PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 29 NOVEMBER 2019

To: PHARMAC Directors

From: Chief Executive

Date: November 2019

PHARMAC's approach to brand changes

Recommendations

It is recommended that you:

note the contents of this paper.

Purpose of paper

The purpose of this paper is to provide the Board with background, context and areas of potential future improvement in PHARMAC's management of changes to funded brands of medicines.

Executive Summary

Brand changes are an important part of PHARMAC's management of the pharmaceutical budget, as they help to free up funding to invest in other treatments without reducing access to already funded treatments. We have significant experience in managing these brand changes in the community and consider a range of activities during the decision-making and implementation process to make these brand changes as smooth as possible for the people that will be directly affected by them.

Despite our best efforts, we are unlikely to identify all the potential issues that may arise during a brand change. Most of these issues relate to difficulties people have with managing change rather than clinical issues with the medicine. These issues can often be exacerbated by media and social media.

We have trialled a range of different activities over the recent years to support brand changes and some of these have now become part of our business as usual approach. The most important part of our management of brand changes is to remain agile to respond to issues that arise.

Background

To help best manage PHARMAC's fixed pharmaceutical budget, we routinely run competitive procurement processes which can result in changes to brands of some funded medicines. We have been operating competitive processes for sole supply of medicines since 1997, when the first competitive tender (for paracetamol) was run.

While only the brand is changing, not the active ingredient or chemical, brand changes can cause public concern - mainly around people:

- not being aware of the change and/or not receiving health professional support or advice at the time of the change;
- thinking the change of brand is a change to a different medicine;

- believing PHARMAC is keeping all the savings for itself/making a profit; and/or
- believing that, because the new brand is usually cheaper, it is of lesser quality.

Deciding on, managing and supporting brand changes is an organisation wide responsibility with all parts of PHARMAC contributing through all steps of the process. This includes considering what the impact of any change may be for consumers, healthcare professionals and the sector at all steps of the process. We always think about the balance of maximising the health gains we can get from the fixed pharmaceutical budget, with potential concerns that may arise during any changes we implement. There is a 'tool-box' of activities and approaches we consider for every brand change. However, we manage each brand change on a case-by-case basis.

While the majority of patients experience no negative effects from changing brands of funded medicines, we acknowledge that there can be a very small number of patients who will be negatively impacted during a change.

Our process for deciding on and implementing changes to funded brands

Medsafe, as the medicine regulator in New Zealand, has as one of its roles to assess whether a generic medicine is bioequivalent to the originator medicine. If a medicine is bioequivalent, then we consider, from a clinical standpoint, there is no reason why a change in brand would not be possible for the majority of people taking that medicine.

When we run competitive processes, we often award all or almost all of the market to a single supplier. If the selected supplier is different from the incumbent, a brand change for most people is generally required.

However, before we make these kinds of decisions, we seek clinical advice to make sure a brand change would be appropriate and identify any particular patient groups for whom a change in brand would not be clinically appropriate. We also consider what length of transition period is appropriate for individual funded brand changes on the basis of the specific consumer groups impacted.

When we look at the proposals we receive to competitive processes, we consider the level of change that would be required, and don't solely focus on the cost savings. For example, with the venlafaxine brand change, we chose the proposal where the product closely resembled the incumbent (i.e. it has a 'brand', came as a capsule and was in a blister pack) rather than another proposal that would have provided us with greater savings. This was based on evidence about how the look of the product impacts whether it would be accepted and trusted by consumers.

During our public consultation on proposed brand changes, we seek to understand what impacts changes might have on people. Recently, we have begun to include specific questions in our consultation letters about the types of information, education, support and activities that could be useful to help support any proposed change in brand. Answers to these questions, and/or feedback to consultation in general, helps us to plan for and decide what implementation activities are required to try to make the change in brand as smooth as possible. Sometimes issues that are raised in consultation mean we don't go ahead with the proposal as planned or we increase/change our planned interventions or support.

For every medicine brand change decision that we make, we consider the impact on patients and the health sector and what might be needed to support the change. Supporting clinicians and people who use medicines to make these kinds of changes is an important part of our work. There is no one-size-fits-all for the activities we undertake to support brand

changes as each brand change is different. However, there are some activities that we do consider for all brand changes, which include:

- sharing the notification of the decision widely with health professional and consumer groups;
- providing information on PHARMAC's website about each brand change and timings;
- actioning a Brand Switch Fee (BSF) for community pharmacists (currently $5) to acknowledge extra time to counsel patients with a brand change (there are some standard, agreed criteria for whether a BSF is appropriate, including if this is the first time there has been a brand change for the medicine and if people take this medicine regularly for a chronic condition, rather than as a short-course for acute management, e.g. antibiotics);
- producing leaflets to be used by healthcare professionals when supporting patients, including photos of the medicines; and
- providing education material for prescribers (such as written articles and webinars).

