EPILEPSY WAIKATO
CHARITABLE TRUST
Leading the way *He arahanga whakamua*

25 September 2018

Lisa Williams,
Director of Operations
C/- Alexander Rodgers
PHARMAC

Dear Lisa,

Re: Feedback to PHARMAC on a proposed change to the funding of lamotrigine dispersible tablets used in the treatment of epilepsy and/or bipolar disorder

The Epilepsy Waikato Charitable Trust (EWCT) is concerned that PHARMAC wishes to

• reduce the funded brands of lamotrigine 25 mg, 50 mg and 100 mg dispersible tablets to just one funded brand (Logem);

• make Logem the only funded brand of 25 mg, 50 mg and 100 mg dispersible tablets in both the community and hospital settings.

As you may appreciate, epilepsy is a complex neurological condition that is mostly managed by anti-epileptic drugs (AEDs). The sole aim of this treatment is to reduce seizures. Once long-term remission has been achieved it then becomes important to avoid even a single break-through seizure subsequently. The social, emotional and financial burden to a person enduring a break-through seizure is immense and such people are then more at risk of a seizure-related death either with status epilepticus or SUDEP. It is therefore incomprehensible that PHARMAC would entertain changing a branded anti-epileptic medication with a generic brand when there is more risk in 'switching' medications for people with epilepsy, who hold on tightly to their established medication regimes, than with any other medical condition.

Establishing seizure control can be a heartache for people with epilepsy. It can take months, even years, to get the medications just right. Quite often a number of AEDs have to be tried at various doses to identify which treatment is most effective and tolerable. Neurologists always aim for monotherapy but, more often than not, additional AEDs are used as adjunctive therapy (always with titration according to therapeutic responses) to get full seizure-control. Multiple AEDs added to the daily regime of seizure treatment increase the potential risk of side effects, and using a generic brand has the potential to differ in its therapeutic response even though it is defined as bioequivalent to the branded one.

Bioequivalent studies are usually carried out with single doses on small numbers of healthy volunteers, who are not receiving other therapies, to eliminate factors that cause variations

in results. PHARMAC staff would likely be aware of such bioequivalent studies when choosing Logem over lamotrigine. However, it is well known that each person with epilepsy will respond to AEDs differently. **We would therefore strongly recommend that PHARMAC uses caution, and cancels this proposal, because of the very significant risk to ~10,000 vulnerable people currently taking lamotrigine**. Some queries to consider with regard to the proposed switch are as follows:

- What if there are serious consequences to any person with epilepsy in that 'switch"?
- What about the potential for breakthrough seizures resulting in a loss of a driver's licence, job, self-esteem, depression or suicide?
- What if neurologists become so tied up in complex management regimes in order to control seizure on each of their clients?
- What if some people have 'brittle' epilepsy and simply cannot tolerate generic medications?
- Will the savings made from generic prescribing of AEDs outweigh the cost of adverse consequences in some patients?

There is a human cost to PHARMAC's proposal and people with epilepsy, already disadvantaged in the community, stand to suffer further, including some potentially fatally, as a result of taking a generic brand of medication that may, or may not, produce a satisfactory cost-saving result to the government. Epilepsy is a complex neural pathway condition largely treated with medications, and a medication 'switch' may just be the undoing of many people with epilepsy tenuously holding onto their lives.

Yours faithfully

Maria Lowe
Epilepsy advisor

On behalf of
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Note: EWCT (www.ewct.org.nz) is a regional epilepsy provider not associated with Epilepsy New Zealand