the brand change.

Supporting health professionals to positively influence patients

Health professionals play a pivotal role in supporting patients through brand changes, especially for vulnerable patient groups such as mental health consumers. This transaction would impact on the workload of those health professionals, so it would be important they understand the benefits of the decision and feel as positive about the brand change as possible.

We would take a "team health" approach to our messaging to health professionals about this change, acknowledging upfront:

1) This change could be difficult for some patients and health professionals have a major impact on influencing patient acceptance of the change.
2) The change would mean $15 million of savings over 3 years and we would look for meaningful ways of communicating the significance of these savings to the wider health system.
3) The health care team is pivotal in making savings possible by supporting their patients through a brand change.
4) The removal of the Special Authority from all brands of venlafaxine and a change to all at once dispensing.
5) No 225 mg tablet means the small number of patients taking this strength would need to move to other strength of tablets/take multiple tablets.

Activities to support this approach would include:

- Targeted communications, including email updates, items for newsletters and potentially paid media opportunities to provide information to healthcare professionals about the change;
- Developing web-based interactive training programme for primary healthcare professionals, equipping them with the skills needed to positively influence patients through a change of medicine and convey confidence in generic medicines to patients;
- A brand switch fee would be paid to community pharmacy as a means of targeted funding in recognition of the additional patient counselling.

The patient experience of the brand change

People currently taking the Efexor-XR brand

Changing brands is likely to be particularly difficult for people taking Efexor-XR due to a strong brand loyalty. Efexor-XR has been listed on the Pharmaceutical Schedule since 2004 and Pfizer has actively marketed Efexor-XR directly to patients through various media including television.

The strong brand loyalty is reflected by the minimal uptake of the funded Arrow-Venlafaxine XR tablet. Arrow-Venlafaxine XR was listed in 2011 without a Special Authority, which meant reduced administrative burden for prescribers and wider access to new patient groups and prescribers (as only vocationally registered GPs and specialists can make Efexor XR Special Authority applications). Despite this, Pfizer's Efexor-XR still accounted for 68% of the total amount of units dispensed in 2015/2016.

Early engagement with the supplier means there are minimal differences in the appearance and packaging between the Enlafax XR brand and the Efexor-XR brand. However, given the strong brand loyalty and based on our experience with similar brand changes in the past, we consider this brand change could be challenging for people taking the Efexor-XR brand and they would require reassurance from their health care team.

People currently taking the Arrow-Venlafaxine XR brand

People taking the Arrow-Venlafaxine XR brand may also find it challenging to change brands. Arrow-Venlafaxine XR has not been actively marketed directly to patients in the same way as Efexor-XR; therefore we do not consider that this group of patient will be as brand aware.

However, the Enlafax XR capsules and packaging would look different from the Arrow-Venlafaxine tablets so patients would need reassurance that they will receive the same clinical effects from taking Enlafax XR.

Approximately 700 of the 45,000 people taking venlafaxine chronically take the 225 mg strength of Arrow-Venlafaxine. This proposal would result in the 225 mg strength no longer being an option for people, and in order to remain on funded treatment they could take:

- 3 x 75 mg capsules; or
- 1 x 150 mg capsule and 1 x 75 mg.

People will be able to choose which option works best for them, bearing in mind that if they choose to take one 150 mg capsule and one 75 mg capsule they may also have to pay an extra co-payment. We would ensure that pharmacists and prescribers are aware of this change and are equipped to discuss the options with their patients.

Improving the patient experience during the brand change

Given the challenges of changing brands of anti-depressants, the removal of the 225 mg strength and the active marketing of Efexor XR, we propose to undertake the following activities to improve the patient experience of the brand change:

- Development of specific patient information resources to provide information about the change for consumers, including options for people taking the 225 mg strength.
- A dedicated PHARMAC 0800 line, support by a pharmacist, for patient enquires.
- Engage with patient support groups such as the Mental Health Foundation, and mental health support phone lines to ensure people are well supported during the transition.
- Engaging the University of Auckland to further their research into the influences of branding on patient experience of a brand change with a specific focus on the impact of direct to consumer advertising. This research would occur during the brand transition and gives patients reassurance that PHARMAC is committed to improving their experience during brand transition and give patients additional avenue to share their experience.

