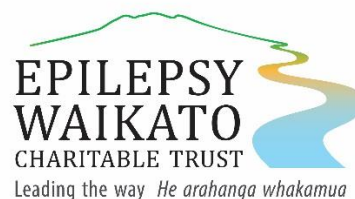


Epilepsy Waikato Charitable Trust (EWCT)
P.O. Box 633
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18 December 2019



To whom it may concern [PHARMAC]

Re: Lamotrigine/Logem brand switch

A year ago, EWCT was notified (by a representative of GSK) of Pharmac's decision to cease funding Lamotrigine, preferring instead to fund the generic brand Logem. We sent out a notification to our clients of this event and we wrote a submission to Pharmac asking for that decision to be reversed. At no stage did we exacerbate the situation, preferring to take a more reasoned approach to Pharmac's decision. However, we discovered that many of our clients were not told by their GP, neurologist, nor pharmacist of this brand switch and so did not receive the support or advice as recommended by Pharmac. In fact, the brand switch appears to have been poorly implemented, which has left many people living with epilepsy even more anxious about their condition than before. These negative feelings have not been helped by news reports of four deaths, possibly linked to the switch, and there is now uncertainty in the minds of many regarding the outcomes of their new treatment option, which has been imposed on them by Pharmac.

In the recently updated BPAC article (<https://bpac.org.nz/2019/docs/lamotrigine.pdf>), it was stated that Pharmac referred to UK's MHRA 2014 guidelines on prescribing anti-epileptic medications. These guidelines were in fact not a proposal, as was implied in the BPAC article, but rather clear advice on which medications can be switched. The BPAC article totally disregards the category-2 classification system, which Lamotrigine falls into, by wilfully omitting these words:

"The need for continued supply of a particular product should be based on 'clinical judgement' (the doctor's judgement of the risk of problems) and in consultation with the individual. **This means that a doctor should decide, with the individual, whether it is important to always stay on the same version or whether it is ok to switch between different versions.**" [*emboldened emphasis is in the original MHRA document*] (<https://www.epilepsysociety.org.uk/mhra-guidance-anti-epileptic-drugs#.XfMgdZMzblU>)

The Pharmac clinical advisory groups (i.e. neurology and mental health joint advisory team) recommended that 'changes between approved formulations of Lamotrigine produced by different manufacturers would be unlikely to result in problems for patients with epilepsy or mood disorders, and that the change of the funded brand of Lamotrigine should proceed'. And yet, by the end of October 2019, Pharmac had received notification that three deaths had been reported to the Centre for Adverse Reactions Monitoring (CARM) over the suspicions of three deaths being linked to the change.

According to Pharmac's website, 1,155 people have applied for 'exceptional circumstances for funding Lamotrigine'. So far, 934 people (81%) have been approved by Pharmac and 205 are still being assessed. Only eight people have been declined. These figures contradict an earlier statement made by Pharmac that there was 'no pharmacological reason to suggest there would be a clinical problem'. In fact, the assurance of Logem being bioequivalent may not ring true even for those people with well controlled epilepsy. The small differences in pharmacokinetic properties have affected seizure control

or tolerability in those 934 people which would have been avoided had Pharmac followed MHRA's guidelines for prescribing anti-epilepsy medications. In Pharmac's desire to save thirty million dollars over five years, this brand switch, and subsequent treatment failure, has led to higher indirect medical costs, and has jeopardised medication adherence and trust of the medical system that has put cost first, over the quality of life, for those living with epilepsy. The economic costs of prescription medications are small compared with the costs of diagnostic evaluations, emergency care, outpatient neurology or paediatric appointments, diet therapy, speech, occupational therapy, physiotherapy and neuropsychology support (not to mention the human costs associated with living with epilepsy, discussed below).

By the time social media, and Guyon Espiner (via TV documentaries), had alerted people to the problems others were experiencing on the brand switch, BPAC produced another article on the 'Nocebo Effect'. Was BPAC attempting to belittle genuine concerns of people living with epilepsy, or to dupe the medical professionals further into believing that the brand switch was not a problem? After all, Pharmac's clinical advisory group had apparently read 50 scientific articles and was confident of its decision to allow the brand switch to go ahead. The advisory panel also asserted that any seizure activity following the brand change was unlikely to be because of the change.

Living with epilepsy involves more than just seizures: people face numerous challenges, including comorbid diagnoses and an increased risk of sudden death. Sudden death in epilepsy (SUDEP) is the most common cause of epilepsy-related death. Recent estimates suggest that SUDEP affects approximately 1/4500 children and 1/1000 adults. Up to 84% of people with epilepsy have at least one comorbid condition. People with epilepsy also face social challenges in independent living and in school, driving limitations, and employment uncertainties. Moreover, epilepsy remains highly stigmatised, which negatively affects quality of life and leads to anxiety, depression, and sometimes for people to become suicidal.

In fact, anxiety and depression are so common that the overall rate of adults and children with epilepsy experiencing a mood disorder stands at 25-50% higher than that of the general population. According to a recent report from Denmark, people with epilepsy have triple the risk of an attempted suicide and at least double the risk of death by suicide, compared with the risk levels of the general population. A brand switch in anti-epileptic medications would therefore heighten a person's anxiety level well beyond the 'nocebo effect' because in reality most are already living anxiously.

The Ministry of Health has acknowledged in its draft report, "Living well with epilepsy" (2019), that epilepsy is a hidden condition and has a low priority in many health systems. The most likely reason for this low priority is the lack of understanding of the experience of living with the condition. Would this be the case here with Pharmac's brand switch decision? Do the people who have made the decision understand the difficulties that people have finding the medication that works for them? It can often take years of trial and error, of frustrations, anger, and of enduring side effects to get the medication right. In 30% of cases there is no seizure control and so switching from one medication to another only adds to increased anxiety and uncertainty. The additional SUDEP statistics add to the woes of living with epilepsy.

Epilepsy is a complex neurological condition that is often difficult to diagnose and encompasses at least 40 seizure types. There are 25 syndromes that are associated with it. Epilepsy is a spectrum disorder with a range of severities, and it can appear at any age with the prevalence appearing mainly in childhood and in the elderly where there are major funding gaps in services. Many people living with epilepsy are disadvantaged in New Zealand because of their ethnicity, low socioeconomic status, and difficult geographical locations. We know then that these same people, and Māori in particular,

will struggle through any brand switch of medication without the knowledge and support to help them.

To make it fairer and safer for all people living with epilepsy, we propose that Pharmac adheres to the MHRA (UK) guidelines in prescribing anti-epileptic medications. We strongly urge that there be no further brand switch of anti-epileptic medications because of the difficulties associated with these drugs.

We also ask that Pharmac notifies all epilepsy providers, including the Epilepsy Waikato Charitable Trust (EWCT), of any possible medication changes, so that we may support our clients better.

Yours faithfully,

Maria Lowe (epilepsy advisor)

On behalf of Epilepsy Waikato Charitable Trust (EWCT)

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

Resources:

<https://ewct.org.nz/epilepsy-medication/>

<https://ewct.org.nz/driving-and-epilepsy/>

<https://ewct.org.nz/living-challenges-epilepsy/>

<https://ewct.org.nz/children-and-epilepsy/>

<https://ewct.org.nz/taking-anti-epileptic-medications/>

<https://ewct.org.nz/epilepsy-and-the-elderly/>

<https://ewct.org.nz/sudep/>

<https://ewct.org.nz/epilepsy-and-employment/>