Lamotrigine

Key messages

- Logem works in the same way as the other two Lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Making brand changes like moving to sole supply helps us make more medicines available to more New Zealanders by freeing up money to fund other medicines In the case of Lamotrigine this is more than $30 million over the next 5 years.
- A small number of people aren't able to change brands due to complicated medical reasons. We will continue to fund the brand those people are currently on through our exceptional circumstances programme.

Supporting information

- We rely on the advice of our expert clinical advisors about the evidence and potential impacts on affected people for all medicine funding changes, including generic medicines. If our expert clinical advisors said it is not appropriate, we wouldn't make a change. In the case of Lamotrigine, the proposed change, including all the consultation feedback PHARMAC received on the proposal, was examined by a joint meeting of our mental health and neurological subcommittees.
- For the Lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we put in place a five-month transition period to allow people time to change brands and created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients. We also developed a range of resources for health professionals, including patient information leaflets they could give to consumers and an online 'Beyond the Brand' learning module about brand changes, and we put up to-date information about brand changes on the PHARMAC website.
- There is a shared responsibility across the health sector to ensure patient safety is considered when changes to brands are made.
- Medsafe ensures generic medicines are bioequivalent (therapeutically the same) as the original product and that the manufacturing process safety standards are met. Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of medicines use and contribute to international knowledge of pharmacovigilance. We liaise closely with Medsafe, about brand changes and reports to CARM, to make sure we're doing everything possible to ensure the smooth transition between brands.
- All medicines have side effects Some patients taking medicines used for prevention of an illness or condition will experience breakthrough episodes, regardless of brand. It can be difficult to determine whether such incidences are linked to a change in brand of medicine or if they are related to the underlying condition It is also difficult to predict which brand changes are likely to result in more adverse reactions and which patient groups are most likely to be impacted.

Brand changes

Key messages

- PHARMAC funds generic medicines that Medsafe has assessed as being safe, effective and of good quality. PHARMAC gets advice from clinical advisory committees before it considers funding a generic medicine.
- We understand that some people find changing brands challenging, irrespective of the medicine they're taking, and we consider that before we make any decision of this kind.

Supporting information

- Generic medicines are brands of medicines made by companies that didn't develop the original drug themselves.
- All generic medicines have to be approved by Medsafe and go through bioequivalence testing to make sure that they work the same way as the original brand of that medicine
- Because generic medicines have to have the same active ingredient in them as the original medicine, they have the same risks and benefits as the original brand medicines.
- Brand changes are common, with around 60 brand changes of funded medicines per year This activity helps us to get the very best from New Zealand's fixed medicines budget.
- Research shows that people who are taking a generic medicine are more likely to think that generic medicines in general are just as effective, safe and have the same number of side effects as branded medicines, than those taking the original brand

Umbrella statement
Logem works in the same way as the other two Lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands

Core message 1
Before making this decision, we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine.

Core message 2
A small number of people aren't able to switch brands due to complicated medical reasons, and we will continue to fund the brand those people are currently on through our exceptional circumstances programme

NZTA specific
NZTA are not enforcing a mandatory stand down period from driving As a precaution they are recommending that health practitioners whose patients have or will be transferring brands consider a voluntary stand down from driving during the eight-week early transition period after switching medications, **should they have any concerns when considering an individual patient's medical history** and other relevant factors.

Out of pocket specific
Following the change to the Logem brand, some people might want to discuss concerns with their GP and get additional support to make a successful change. In these cases, the GP can waive the patient's visit co-payment and PHARMAC will reimburse the GP clinic

For John

Logem works in the same way as the other two Lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands

I do not believe that there is any pharmacological reason to suggest there would be a clinical problem for patients with epilepsy or mental health conditions to change the brand of lamotrigine they use.

There are a small number of people who aren't able to switch brands due to complicated medical reasons PHARMAC will continue to fund the brand they are currently on through their exceptional circumstances programme. \

Moving to a single funded brand of lamotrigine will avoid ongoing, potentially unmanaged, brand changes for patients We know that sometimes consumers are given whichever lamotrigine a pharmacy had in stock Without knowing it they might have one brand one month, and a different brand the next.

Dispensing data for 2018 shows that around half of all patients who collected a funded prescription for lamotrigine, have changed brands at least once since they started on lamotrigine. Around 4,000 patients have changed brands two or more times.