Despite best efforts, some patients will likely struggle with the change

Based on previous experience with similar changes in brand, it is likely that some patients would not be able to change brands and they would need to change to a different treatment. There are 16 other funded antidepressant medications available and as part of our communications to health professionals a link to Best Practice Journal articles on appropriate pharmacological treatment options.

Some patients may need longer to change brands of medicines. We have included an "alternative brand allowance" clause in the contract with the supplier. This would allow PHARMAC to subsidise an alternative brand of venlafaxine during the sole supply period for up to 100 patients for a maximum period of 12 months, to allow additional time to transition patients to Enlafax XR. This would be activated if a prescriber applied through NPPA for a different brand of venlafaxine (likely to be one of the incumbent brands) because their patient was having difficulty with the brand change but the patient did not qualify under the NPPA.

Key Messages

These would be the key messages should the proposal be accepted.

General

- From 1 September 2017, Enlafax XR will be the only brand of venlafaxine fully funded; Efexor-XR and Arrow Venlafaxine will no longer be funded.
- Changing from Efexor-XR to the Enlafax XR brand of venlafaxine has meant $15M worth of savings (over 3 years) that can be used to fund other treatments for other patients.
- This change also coincides with changes to prescribing rules meaning more health professionals are able to prescribe the Enlafax XR brand of venlafaxine, and there is less administration for them.

- The change means that from 1 June 2017 there would no longer be a fully funded 225 mg tablet of venlafaxine. Patients can still get funded access to this strength if they need it by receiving the following combinations of strengths from their pharmacy:
    - 3 x 75 mg capsules; or
    - 1 x 150 mg capsule and 1 x 75 mg
- Sometimes changing medications can be difficult, so we have developed material for patients to help them understand it. We have also developed information for health care professionals to use with their patients in their consultations and discussions with patients.

People taking venlafaxine and their families, whānau and support groups

- From 1 December 2017 if you take venlafaxine, you can get three months of medication at once, minimising your visits to the pharmacy. If you want to stay with the smaller quantities, then talk to your doctor or pharmacist.
- Medsafe, the agency that approves medicines for use in New Zealand, carefully considered the safety and effectiveness of Enlafax XR. People can expect to get the same clinical benefit from Enlafax XR as from Arrow-Venlafaxine and Efexor XR.
- If people are concerned about taking the Enlafax XR brand they should talk with their health professional.

People who are struggling with the brand change

- People can expect to get the same clinical benefit from Enlafax XR as they did from Arrow-Venlafaxine and Efexor XR. PHARMAC has asked researchers from the University of Auckland to explore the patient experience during a brand change and share their experiences of this particular one with the researchers. If you would be interested in contributing to this research we can send you the details.

Hospital pharmacy and secondary care clinicians

- From 1 June 2017, you will be required to give the Enlafax XR brand of venlafaxine with a 1% DV limit.

Community pharmacy

- From 1 September 2017 to 1 December 2017 a brand switch fee would apply to dispensing of Enlafax XR brand in recognition of the additional support patients would require to change brands and we have prepared some material for you to share with people who are undergoing this brand change.
- From 1 December 2017 the default dispensing for venlafaxine would change to allow up to 3 months of medication dispensed at once. If a pharmacist considers an individual needs more frequent dispensing then:
    - For LTC registered patients, the pharmacist can alter the dispensing as appropriate to meet that patient's needs; or
    - For Core (non-LTC) patients, the pharmacist can authorise monthly dispensing. If more frequent dispensing is required the pharmacist would need to discuss it with the prescriber.