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Leading the way *He arahanga whakamua*

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Below is EWCT's response to a letter published in the New Zealand Herald *on 19 December 2019 by Prof Peter Davies that was headed "Open mind on drug reassuring" (a copy of Davies' letter is given on page 2 below).*

Pharmac's unfortunate experiment

Prof Peter Davies' letter (19 Dec) about the Lamotrogine switch for people with epilepsy is anything but reassuring. Firstly, that four deaths (a fifth has been announced by Medsafe NZ) may be associated with the switch to the generic drug, Logem, cannot be simply waved away as potentially insignificant in a statistical sense. The findings of the previous decade-old study cannot predicate the cause of the deaths that have occurred during the switch in 2019. In other words, having an open mind cuts both ways, and so the possibility that the switch may have contributed to the deaths must be examined – which is why the matter is before the coroner.

Secondly, Davies' letter is somewhat naïve in that the switch has very significant impacts on many people with epilepsy, and these can be far more than 'some side effects' (in addition to the possibility of sudden death or SUDEP). Living with epilepsy involves more than just seizures: as well as comorbid diagnoses, people face numerous social challenges including independent living and in school, limitations in driving a car, and employment uncertainties. Moreover, epilepsy remains highly stigmatised, which negatively affects quality of life and can lead to anxiety and depression.

Thirdly, the decision by Pharmac to make the switch despite warnings from Medsafe NZ and others must be seen as an unfortunate experiment. For a person living with epilepsy it can take months or years to find the right medication that controls seizures. Once that medication is found then a person will hold onto it tightly through fear of having another seizure. Pharmac 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'. However, according to Pharmac's website, 1327 people have applied for 'exceptional circumstances for funding Lamotrigine'. So far, 1248 people (94%) have been approved by Pharmac (others are still being assessed; only a handful – 6 – has been declined). These figures thus contradict Pharmac's earlier statement that there was 'no pharmacological reason to suggest there would be a clinical problem'.

Fourthly, 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 1248 (+) people which would have been avoided had Pharmac followed the UK's Medicines and Healthcare products Regulatory Agency (MHRA) guidelines for prescribing anti-epilepsy medications.

Fifthly, the Pharmac 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 social costs associated with living with epilepsy).

Signed
Maria Lowe (epilepsy advisor for EWCT)
David Lowe (chair, EWCT Trust Board)

On behalf of Epilepsy Waikato Charitable Trust (EWCT), Hamilton www.ewct.org.nz

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

Letter below is copied from *NZ Herald* 19 December 2019

Open mind on drug reassuring

Pharmac is being criticised (*NZ Herald*, December 18) for failing to move quickly enough on public concern that a brand of epilepsy medication – Logem – is associated with deaths among those who have switched to it from the existing brands (Lamotrigine and others, all of which are pharmaceutically equivalent).

It is reassuring that the head of Epilepsy New Zealand, Ross Smith, is reported as saying that we need to keep an open mind about whether a causal link has been proven in this case (now with the coroner).

In recently completed doctoral research I co-supervised into exactly this issue – the introduction of new brands for epilepsy competing with Lamotrigine (just over 10 years ago) – we found the death rate among those who stuck with the original brand was the same as those who switched to the new ones (just under 1 per cent).

In other words, deaths do occur among patients on epilepsy medication – unfortunately – but it does not seem to be related to the brand of medication being taken, or any switch between brands, even while patients do perceive and report some side effects in these circumstances.

Peter Davis, Emeritus Professor in Population Health and Social Science, University of Auckland.