From: Sheldon Brown <Withheld under section 9(2)(a)>
Sent: 23 June 2020 10:43 AM
To: Web Enquiry <enquiry@Pharmac.govt.nz>
Subject: Generic anti depressant medications

Hi there,

I host a mental health radioshow called Take It From Us on community radio in Auckland and have broadcast items about the switch of 'branded' anti depressants to generics following the changes to Effexor. I have now been made aware of other generic anti depressant drugs being introduced, namely Lamotrigine, Fluoxetine and Sertraline.

Could PHARMAC confirm that these three anti depressants are being switched to generics please
Are there other psychiatric medications that are in the pipeline for a switch from branded to generic?
What is the timing of these switches?
What information will be released to accompany the changes?
Can users of the branded medications still access them after the switch?
What is the likely cost at pharmacies if they chose to continue the branded meds?

Looking forward to hearing

Regards,

Sheldon Brown
Sheldon Brown
Radio Host

ember
KOROWAI TAKITINI

Office: 09 523 2790
Mobile: Withheld under section 9(2)(a)

Listen to our own mental health radio show on every tuesday at 12:30 P.M. on PlanetFM 104 6 or go to
http://www.planetaudio.org.nz/takeitfromus

From: Media
Sent: Tuesday, 23 June 2020 12:36 pm
To: 'Withheld under section 9(2)(a)' <Withheld under section 9(2)(a)>
Subject: FW: Generic anti depressant medications

Hi Sheldon, as discussed I am your best point of contact As background reading I suggest the following:

https://www.pharmac.govt.nz/medicines/my-medicine has changed/lamotrigine epilepsy drug-changes/
https://www pharmac govt nz/medicines/my-medicine has changed/sertraline/
https://www.pharmac.govt.nz/medicines/my medicine has changed/fluoxetine-fluox-is-the new funded brand/

Kind regards
Jane Wright | Senior Communications Advisor, Media

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
M: Withheld under www.pharmac.govt.nz
We are constantly updating our website with information about medicine supplies.
See our latest updates at pharmac.govt.nz/covid19

Take it from us Tuesday 30 June 2020

PHARMAC pre-record on Monday June 29@9.30am

……That's our theme music from Joe Cocker, his track called Respect Yourself; I'm Sheldon Brown with technician Declan Curran, and this is mental health radio Take It from Us, promoting mental healthiness, that's our new promotional line Take It From Us is bought to you and funded by Ember Wellbeing Trust, and thanks again to the Trust for renewing its commitment to mental health radio for another two years through to 2022

For about two years there's been a debate about branded and generic mental health medications, and reactions from volumes of users that there are side effects from the generic replacements In October 2018, this radio show covered the issue when the Effexor branded anti-depressant was replaced with a generic Enlafax. We said at the time: "A 'generic' anti-depressant is grabbing headlines for all the wrong reasons as complaints mount to authorities about Enlafax, a replacement for one of the most common anti depressants. Both New Zealand's mainstream television channels have run stories detailing serious side effects of the replacement anti depressant and so far Pharmac has received at least 240 complaints about it A Facebook group has formed with 800 members called Enlafax problems with medication brand change NZ, and telling experiences with the generic drug, and a petition has been mounted by a Sarah Macrae seeking a public inquiry into PHARMAC's patient safety protocols for generic medication The Fb group is also working on a combined complaint to the Health and Disability Commissioner."

The trend to use generic mental health medications has continued with ongoing worries about their effectiveness. Today we talk to PHARMAC's deputy medical director Dr Peter Murray to gain insights into this trend. Dr Murray welcome to mental health radio Take It From Us

Why is there a move to generics in mental health?

- Our job is to make sure New Zealanders have funded access to the medicines they need Making brand changes helps us achieve that by freeing up money to fund other medicines.
- We rely on the advice of our expert clinical advisors about the evidence and potential impacts on affected people for all medicine funding changes, including generics. If our expert clinical advisors say it's is not appropriate, we wouldn't make a change.
- Generic medicines are expert copies of medicines made by companies that didn't develop the original drug themselves.
- Although a generic medicine costs less, it will still work as well as the more expensive medicine. All generic medicines have to be approved by Medsafe and go through bioequivalence testing to make sure that they work the same way as the original brand of that medicine.
- Generic medicines have to be 'bioequivalent' This means that they have to have the same active ingredient, and that ingredient has to be delivered to the body in the same way and have the same effect on the body as the original medicine.
- Research shows that people who are taking a generic medicine are more likely to think that generic medicines in general are just as effective, safe and have the same number of side effects as branded medicines, than those taking the original brand

How many mental health medications have been involved in the past 12 months?

- Brand changes are common, with around 60 brand changes of funded medicines per year. This activity helps us to get the very best from New Zealand's fixed medicines budget
- There have been changes made to five anti depressants in the past 12 months.

