Minister's reports (monthly/quarterly):

May 2016-17

Venlafaxine - PHARMAC has decided to change the brand of venlafaxine, funded as a last-line antidepressant. The decision is anticipated to save $20 million over five years, which will be used to support the funding of additional medicines across a range of conditions. The need for careful implementation was recognised.

There have been several representations made to us about lack of efficacy and adverse effects, and social media discussion groups have had some activity in this regard. Based on our experience, this is consistent with the level of concern usually anticipated from such a change, and we continue to monitor and actively support the implementation of this change.

August 2016-17

Venlafaxine brand change – We'll soon be announcing a significant brand change for venlafaxine – a last-line treatment for depression. People taking either of the two currently funded brands will be required to transition to a new funded brand from 1 April 2017, before it will become the sole funded brand from 1 September 2017. Approximately 45,000 people will need to change brands and some may find this challenging. We also recognise there may be high brand loyalty to the supplier with the majority of the market share, so we've developed a thorough implementation plan to support patients and prescribers through this upcoming brand change. We expect that this decision will generate savings to the CPB of approximately $20.5 million (5-year net present value).

Quarter 2 2016-17

Government expectation

Expectation	**Comment**
Continue to communicate and engage proactively with the public and key stakeholders, and, in particular, to manage brand switches and high profile funding decisions carefully.	Overview: This is core business for PHARMAC. We provide resources and evidence-based information to support brand switches and explain high-profile funding decisions. We communicate with key stakeholders with a view to ensuring they are well informed and understand what each change means. Recent progress: There has been strong focus recently on supporting the implementation of Hepatitis C funding decisions, along with preparations for diabetes test meters and the venlafaxine brand change. Next steps: Continue business as usual, including implementation work related to

	the venlafaxine decision. Key relevance to Output: 1, 2 & 3

Quarter 3 2016-17

Government expectations

Expectation	**Comment**
Continue to communicate and engage proactively with the public and key stakeholders, and, in particular, to manage brand switches and high profile funding decisions carefully.	There has been strong focus recently on supporting the implementation of Hepatitis C funding decisions, along with preparations for diabetes test meters and the venlafaxine brand change. *Relates to Output 2.1*

Quarter 4 2016-17

Venlafaxine – As outlined to you in our previous monthly report, a brand change is underway for the last-line antidepressant, venlafaxine. We have had a number of comments from patients and clinicians regarding efficacy and patients' ability to change. In addition to our regular practice of advising people to refer such reports to CARM, we have connected several people with Auckland Medical School researchers (whose work we partly fund) who are looking at understanding adverse effects reported in product changes.

We anticipate that there may be a further upswing in reporting once the existing brands are delisted from 1 September 2017, which will mean all patients have to change to the new brand.

Government expections

Expectation	**Comment**
Continue to communicate and engage proactively with the public and key stakeholders, and, in particular, to manage brand switches and high profile funding decisions carefully.	There has been strong focus recently on supporting the implementation of hepatitis C funding decisions and a brand change for venlafaxine, along with preparations for potential changes to diabetes test meters. *Relates to Output 2.1*

August 2018-19

Venlafaxine brand switch

In late 2017, PHARMAC changed the funded brand of the antidepressant venlafaxine to Enlafax XR. Two of the three previously funded brands, Arrow-Venlafaxine and Efexor XR, were delisted. As part of the registration assessment process, Medsafe thoroughly reviewed Enlafax XR to confirm its safety and confirmed it works in exactly the same way as the reference brand (Efexor XR).

Despite these assurances, PHARMAC has received an influx of comments from patients who are dissatisfied with their response to Enlafax XR, and we have responded to a number of media stories on this issue.

Quarter 1 2018-19

Media coverage

Media coverage of the venlafaxine brand switch has continued and campaigns for PHARMAC to fund new medicines for breast cancer and cystic fibrosis have also driven increased public and media attention. The breast cancer medicines Ibrance (palbociclib) and Kadcyla (trastuzumab emtansine) received significant attention in the lead-up to the delivery of a public petition to Parliament on 16 October supporting calls for them to be funded.

Applications for funding for both these medicines have been received and both were reviewed at the recent meeting of the Cancer Treatments Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) which took place in September 2018. Clinical advice is the first step in our assessment process, and the advice we have received from the Subcommittee, plus any further advice from PTAC, will be used by PHARMAC to assess these applications, and then rank them against all other funding options.

Venlafaxine brand-switch survey results

PHARMAC commissioned the University of Auckland to survey people who experienced a change in brand of venlafaxine. The survey took place from March to October 2017. The objectives of the survey were to gather feedback from people about their experiences of the change, better understand the impact of brand changes for people.

The results of the survey have just been published in BMJ Open. The study showed that negative perceptions of generics can cause increased side effects. It also showed that trust in pharmaceutical agencies, including drug companies and regulators, is a key factor in patients' belief in the efficacy of the new generic medicine. The results provide valuable information that can be used to inform future brand change activities. Publication of the results may spark further interest in the venlafaxine brand change.

The research confirms that many people find changing brands challenging, whether they are on a generic medicine or a branded medicine. People who were taking a generic medicine (Arrow-Venlafaxine XR) were more likely than those taking a branded medicine

(Efexor XR) to think that generic medicines in general are just as effective and safe, and have the same number of side effects as branded medicines. Psychological factors, such as perceived sensitivity to medicines, are likely to have an impact on whether people experience side effects with a change in brand of medicine.

Medsafe has re-checked the bioequivalence and quality studies for the funded brand of antidepressant, Enlafax XR, and has confirmed they meet international standards. The Enlafax XR brand is also available in Australia, the United Kingdom, the United States and Canada, and no quality or efficacy issues have been identified in these countries with this brand. PHARMAC remains in close contact with Medsafe and would take any appropriate action necessary to manage any safety or efficacy concerns identified by the regulator.