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Guyon Espiner investigates: Pharmac switches epilepsy drug against Medsafe advice

4:47 pm on 27 May 2019

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Pharmac is making 10,000 people with epilepsy change medication even though Medsafe opposed the move. Guyon Espiner asks why the drug-buying agency carries out up to 60 drug switches a year.



In letters to Pharmac, obtained by RNZ, Medsafe warned the drug-buying agency against asking people with epilepsy to switch drugs. Pharmac is going ahead. Graphic: James Sanday

This is the third story in a four-part investigation into how Pharmac works and whether its model is costing lives. You can read part 1 here: The NZ Buyer's Club (<https://www.rnz.co.nz/news/in-depth/390559/guyon-espiner-investigates-pharmac-the-nz-buyer-s-club>). Part 2 is here: Pharmac's secret list (<https://www.rnz.co.nz/news/in-depth/390558/guyon-espiner-investigates-pharmac-the-secret-list>). Part 4 will be online tomorrow. Listen to Guyon Espiner discuss this investigation here: Drugs and Money (<https://www.rnz.co.nz/programmes/the-detail/story/2018696420/drugs-and-money>)

Sophie Cooper* fears she is about to lose her 4-year-old again. She can see days ahead where Maddie Cooper* won't be able to walk or talk, where she disappears into a life of seizures.

It has happened before when epilepsy gripped Maddie's brain and body. "It was every parent's worst nightmare. We just felt like we lost our little girl," Sophie says.

Last year, Maddie was prescribed anti-epileptic drug Lamictal and the nightmare ended.

"The medicine works. Finally, she's at a dose where her seizures are controlled and we feel like we have our little girl back."

Now Sophie worries her daughter is about to slip away again. Sophie is being forced to switch from giving Maddie Lamictal to administering a generic drug.

Maddie is one of more than 10,000 patients with epilepsy who is being pulled off Lamictal because New Zealand drug-buying agency Pharmac has cut a deal to buy a cheaper, generic medicine.

Pharmac is going ahead with the switch despite being advised not to by Medsafe. The medicine safety watchdog has told Pharmac the drug swap "poses a potential significant safety issue".

RNZ has obtained documents, under the Official Information Act, that show Medsafe told Pharmac in September 2018 that its plan "goes against international consensus on switching brands of anti-epileptic medicines".

It warned the brand switch "could result in the loss of seizure control" for patients trying to control epilepsy. "A single seizure can be extremely detrimental to a patient's life and all measures should be taken to ensure this risk is minimised."

Sophie Cooper wants Pharmac to drop its plan, which will come into full effect by October, or at least make children exempt from the switch. "The thought of going backwards, of doing anything to risk that, is unbearable."

Read Medsafe's warnings (obtained by RNZ under the Official Information Act) to Pharmac here (<https://www.documentcloud.org/documents/6025152-MedSafe-OIA.html>).

So why is Pharmac risking it? The long answer is Pharmac frequently uses a tactic called brand switching to make its model work. The short answer is money.

Unlike other OECD countries, New Zealand's drug-buying budget is capped. Other countries have more flexible budgets and make buying decision drug-by-drug, using formulas that take in cost, a medicine's effectiveness and quality of life to decide whether to fund. (Read more about this in part one of this series. (<https://www.rnz.co.nz/news/in-depth/390559/guyon-espiner-investigates-pharmac-the-nz-buyer-s-club>))

The cap often means that in order to buy new drugs, Pharmac must free up money by reducing spending on drugs it already funds. Brand-switching, after cutting new deals with different pharmaceutical companies, is one of the key tactics Pharmac employs to do this.

The agency typically makes about 60 brand switches a year - that's more than one a week.

This time it happens to be the epilepsy drug Lamictal. The patented drug, with the active ingredient lamotrigine, is made by GSK and is used by people with mental health conditions, such as bi-polar, as well as those with epilepsy.

Pharmac currently funds Lamictal and two other brands of lamotrigine, but as part of its strategy to free up money, the agency put the supply of lamotrigine out to tender. Pharmaceutical company Mylan came back with the best price offer for its copy-cat drug, Logem.

Pharmac's new deal with Mylan means from October the other drug companies are all but axed as suppliers. Logem will be the only publicly-funded lamotrigine medication available.

It's a win for Mylan, as its drug is currently the least popular of the three Pharmac-funded lamotrigine medicines and soon it will enjoy a virtual monopoly. In return, Mylan is offering Pharmac cheap rates. In fact, Pharmac calculates it will free up \$30 million over five years with the deal, meaning the agency will have \$6 million each year to spend on new medicines.

But caught in the middle of this type of commercial deal are patients, many of whom feel their conditions are well-managed with existing medication and don't want to risk switching brands.

Epilepsy affects 48,000 New Zealanders. It's a serious condition - every year about 40 people in this country die from sudden unexplained death due to epilepsy.

Epilepsy New Zealand chief executive Graeme Ambler says studies suggest up to 25 percent of the 10,000 people who take Lamictal could be at risk from the change. "The potential impact is that a person will have a seizure and that seizure can range from nothing, through to self-injury, through to embarrassment through to loss of a job."

Pharmac is aware of these sorts of fears. Medsafe told Pharmac patients using anti-epileptic drugs, including lamotrigine, should only be switched to a generic on the advice of a specialist.

