Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

23 March 2021

Ashley Bloomfield
Director-General of Health
Ministry of Health

By email: ashley.bloomfield@health.govt.nz

Tēnā koe Dr Bloomfield

Enquiry: **PHARMAC - Lamotrigine Sole Supply Decision**
Our ref: **E20HDC00933**

I am writing in relation to the Board of the Pharmaceutical Management Agency's (PHARMAC) decision to change the funded brand of lamotrigine from Lamictal, Arrow-Lamotrigine, and Logem to Logem only (Logem brand change decision).[1]

I acknowledge and welcome the Prime Minister and the Minister of Health's announcement that an independent review of PHARMAC will be conducted this year. I recognise that this review is broader than the Logem brand change decision, but note that the Minister of Health referenced concerns about the safety of substituting medicines due to cost and availability when making this announcement.[2]

My Office has received three complaints and one enquiry, which raise concerns about the Logem brand change decision and about the way in which the brand change was implemented and communicated to consumers. The assessment of these complaints and enquiry was commenced under the oversight of my predecessor, Anthony Hill, and following my appointment in September 2020, I have now carefully considered the issues raised, alongside the Deputy Health and Disability Commissioner, Rose Wall.

As part of my Office's assessment of this matter, HDC obtained information from consumers, prescribers, pharmacists, and PHARMAC. In addition, we closely followed the commentary in the public arena, and considered the report PHARMAC commissioned to review its decision, relevant articles, and the publicly available information provided during the coronial inquest hearings in relation to the Logem brand change.

Following this assessment, my primary concern is that there is a lack of clarity regarding who is responsible for managing and communicating brand changes to consumers,

[1] This decision was announced by PHARMAC on 11 April 2019 and implemented on 1 May 2019.
[2] The announcement was made on 2 March 2021 and can be found here: https://www.beehive.govt.nz/release/govt-announces-review-pharmac.

particularly when those changes can cause significant adverse effects. There are also a number of other related issues which caused me concern. These are detailed below.

1. Prescription practice and brand changes

As I understand, it is not uncommon for general practitioners (GPs) to prescribe medications generically. This practice can lead to prescribers relying on PHARMAC to determine that the brand of medication supplied to their patients is bioequivalent and safe. If GPs are not aware which brands of medication are being dispensed to their patients, it is unlikely that they will know when a patient's regular brand of medication has been switched, or be in a position to inform their patients of the brand change. Where such brand changes have clinical/therapeutic consequences, this is problematic.

Further, it seems some GPs do not consider that it is part of their role to inform patients of brand changes and instead rely on pharmacists to communicate this information at the time the medication is dispensed. Some GPs also assume that pharmacies will contact them about any significant brand changes, or any deviation to the patient's usual prescription.

Lastly, some GPs have also reported that they were not aware that the Logem brand change could lead to a change in seizure activity and/or other adverse effects.

2. Frequency of brand switches

In light of the frequency of generic substitutions following subsidised brand changes, some GPs may not actively look out for, or retain information on brand changes or the date of implementation. One perspective which has been reported to HDC is that keeping updated with every brand change and being responsible for informing patients of these changes is not realistic or reasonable. This perspective is not the view of HDC. I do not wish to make any comment about how frequently medication brands are changed as that is a matter for PHARMAC. However, it is important to ensure that prescribers are aware of brand changes and are assisted in retaining salient pharmacological information when prescribing.

3. The timing and mode of communication of the brand change

There have been reports that PHARMAC's communication to some GPs was either not received, not read, or only skim read and not retained, which meant that information was not relayed to patients in advance of the Logem brand change.

HDC has also been advised that some GPs do not regularly access PHARMAC's website and are therefore unware of the notifications about the brand changes documented there.

Further, some GP practices may not formally monitor brand changes and it appears that commonly used practice management systems (PMS) have a limited capacity to do so.[3] In my view, it is important that PHARMAC carefully considers the way in which it communicates brand changes to prescribers, pharmacists and consumers.

[3] I am advised that it is possible in MedTech to add and remove specific brands from the prescribing database at the time of scheduled updates, but there is no 'real-time' link with PHARMAC/the Pharmaceutical Schedule to ensure PMS' contain current information.

4. Pharmacies

HDC has been advised that the Logem brand switch was particularly complicated due to having to coordinate dispensing dates with new stock availability, funding issues and patient preferences at the time of each dispensing. In one instance reported to HDC, a patient chose to halve 100mg tablets (to make up 250mg) to save money while waiting for funding for an alternative brand. In my view, this practice puts consumers at risk.

Complications can also arise when family members or caregivers collect medicines, as pharmacists do not always have the opportunity to talk with the patient about the brand switch. Further, as some patients visit multiple pharmacies, it can also be difficult to follow their dispensing history.

5. Conclusion and next steps

I accept that for some primary care providers, the notification and direction PHARMAC provided about the Logem brand change would have been sufficient. However, this was not the case for other primary care providers.

As stated, I am concerned about the lack of clarity regarding who is responsible for managing and communicating brand changes to consumers, particularly when those changes can cause significant adverse effects. At present, there seems to be a blurred line of responsibility between PHARMAC, prescribers, and pharmacists. In my view, it is essential that health care providers communicate effectively with their patients to ensure that any risks associated with a brand change are carefully managed and mitigated. In order for this to occur, PHARMAC must ensure that providers are appropriately informed of these changes and alerted to the associated risks in a timely manner.

Due to the potential ongoing risks for consumers, many of whom are particularly vulnerable, I have therefore decided that it is desirable in the public interest to refer my concerns to the Ministry of Health for its consideration. This referral is made in accordance with section 59(4) of the Health and Disability Commissioner Act 1994.

In light of risks identified, I suggest the Ministry consider consulting with PHARMAC, prescribers, pharmacists, and their professional bodies to clarify the lines of responsibilities for managing the implementation and communication of brand changes.

The Ministry may also wish to discuss the following matters with the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), PHARMAC, the Medical Council of New Zealand (MCNZ), the Pharmacy Council, and the Royal New Zealand College of General Practitioners (RNZCGP):

- The resources currently available to prescribers and pharmacists regarding Sudden Unexplained Death in Epilepsy (SUDEP), and the impacts of brand changes for patients with epilepsy, with a view to developing an educational resource if it is necessary.

- Whether there are ways in which PHARMAC, pharmacies and general practices can improve their systems and processes to ensure effective monitoring and communication of brand changes. One possible solution could be to improve the way a PMS obtains information from PHARMAC and alerts prescribers to brand changes.

I would appreciate being advised of the outcome of any action taken by the Ministry. Correspondence can be sent to: hdcresponses@hdc.org.nz.

I further advise that I have concluded my assessment of the individual complaints and will be taking no further action on those matters pursuant to section 38 of the Health and Disability Commissioner Act 1994.

I have advised PHARMAC of these decisions and informed it that you may be in contact in the near future.

Thank you for your assistance with this matter.

Nāku iti noa, nā

Morag McDowell
Health and Disability Commissioner

Cc PHARMAC
Health Quality and Safety Commission
New Zealand Pharmacovigilance Centre
Medsafe
MCNZ
RNZCGP
Pharmacy Council
Chief Coroner