

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.

Venlafaxine brand change – activity over the next 3 months

To support the implementation of the venlafaxine brand change, some additional communications activity is planned.

Highlights:

Objective	Communications activity	Channel	Timeframe	Audience	Comments
Patients know where to go for support	Patient information leaflet	Via pharmacy	Done	Patients	Does this need to be refreshed now?
	PHARMAC website	PHARMAC website	Done	Patients/pharmacy/GPs	Does this need to be refreshed now?
	Information for 0800	0800	Done	Patients	Do we need to review the material that the 0800 line has to help talk to patients? Do we need to have a formal escalation point (ie some from the MD) to transfer calls to if needed? (since Peter is leaving)
	Information for key channels that patients refer to	Key channels that patients refer to (like Facebook)		Patients	An extension of the patient information leaflet that can be distributed to get to another audience? We could use other people to post/share this information or send direct to the admins to share.
Those supporting patients have	Generics Learning Module	Twitter push	During July	Pharmacy GPs and Primary Care	Tweets drafted for review (see below)

the information they need	Op-Ed - Change is hard - here's how you can manage by Keith Petire	Pharmacy Today NZ Doctor	During July for August	Pharmacy General practice	
	Op-ed - Changes to medicines are carefully considered - PHARMAC piece with Cathy Stephenson, Chair of TMESC	PHARMAC website Pharmacy Today NZ Doctor		Patients Pharmacy General Practice	
	Reminder to GPs - change is coming up, here's the resources you need	Letter	August	GPs	
	Update to Pharmacy - thanks for the support, remember you can order resources here - if people are really concerned, send to their GP	Update fax			
HCP and patients are reassured about generics in general	Op-ed - Here's how the science works (Nano girl)	TBC		Patients	

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Tweet	Image	Tag
<p>What you say & how you say it can affect how your patients respond to medicine changes. Earn CME pts & learn more: learnonline.health.nz</p>		<p>@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news @PharmacyToday @KeithPetrie</p>
<p>#BeyondTheBrand Learn more about the science behind generic medicines and branding and earn #CME points online: learnonline.health.nz</p>		<p>@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news @PharmacyToday @KeithPetrie</p>
<p>In 2012 \$24b was spent on targeting meds at health professionals in the US. Learn about how branding impacts you: http://learnonline.health.nz</p>		<p>@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news @PharmacyToday @KeithPetrie</p>
<p>Branding impacts everyone, everyday. Learn about how branding influences they way you talk to patients about meds: learnonline.health.nz</p>		<p>@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news</p>

		@PharmacyToday @KeithPetrie
Want to learn how to communicate brand changes & earn CME points? Check out #BeyondTheBrand - http://learnonline.health.nz/		@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news @PharmacyToday @KeithPetrie
Changing brands of medicines can be difficult. #BeyondTheBrand has great research by @KeithPetrie that looks at why: learnonline.health.nz		@RNZCGP1 @PharmacyGuildNZ @PharmSocNZ @NZMAchair @NZDoctor_news @PharmacyToday @KeithPetrie

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E&I activity plan to support the venlafaxine brand change

These items are not BAU activities.

Focus	Stakeholder	Activity	Purpose:	To do list:	Who is involved	Timeline
Venlafaxine brand change	Consumers	Patient information leaflets	Provide consumers with information about the brand change	<ul style="list-style-type: none"> Working with Write group Need to be translated into Maori etc 	Lead: Sarah Review: Medical and TGM Sign off: Janet	Send to printers on 12 March
		Template letters for enquires team	To reduce workload on team when responding to enquires.	<ul style="list-style-type: none"> Create template Work with comms to ensure it is easy to use 	Lead: Sarah Review: Janet, Medical and TGM Sign off:	
		Information for a web page	Provide consumers and HCP with information about the brand change		Lead: Sarah with Jennifer Review: Medical, TGM, Ants Sign off: Janet	Done
		0800 line support	Ensure 0800 line (PHARMAC and Mylan) are well supported	<ul style="list-style-type: none"> Contract additional 0800 support 	Lead: Communication team Support: Implementation team	In process
		Health/lifestyle blogger to write about their experiences	Provide positive messages in patients "social network" around brand changes	<ul style="list-style-type: none"> Meet with HPA to explore possibilities/ learn from their experiences Consider approaching Cathy Stephenson who writes for the Dominion Post 	If we go ahead with a Lead: Anthony Review: Sarah, Janet, TGM, and Medical Sign off: Kerri	Unlikely to proceed
		University of Auckland - Patient experience survey	Give consumers additional outlet for their experience.	<ul style="list-style-type: none"> Researchers to meet with comms team Create some key messages around the research 	Communication and Implementation team	Done
	Mental Health Foundation	Meet with the MHF	Ensure they are aware of the support material developed for consumers	<ul style="list-style-type: none"> The MHF do not provide consumers with information regarding pharmaceuticals. Recommended approaching Homecare Medical 		Done
Generics acceptance	Health professionals <ul style="list-style-type: none"> Doctors Pharmacist Nurses 	Generics learning module to be loaded on the MoH website.	To provide HCP with knowledge and skills to positively influence patients through a brand change	<ul style="list-style-type: none"> Start CPD/CME conversations with professional bodies Work with MoH regarding hosting Promote the learning module at Goodfellow symposium (24 March) Rural Health Conference (30 March) Inside Cover of the Schedule, Pharmac Website landing page 	Lead: Sarah Review: SME and stakeholder reference group Sign off: Janet	Done
		Keith Petrie article in NZ Doctor and Pharmacy Today on Placebo/nocebo	Increase HCP awareness of the need to support patients through a brand change	<ul style="list-style-type: none"> Unlikely to proceed. 	Lead: Ants Support: Sarah	Done
		GEMS on the generics research	Increase awareness of the impact HCP can have on patient changing brands	<ul style="list-style-type: none"> Meeting with Goodfellow to discuss their research. Need to send information to Goodfellow on what a GEM 		Unlikely to proceed
Venlafaxine brand change	General Practitioners	Communications regarding transition through normal channels (GPNZ, NZMA, rural doctors, RCGPNZ)	To make GPs aware of: <ul style="list-style-type: none"> brand change the resources that have been developed the venlafaxine research 		Lead: Sarah Review: TGM and Janet Sign off: Bryan	Done