We also have our 0800 line (answered by a pharmacist) for patient and health professional enquiries. Through this service we have responded to numerous enquiries from health professionals and consumers about brand changes.

What have we recently done differently to support brand changes?

Every brand change we undertake helps us to get better at considering what we may need to do for future brand changes. We don't necessarily undertake a formal 'review' of every brand change. However, we utilise learnings and experience from them to create the appropriate support for future decisions.

Some examples of recent activities we have implemented, and that we now consider part of our 'tool-box' to consider for every brand change, are:

- ***Developing a separate exceptional circumstances application process that enables us to consider funding applications for an alternative brand.*** This means that individuals can be funded to stay on their original pharmaceutical brand if a brand change would be clinically challenging for that patient. This process allows us to assess appropriately how people could access the alternative brand allowance (ABA) that we have negotiated with suppliers as part of the RFP process. We initiated this separate process for the 2018 blood glucose meter sole-supply arrangement (where we received no applications), and we are currently using it for the lamotrigine brand change.
- ***Engaging consumers in the decision-making process.*** For the 2017/2018 competitive process for funded blood glucose testing meters, we supported Diabetes New Zealand to undertake user testing with their members as part of the commercial decision-making process. This was to get patients' views about the support that would be required if there was a change in brand, in advance of any consultation process.
- ***Providing people with extra time or an extra visit to their prescriber to help them manage the change.*** We created an ad-hoc process during the 2012/13 blood glucose meter change where people were provided with a one-off supply of blood glucose test strips of their current brand to carry them through until they had their next GP appointment. For the current lamotrigine brand change, we have a process to reimburse the co-payment portion of the cost of an extra visit to a GP for patients who need additional support.

- ***Providing support for people who require additional tests following a change in brand.*** For the current flecainide brand change, we received advice that some clinicians may consider their patients require additional monitoring, but that this was not required for everybody. We have put in place a process to reimburse the co-payment portion of the cost of an extra visit to a general practitioner for patients who need blood plasma monitoring.
- ***Trialing new opportunities for consumers to engage with PHARMAC in 'real-time'.*** For example, as part of the recent consultation for the respiratory inhaler proposal (Board agenda item 9.6) PHARMAC held an 'ask me anything' Facebook live event so consumers could ask us questions about the proposal.

Patients get information about brand changes from a range of sources

For most PHARMAC-initiated brand changes, we do not have access to individual patient contact details and information. This means we are not able to proactively and directly communicate with individual patients who might be affected by a change in funded brands[1].

Instead, we rely on communications with healthcare professionals about changes in funded brands, publicly available information on our website, and consumers and consumer groups who have 'signed up' to PHARMAC's distribution lists as our main channels of communications with people who might be affected by changes in funded brands.

Healthcare professionals are at the point of change for consumers

Front line healthcare professionals are best placed to communicate directly with the patients they see on a regular basis about the risks and benefits of medicines (in general) as well as letting them know about brand changes. Our focus has been on providing healthcare professionals with the information and resources they need to support and positively influence patients through a change of medicine and convey confidence in generics to patients. We know people in the health sector have long institutional memories, and previous brand changes where there have been significant concerns raised will have an impact on the acceptance or otherwise of future brand changes. For example, health professionals still remember, and raise with us, the 2005 salbutamol inhaler sole-supply decision (where there was a move from the Ventolin brand to the Salamol brand) where we had to reverse our original decision.

Over the last ten years, we have developed several resources for healthcare professionals that have provided education and information about generic medicines (in general) and about supporting patients with a brand change. This has included utilising our service contracts for the responsible use of medicines to develop a nationwide series of events in 2009 and a 'special edition' of BPACnz material focussing on generic medicines. We also developed an online learning module in 2017, Beyond the Brand, that provides advice and information for healthcare professionals about how to counsel people through a brand change. We also develop specific materials when we consider the change in brand may be more difficult to manage, e.g. with the recent lamotrigine brand change.

Community pharmacists have a key role in counselling patients at the point when a new brand is dispensed to the patient. We often hear from patients that it was not until they got the medicine home that they realised a brand change was occurring. There is no reason for us to think that this occurs for the majority of patients, and it is likely that most people get some information about the brand change at the point of dispensing. Community

[1] The exception to this is when a brand change occurs with medicines that are funded via our Special Access panels. In those cases, we have been able to communicate directly to consumers about potential changes so they are fully aware of what is planned, and when decision is made, e.g. imatinib brand change in 2014.

pharmacists continue to be an important channel for information about brand changes. We will keep engaging with the Pharmacy Guild, the Pharmaceutical Society and DHBs about the best way we can keep community pharmacists informed and with the right information to support patients with a change.