Can we run through the specific medications in terms of when the switch was made, and how it went?

Lamotrigine

Moved to only funding Logem (stopped funding of Arrow Lamotrigine and Lamictal) on 1 October 2019

- This medicine is prescribed more commonly for epilepsy but also as an anti-depressant.
- There was a lot of coverage in the media and concern with those taking the medication about moving to one brand of lamotrigine as there were three previously funded.
- Because of that anxiety, a month after the move to one brand of lamotrigine we advised those people taking lamotrigine who had concerns about the change that they could talk with their doctor about remaining on their current brand. They could stay or transition back to their preferred brand as we widened the criteria for lamotrigine exceptional circumstances.
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. It is used widely overseas, including in Australia, Canada, Germany, UK, Spain, France and the Netherlands.

Paroxetine

Available from 1 October 2019, the brand change was from 1 March 2020

- The funded brand of paroxetine changed from Apo-Paroxetine to Loxamine Both medicines are generic medicines, so this change means a different generic brand is funded
- As far as I am aware we haven't had any issues raised by people since changing to Loxamine.

Sertraline

Available from 1 October 2019, the brand change was from 1 March 2020

- The funded brand of sertraline changed from Arrow-Sertraline to Setrona. Both brands are generic medicines, so this change means a different generic brand will be funded
- We have received a couple of enquiries from people taking sertraline concerned about the change of brands

Fluoxetine

From June 2020 arrow fluoxetine dispersible tablets changed to Fluox From September 2020 arrow-fluoxetine capsules are changing to Fluox.

- Fluox has previously been funded, so this might mean some people are returning to a brand they've used before
- Arrow Fluoxetine and Fluox are both generic brands of fluoxetine.

I'll leave Lamotrigine till last as that was quite confidential and isn't just a mental health medication.

So where are we with Fluoxetine which of course was originally branded Prozac, a very common medication for depression and anxiety?

- Prozac was the (original) brand of fluoxetine but was not the latest funded brand of fluoxetine Prozac hasn't been the funded fluoxetine since 2001
- The funded brand of fluoxetine is changing from Arrow Fluoxetine to Fluox. Fluox has previously been funded, so this might mean some people are returning to a brand they've used before. Arrow-Fluoxetine and Fluox are both generic brands of fluoxetine.
- There has been increasing disruption to supply of certain fluoxetine recently, made worse by COVID 19, and we believe that the change of brand of fluoxetine from Arrow-Fluoxetine to Fluox will in fact give much welcomed security of supply to those who use it

My understanding is that the latest change involves a switch from one generic to another. Is this the first time that has happened (generic to another generic)?

- Paroxetine, sertraline, and fluoxetine all went from one generic to another generic The vast majority of our funded antidepressants are actually generics.
- Generic medicines are expert copies of medicines made by companies that didn't develop the original drug themselves.
- Although a generic medicine costs less, it will still work as well as the more expensive medicine. All generic medicines have to be approved by Medsafe and go through bioequivalence testing to make sure that they work the same way as the original brand of that medicine
- Generic medicines have to be 'bioequivalent'. This means that they have to have the same active ingredient, and that ingredient has to be delivered to the body in the same way and have the same effect on the body as the original medicine.

The latest to change I understand is Sertraline – occurring this month –what's happening with this anti-depressant and anti-anxiety drug?

- The funded brand of sertraline has changed from Arrow Sertraline to Setrona. Both these brands are generic medicines, and generics have been funded for the past five years.
- Setrona works work in the same way as Arrow Sertraline Setrona has the same active ingredient and is delivered to the body in the same way.
- Setrona has been thoroughly evaluated by Medsafe to ensure it's safe and works the same as the other brands.
- It's understandable that you might have questions about changing your medicine, but you shouldn't notice any difference when you change to Setrona If you have any questions or concerns about changes to medicines, you should talk with your doctor, nurse or pharmacist

On the Enlafax Facebook group page, I've seen one expression of concern about the switch from Sertraline to a generic. What reaction has PHARMAC received to date?

We have received a couple of enquiries from people taking sertraline concerned about the change of brands.

The last drug I know of is Lamotrigine which treats epilepsy, and I understand is also a mood stabiliser and used to address bipolar disorder. This attracted much publicity, and there were serious outcomes as a result of the switch. What's the latest here?