	Pharmacist	Meet with Pharmacy Guild and PSNZ to discuss what resources we are developing and what additional resources they would recommend.	Create champions for the change and ensure they support our work.	<ul style="list-style-type: none"> Contact beginning of March 2017 Meeting with Guild on Thurs to outline resources developed, 		Done
		Thanks you to pharmacy for all the good work	Positive re-enforcement to recognise good behaviour.	<ul style="list-style-type: none"> Meet with E&I managers to discuss options Meet with comms team 		
		Communication regarding Schedule changes through the normal channels	To make pharmacy aware of: <ul style="list-style-type: none"> brand change brand switch fee the resources that have been developed the venlafaxine research 	<ul style="list-style-type: none"> Craft a venlafaxine news story 		Done
		Pacific pharmacist's groups	To make pharmacy aware of: <ul style="list-style-type: none"> brand change brand switch fee the resources that have been developed the venlafaxine research 	<ul style="list-style-type: none"> Agnes to send information to her Pacific island pharmacist. 		Done
	Nursing		To make nurses aware of: <ul style="list-style-type: none"> brand change the resources that have been developed the venlafaxine research 	<ul style="list-style-type: none"> Need to work on identifying communication channels for nursing Email Lois regarding resources developed for nurses. Sent via E-panui 		Done
	Secondary care	Communications to; <ul style="list-style-type: none"> Hospital pharmacists Mental health hospital pharmacists 	To make pharmacy aware of: <ul style="list-style-type: none"> brand change the resources that have been developed the venlafaxine research use pharmacy channels to pass on information 		Lead: Sarah Review: TGM, Janet and Medical Sign off: Sarah F	Done
	Counsellors	Communications through the NZAC	To make them aware of: <ul style="list-style-type: none"> brand change the resources that have been developed the venlafaxine research 	<ul style="list-style-type: none"> After the meeting with HPA assess the best approach. Sent communications to NZAC newsletter 		Done

Risks:

- 1) Patients taking Arrow-Venlafaxine 225 mg tablets – will get patient numbers closer to the time.
- 2) pharmacy
- 3) Media
 - a. Consumer complaints
 - b. Deborah Hill Cone

Venlafaxine brand change

Key messages for people taking venlafaxine

Venlafaxine is used to treat depression and relieve abnormal anxiety (also known as generalised anxiety disorder).

What's changing?

The funded brand of venlafaxine is changing from Arrow-Venlafaxine XR and Efexor XR to Enlafax XR

Enlafax is available from 1 April 2017

- **From 1 April 2017** Enlafax XR will be fully funded and available for patients
- **From 1 June 2017** a part payment may be required for Arrow-Venlafaxine XR and Efexor XR
- **From 1 September 2017** only Enlafax XR will be fully funded. Arrow-Venlafaxine XR and Efexor XR will no longer be available.
- **1 December 2017:** The default dispensing on venlafaxine will be changed to three months at once (stat)
- If you do want to keep using your current brand of venlafaxine, you can ask your pharmacist to check the price and availability. PHARMAC cannot guarantee the availability or price of Arrow-Venlafaxine XR or Efexor XR after 1 September 2017.