Anecdotal feedback we receive from prescribers is that they do not generally provide information about a brand change to their patients, as they consider this part of the role of the community pharmacist. Furthermore, most prescribers are not concerned about brand changes as, given the alternative brand will be bioequivalent, they have no clinical concerns with a change (meaning they may not even engage with information about brand changes when it is shared with them).

Media and social media channels can have an impact on people's acceptance of brand changes

While the majority of brand changes we undertake are implemented without a lot of concern, there are some where the media pick up on changes and create, potentially provocative, stories about the changes. Brand changes can gain significant media coverage. This is not unusual and media coverage is a recurring theme with some brand changes we undertake, with frequent media coverage of brand changes over the past twenty years. We know that the media utilise individual people's stories and anecdotal feedback to generate interest in stories, and the coverage of brand changes is no different. Negative media coverage regularly inflates the amount of patient concern about brand changes, which can make it difficult to identify whether there are significant issues, or whether the media coverage is itself stimulating increased patient anxiety about the change (while there is no clinical impact), sometimes referred to as the 'nocebo effect'[2]. Recent research by the University of Auckland has shown that media coverage has a significant impact on the number of adverse events that are reported, and that television coverage has a much greater impact than print media coverage.

We are engaging more proactively with the media as part of our Communications and Engagement strategy, including by providing clinical experts as spokespeople on brand changes. We are hopeful that this will help provide reassurance and lead to more balanced reports about our work, including brand changes.

We also know that people link with groups or individuals on social media to find out information about brand changes or to voice their concerns. When people engage directly with PHARMAC's social media presence, e.g. on our Facebook page, we can provide appropriate responses to any questions or concerns. However, sometimes 'closed' groups are created where we can't see the comments or questions that are being raised and so we don't know how accurate any information sharing might be.

We are unlikely to identify all concerns in advance of each brand change

While we have many years of experience with brand changes and have a good idea of the types of concerns and questions that arise with them, each brand change is different. We know that there may be issues that occur with a brand change we have not identified in advance; our work aims to minimise these instances.

The things that concern people about brand changes have also changed over the years. For example, for brand changes during 2007 – 2010, frequent questions related to country of origin and a lack of understanding about what bioequivalence meant. More recently, the

[2] The nocebo effect is the opposite of the placebo effect. It is when a negative outcome occurs due to a belief that the intervention will cause harm. For medicines, it implies that people are more likely to experience an adverse effect if they expect or are worried about the adverse effect

questions and issues have related more to people's perceptions that some therapy areas should not be subject to brand changes as people believe the condition that is being managed reacts more frequently to subtle changes in a medicine.

What is most important is that we are agile and responsive to issues as they arise. We are confident that the processes we undertake, such as seeking clinical advice and our consultation processes, are appropriate to gather the information we need for decision making. We are also keen to try different ways to engage with those who would be affected by any brand change during consultation to uncover particular issues so our activities to support implementation are appropriate.

We are committed to continuous improvement to support brand changes

Our work to plan and implement brand changes is core to elements of our strategic direction, in particular the Enhance Key Functions and Public Understanding, Trust and Confidence strategic priorities. While we have made ongoing improvements to the management of changes to funded brands of medicines over the past few years, we are always considering how we can further improve our processes. For example, we are currently supporting research through the University of Auckland looking at whether a text message to patients from their community pharmacy informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. If we find this to be successful, we can encourage community pharmacies to roll out this service to their patients in future.

For some significant previous (and current) brand changes, such as the original paroxetine brand change, the diabetes blood glucose meters change, the venlafaxine brand change and the lamotrigine brand change, we have implemented an alternative brand allowance (ABA) process. This has assessed applications for continued funding of people's previous brand of pharmaceutical. This is a manual process that is managed internally, and we are now looking at how we could incorporate an ABA automatically as part of the community pharmaceutical schedule. We already do this with the hospital pharmaceutical schedule, where there is a discretionary variance (DV) limit of, usually, 1% where hospitals can purchase a different brand of medicine should the brand that has been awarded sole-supply not meet some niche patient requirements. We are currently investigating how we might implement a process of this type in the community including identifying a potential commercial transaction we might trial it with, and the process we would put in place to manage this.

We have not had a formal method of reviewing most brand changes after they are complete. We plan to use our internal mechanisms, including our clinical review group, to complete lessons learned reflections from brand changes. This will help provide us with recommendations of other options or tools we might want to use in future brand changes, as well as create efficiencies with current processes. It will also ensure that these learnings are documented so they are part of the organisation's institutional memory, rather than sitting with individuals.

Overall, our aim is to be thoughtful in our decision making, proactive where possible, and responsive when required with respect to brand changes.