- Lamotrigine is used to treat epilepsy and some mental health conditions, such as bipolar disorder.
- On 1 October 2019 the funded brand of lamotrigine changed from Lamictal, Arrow Lamotrigine and Logem to Logem only.
- We made the decision to go to a single brand of lamotrigine because the advice of our expert clinical advisors said it was appropriate, and they are still supportive of the sole supply arrangement
- There was a lot of coverage in the media and concern with those taking the medication about moving to one brand of lamotrigine as there were three previously funded
- Because of that anxiety, a month after the move to one brand of lamotrigine we advised those people taking lamotrigine who had concerns about the change that they could talk with their doctor about remaining on their current brand. They could stay or transition back to their preferred brand as we widened the criteria for lamotrigine exceptional circumstances
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines It is used widely overseas, including in Australia, Canada, Germany, UK, Spain, France and the Netherlands.
- PHARMAC commissioned an independent review of decision making and implementation processes for the lamotrigine sole supply decision. The review also looked at what we could do to improve future brand changes
- The review found that PHARMAC's process was evidence based, robust, and of a high standard.
- We are always looking to improve our work. This review confirms that we need to focus more on consumers
- We are considering how we can better engage with consumers when planning for and implementing changes in funding arrangements

How well do you think PHARMAC is communicating these changes to users, and just as importantly to prescribers?

- We know we need to get better at communicating these changes, and are considering how we can better engage with consumers when planning for and implementing changes in funding arrangements
- We understand that some people find changing brands challenging, irrespective of the medicine they're taking, and we consider that before we make any decision of this kind

What is PHARMAC's communications strategy?

- The way that health care professionals explain brand changes to consumers can strongly influence how consumers react to a change of brand To help prescribers and pharmacists to support people changing brands, we have developed a range of resources for them. This includes patient information leaflets, access to an online 'Beyond the Brand' learning module about brand changes, and we put up to date information about brand changes on the PHARMAC website.

What assurances does PHARMAC release on this issue?

- All these medicines work in the same way as the previously funded medicine.
- They have the same active ingredients and are delivered to the body in the same way.
- They have all been thoroughly evaluated by Medsafe to ensure they are safe and work the same way as the other brands.
- It's understandable that you might have questions about changing your medicine, and I encourage anyone with questions or concerns about changes to medicines to talk with their doctor, nurse or pharmacist.

I have a personal interest in this issue as a user of Effexor and someone who suffered unexplained and never experienced before side effects from Enlafax. Those side effects were real for me, and influenced me to return to Effexor and pay for that drug. Is Effexor and other branded mental health meds going to continue to be available to us?

As PHARMAC does not hold a contract for the Effexor brand of venlafaxine, we are unable to guarantee price or availability Individuals wanting to continue treatment with the Effexor brand of venlafaxine can check with their pharmacist to confirm price and availability

Has this issue gone away for PHARMAC in terms of the Effexor/Enlafax switch now?

- Some people felt that the new brand was not as effective as their original brand
- Medsafe, which is part of the Ministry of Health, has advisory committees who provide expert advice on the safety and quality of medicines the Medicines Adverse Reactions Committee (MARC) and the Medicines Assessment Advisory Committee (MAAC).
- Both these committees conducted a review of the product information and the adverse report information that Medsafe had received for Enlafax XR They found that the rise in adverse reaction reporting that accompanied the brand change was not caused by medicine safety or quality

From: Media [mailto:media@pharmac.govt.nz]
Sent: Monday, 29 June 2020 1:07 p.m.
To: Sheldon Brown <Withheld under section 9(2)(a)>
Subject: Follow up on your interview

Hi Sheldon, hopefully your interview with Pete went well I would love to hear the interview do you think Isentia picks up your show in media monitoring? Or are you able to send me a copy of it?

Many thanks!

Jane Wright | Senior Communications Advisor, Media
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
M: Withheld under www.pharmac.govt.nz

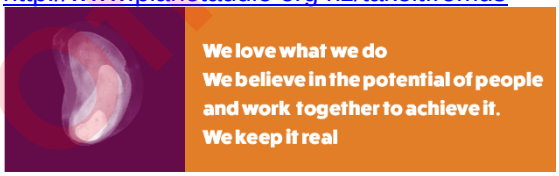
From: Sheldon Brown <Withheld under section 9(2)(a)>
Sent: Monday, 29 June 2020 1:12 pm
To: Media <media@pharmac.govt.nz>
Subject: RE: Follow up on your interview

Thanks Jane for arranging, you can listen live on www.planetaudio org.nz/takeitfromus at 12 30pm this Tuesday or anytime in the following five weeks as it is present on the web for that time. His comments were about 25 mins long and I will feature them immediately after the introduction I thought it went well.