Enlafax XR works the same as the other brands

- Enlafax XR will work in the same way as Arrow-Venlafaxine XR and Efexor XR. Enlafax XR has the same active ingredient as the other brands and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Enlafax XR has been thoroughly evaluated by Medsafe (part of the Ministry of Health) to ensure it's safe and works the same as the other brands.
- You shouldn't notice any difference when you change to Enlafax XR. If you have any questions or concerns about changes to medicines, you should talk with your doctor, nurse or pharmacist.
- There's more information about medicines and changes to medicines on PHARMAC's website: [The facts about generic and biosimilar medicines.](#)

Are you taking Arrow-Venlafaxine XR 225 mg tablet?

Enlifax XR doesn't come in a 225 mg strength. If you currently take this strength as a single tablet, you'll need to change to take:

- three of the 75 mg capsules, or
- one 150 mg capsule and one 75 mg capsule - with this option there may be an extra co-payment.

Your doctor or pharmacist will be able to talk you through what you need to do if this affects you.

Why is your brand is changing?

A decision to change a medicine, especially one as important as venlafaxine, isn't taken lightly. We've received expert advice about the appropriateness of making this change.

Our job is to make sure New Zealanders have access to the medicines they need. Making changes to medicines helps us achieve that by freeing up our limited budget to fund other medicines in the community. With venlafaxine we're able to save almost \$6 million every year, which we can use to widen access to and fund more medicines.

Research into brand changes - tell us how you feel about changing brands

PHARMAC will often make decisions that mean people need to change the brand of their medicines. We want to make sure that any change goes as smoothly as possible, so we want to learn more about how brand changes impact people taking medicine.

PHARMAC has asked researchers from the University of Auckland to explore this further. We want people to share their experiences of changing venlafaxine brands.

If you're interested in sharing your experiences and taking part in the research, click here: [Venlafaxine Brand Switch Survey](#)

All responses will be confidential. Participation in this research is voluntary.

General information for healthcare professionals

Healthcare professionals play an important role in supporting patients through changes to their medicines. We'd like to support you as you help your patients through the changes to venlafaxine.

You can order patient information leaflets for free from www.pharmaonline.co.nz or you can download them from www.pharmac.govt.nz/venlafaxine.

Field Code Changed

Key points to advise your patients about Enlafax XR:

- Enlafax XR has the same active ingredient (venlafaxine) as the other brands. This means the new brand of medication is just as safe and works exactly the same as the old brand. They shouldn't notice any difference in how it affects them.
- Enlafax XR comes in capsules and will look different from Arrow-Venlafaxine XR and Efexor XR - this will not affect how well the medicine works for them.

Information for community pharmacists

Pharmacists play an important role in supporting patients through changes to their medicines. We'd like to support you as you help your patients through the changes to venlafaxine:

- We are sending 20 patient information leaflets to community pharmacy as part of the March Schedule Update, which you may find useful when counselling patients. More leaflets can be ordered from www.pharmaonline.co.nz
- Patient information leaflets in Māori, Cook Island Māori, Tongan and Samoan can be downloaded from www.pharmac.govt.nz/venlafaxine. For printed copies please email us at enquiry@pharmac.govt.nz
- A brand switch fee will be applied to dispensing of Enlafax XR from 1 September 2017 to 30 November 2017.

Key messages for issues as they arise

Dose titration

Efexor XR has small pellets inside the capsules which we understand that some people remove to change their dose slowly, although this is not recommended on the datasheet. Enlafax XR capsules contain larger pellets meaning people will not be able to change their dose in quite the same way.

The recommendation for both Efexor XR and Enlifax XR is that they should be swallowed whole and the capsules should not be opened. We suggest if people are concerned about their dosing they should talk to their doctor about possible options.

People who are really struggling to change brands

For the majority of people changing brands will be a smooth transition. We understand that there are a few patients for who changing brands will be a real struggle. We recommend those patients to contact their doctor in the first instance. We can work with the doctor to find a solution for these patients.

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From: Janet Mackay
Sent: Friday, 29 July 2016 11:24 AM
To: Matthew Wolfenden
Cc: Geraldine MacGibbon; Sarah Le Leu
Subject: Venlafaxine Implementation Lead

Hi Matthew,

Thanks for organising and running the RFT evaluation session yesterday. Talked with Sarah Le Leu after the meeting and I'm really pleased to say she will be the Implementation Lead on this transaction.

That means that she'll be involved in providing the oversight, advice and support for the Implementation section of the decision paper as well as progressing with any activities etc. that are needed to be done in order to make the transition a successful one. Naturally she'll be working closely with the TGM (and you) on this.

Given I was at the RFT meeting yesterday, I'll still review the minutes of that but will also ensure that Sarah sees them/reviews as well given she'll take the lead on the implementation side of things.

I know Sarah will be able to provide heaps of great insight and experience to ensure this transaction (should a change be the ultimate proposal that's decided) progresses successfully.

Cheers,

Janet

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