PHARMAC
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MEMORANDUM FOR BOARD MEETING 30 OCTOBER 2020

To: PHARMAC Directors

From: Chief Executive

Date: October 2020

Update on actions post review of lamotrigine sole supply decision

Recommendations

It is recommended that you:

> **note** the actions that PHARMAC staff have been undertaking in response to the recommendations of the independent review of the lamotrigine sole supply decision; and
>
> **note** that we are embedding these actions into our standard processes as part of continuous improvement, and we will continue to seek ways to strengthen our decision making and implementation processes.

Purpose

This paper provides the Board with an update on actions PHARMAC has been undertaking to respond to the recommendations in the review of PHARMAC's lamotrigine sole supply decision.

Background and recommendations from the lamotrigine review

In February 2020, PHARMAC commissioned an independent review of its decision-making and implementation processes when awarding sole supply for lamotrigine to Mylan's Logem brand. The review was conducted by Jonathan Coates of Claro Law, and PHARMAC received the final report in May 2020.

At its meeting in May 2020, the Board was provided with the review report. The Board requested an update on PHARMAC's response to the recommendations of the review which were, in summary:

- consideration of involving the Consumer Advisory Committee (CAC) earlier and encouraging the CAC to play a more substantive (though advisory) role in PHARMAC's funding decisions; and
- seeking input from PTAC or its subcommittees at a time closer to issuing a request for proposals (RFP).

Response to the public release of the review

On 5 June 2020, PHARMAC publicly released the independent review report. This included publishing the report on our website, a media release to all media about the review, and sharing the report with all those who engaged with us during the lamotrigine brand change, including members of the public and health professionals.

In the week following the public release of the review, there were seven media stories, including commentary from families of those whose deaths have been referred to the Coroner. There was ultimately balanced reporting of the outcome of the review.

The Board agenda item 11.1 (Legal Report) provides an update on the current Coroner's inquiry into deaths of people taking lamotrigine.

PHARMAC's actions in response to the report recommendations

We are seeking to engage the CAC earlier, and more substantively, in our decision-making processes, and to ensure PTAC and/or its subcommittees is engaged sufficiently close to when RFPs are issued. We are reviewing and updating the Terms of Reference (ToR) of both statutory committees as part of an overall consideration of how PHARMAC seeks and receives expert advice (as per the Expert Advice at PHARMAC paper considered by the Board at its September 2020 meeting).

While the review of the ToRs is not yet complete, we are already making changes to our processes as noted below, and we will continue to look for ways to strengthen our processes around brand changes.

Involvement of the Consumer Advisory Committee in funding decisions

In the current CAC ToR (in place since April 2010), it is specifically noted that the CAC does not have a role in pharmaceutical funding decisions.

We have been looking at how we can strengthen the role of the CAC and, as part of this, have been reviewing the ToR. At its September 2020 meeting, the PHARMAC Board was provided with a draft revised Terms of Reference for the CAC. In the draft, the purpose of the CAC has been broadened to include within the CAC's remit, PHARMAC's ability to seek the views of the CAC on PHARMAC's funding decisions. This is captured within the revised purpose of the CAC as 'The CAC will advise PHARMAC on PHARMAC's approach to gaining consumer perspectives to inform its strategic, policy and operational activities'. We plan to start public consultation on the revised draft ToR in November 2020.

We are actively looking for opportunities to seek the CAC's advice earlier on future pharmaceutical transaction work where we know there is likely to be public interest in any decision that may be made.

We had planned to engage with the CAC early on the proposed trastuzumab RFP, a current medicine competitive process. Originally the CAC was provided with a paper about early engagement with stakeholders on this RFP for their August 2020 meeting. Due to the return to COVID-19 Alert Levels 2 and 3, there has been a delay in engaging with the CAC on this paper, though it is on the agenda for the CAC meeting on 6 November 2020.

Seeking input from PTAC and/or subcommittees closer to issuing an RFP

Since May 2020, we have been engaging with the relevant PTAC subcommittees on some proposed competitive processes. This recent engagement supplements advice and feedback we had already received from the subcommittees about procurement processes for these medicines but is occurring closer to when we intend to initiate the competitive process.

This input includes:

- Seeking advice from the ophthalmology, dermatology, gastroenterology and rheumatology subcommittees and PTAC about a proposed competitive process for adalimumab; and

- Seeking advice from CaTSOP about a proposed competitive process for trastuzumab.

Wherever possible, PHARMAC has engaged with PTAC and/or the relevant subcommittees close to the release of a competitive procurement process. PHARMAC is in the process of completing a procurement policy refresh, which will include creation of guidance documents and refreshing our procurement templates. The processes set out in these documents will include engagement with PTAC and/or relevant subcommittees close to the time that procurement processes are to be initiated.

As part of our expert advice policy work, we have also been reviewing the PTAC ToR (draft brought to the Board at its June 2020 meeting). The provision for consumer representation on PTAC and subcommittees has been included as part of this review (something not previously included).