Pharmac made some minor changes to its plans but dismissed the thrust of Medsafe's concerns. It said several international studies showing adverse effects of switching brands of lamotrigine were sponsored by pharmaceutical companies. Medsafe hit back that the dismissal was inconsistent with Pharmac's own approach, as the drug-buying agency itself accepted pharmaceutical company-sponsored biostudies for funding generic medicine.

Medsafe group manager Chris James wrote to Pharmac that the studies deserved "careful analysis" and should not be "dismissed based on the funding source alone".

James also warned Pharmac a research paper the drug-buying agency said was the best evidence that switching to lamotrigine would be successful had no method validation - in other words, no proof that the analysis used in the research was suitable - and that "from a pharmacovigilance perspective the paper is not meaningful".

He went on to say if Pharmac decided to go ahead with the switch, each patient should be given an information leaflet and should first be reviewed by their GP. "GPs should also refer the most vulnerable patients for specialist intervention to oversee and monitor the switch."

Pharmac rejected the latter recommendation, after its subcommittee on mental health and neurological conditions said "referral of all such patients to a specialist would place an unnecessary and significant burden on specialist providers".

The subcommittee also disagreed patients should be fully informed about the brand switch. Minutes from one of its meetings read: "Members considered that there was a risk of causing unnecessary anxiety about the change if too much emphasis was placed on the change and that caution should be taken with the amount of information provided to patients upfront."

Sophie Cooper, facing the switch with her preschooler, sees this approach as arrogant. "It goes against the very notion of informed consent. Our Health and Disabilities Act is founded on it, and it's not good enough."

Her verdict on the entire switch? "Reckless - I don't know how else to describe it. I think they've put very little thought and consideration into the brand change, specifically in regards to children."

Sarah Fitt says Pharmac thinks long and hard before brand switching. Photo: RNZ / LUKE MCPAKE

Pharmac CEO Sarah Fitt is upfront about why the agency brand switches. "It frees up money to spend on new medicine."

It's not something the agency does lightly though, she says. "We get clinical advice as to whether it's appropriate. We think about it very seriously."

She concedes Pharmac brand switches with vulnerable patients, including those with mental illnesses. "That's based on the advice we get from our psychiatrists and our clinicians as to whether it's appropriate to do. We wouldn't do it if the advice was not to do it or if there was a risk."

Yet in 2017, Pharmac moved 45,000 people with serious mental illnesses to a new brand of antidepressant venlafaxine. It saved \$5 million a year but prompted 142 reports of adverse reactions.

"We thought about that long and hard," Fitt says. "It was something that we planned for a long time and with a lot



of clinical advice. So we take this very, very seriously. We don't want to cause harm to people at all."

Still, she says she is unsure how seriously the 142 people who reported adverse side effects were impacted. She can't say if any of them harmed themselves or died from suicide. "I don't know all the individual details of those 142 cases, but we monitor it very, very carefully. And obviously, if there was any issues of concern, we would have acted on that."

Pharmac saves so much money on brand switching that it is now prepared to spend money studying it. It has gone to Keith Petrie, a professor of health psychology at Auckland University Medical School, who specialises in the "Nocebo effect" and commissioned him to carry out \$400,000 worth of research.

Petrie describes the Nocebo effect like this: "When we're faced with a new medication, and we hear that this particular medication can cause particular side effects, we can be more attuned to noticing those effects and reporting them," he says.

He researched the 2017 venlafaxine switch and says the more the media reported on the side effects of the change, the more people thought they experienced them and reported them.

"Branding confers kind of a positive feeling that people have about the pill that they're taking, so when that it is taken away, say in a switch from a branded to a generic, it can reduce the overall effectiveness of the medicine."

Combine that with human resistance to change and people can mistakenly attribute side effects to a brand switch, he says. "You can see how these things can become self-fulfilling prophecies in some ways and cause real health consequences."

Medsafe touched on this in its warnings to Pharmac over the epilepsy drug brand switch, saying "negative perceptions are a major cause" of brand switch reactions and it expected to see "a significant number" of adverse reaction reports. "Each time these events occur patient and healthcare professional trust in the health system is eroded."

Sophie Cooper is worried her daughter will begin having 15 to 20 seizures a day if she is taken off Lamictal (stock image). Photo: 123RF

Sophie Cooper has little trust in Pharmac. She has a plan to keep her preschooler on Lamictal but knows the



agency's drug switch deal could torpedo it.

She is going to apply for funding for Lamictal under Pharmac's "exceptional circumstances framework", but fears GSK, who makes the drug, may pull it from the New Zealand market if demand for the drug plummets.

"That [sort of thing] has happened before because it's just not commercially viable. They're not our mates, they're pharmaceutical companies! They don't owe us anything - Pharmac does and government do in terms of ensuring that choice exists in the market for these absolutely vital medications."

She remembers Maddie's hardest times, which she thought were in the past, and feels they are on the horizon again.

"We've spent six months not going further than 10 minutes from Starship. We've spent my son's first birthday at hospital, we've spent Christmas watching a child seize... We've spent six months dealing with this crippling neurological condition and finally getting to a point where my daughter is not having 15 to 20 seizures a day.

"The possibility of going back to the way things were is ... I can't countenance it."

*Names have been changed.