Best wishes,

PS Yes I would like to attend you media workshop in Auckland

Sheldon Brown
Radio Host
ember
KOROWAI TAKITINI
Office: 09 523 2790
Mobile: Withheld under section 9(2)(a)
Listen to our own mental health radio show on every tuesday at 12:30 P.M. on PlanetFM 104.6 or go to http://www.planetaudio org nz/takeitfromus



From: Melanie Earley <Withheld under section 9(2)(a)>
Sent: Tuesday, 31 December 2019 11:56 AM
To: Media <Media@Pharmac.govt.nz>
Subject: Fifth death linked to drug change

Good morning,

may I please get a statement or speak with someone on the phone before 3pm today regarding the death of an Auckland man on December 16 which has been attributed as being linked to the drug Logem.

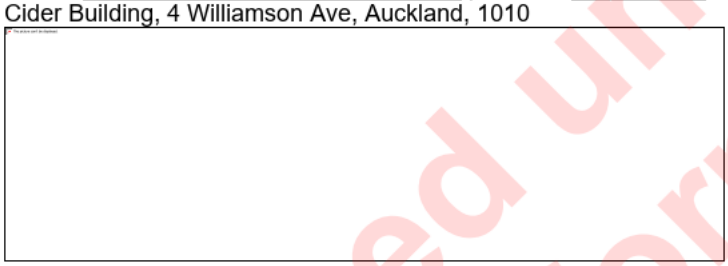
He is the fifth death being investigated by the chief coroner, I was wondering what advice PHARMAC would give those who had been switched to Logem? Should people still stay on it?

Is it safe?

Thanks in advance,

Melanie Earley
Reporter I Central Auckland

Email: Withheld under section 9(2)(a) | **Mobile:** Withheld
Cider Building, 4 Williamson Ave, Auckland, 1010



From: Media
Sent: Wednesday, 1 January 2020 8:20 am
To: Melanie Earley <Withheld under section 9(2)(a)>
Subject: RE: Fifth death linked to drug change

Hi Melanie,

Medsafe issued a media statement regarding this on 20 December https://www.health.govt.nz/news media/media releases/medsafe reinforces advice lamotrigine. I believe this statement your questions

If you have any further queries over the holidays (our team returns to the office on 6 January) – please call the media number on Withheld under

Regards,
Jannel

Jannel Fisher | Manager Communications and External Relations

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Melanie Earley <Withheld under section 9(2)(a)>
Sent: Friday, 17 January 2020 12:11 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Logem and Lamotrigine

Good afternoon,

I have been contacted by a woman who was taking lamotrigine for bipolar disorder and was affected by the brand switch to Logem

She said the switch made her bipolar worse and her mood unstable, she is now being switched back to lamotrigine.

Are these drugs often used to treat bipolar disorder?

What is the advice pharmac is giving people with bipolar affected by the change?

Why were they not told before being switched?

If there's any way you could please get back to me by the end of the day that would be appreciated.

Cheers,

Melanie Earley
Reporter I Central Auckland

Email: Withheld under section 9(2)(a) | **Mobile:** Withheld
Cider Building, 4 Williamson Ave, Auckland, 1010

On Fri, 17 Jan 2020 at 13:21, Media <Media@pharmac.govt.nz> wrote:

Hi Melanie, I will do my best to get back to you before the end of day, but in the meantime check out the information on our website on lamotrigine

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Melanie Earley <Withheld under section 9(2)(a)>
Sent: Friday, 17 January 2020 1:22 PM
To: Media <Media@Pharmac govt nz>
Subject: Re: Logem and Lamotrigine

Great thank you :)

Melanie Earley
Reporter I Central Auckland

Email: Withheld under section 9(2)(a) | **Mobile:** Withheld
Cider Building, 4 Williamson Ave, Auckland, 1010

From: Media
Sent: Friday, 17 January 2020 4:04 pm
To: 'Melanie Earley' <Withheld under section 9(2)(a)>
Subject: RE: Logem and Lamotrigine

Hi Melanie,

Thank you for your email concerning lamotrigine used for treating bipolar disorder. You have said that the woman who contacted is switching from Logem to lamotrigine I want to confirm for you that Logem is a brand of lamotrigine, so I imagine she was switching to one of the other two brands of lamotrigine, not switching back to lamotrigine

There are approximately 12,500 people taking lamotrigine and around 42% of patients are taking it for epilepsy with the other 58% taking it for mental health conditions (including bipolar) or other indication.

Since 1 October 2019, Logem is the sole subsidised brand of lamotrigine. Previously, there were three funded brands of lamotrigine: Arrow Lamotrigine, Lamictal, and Logem

You asked about advice PHARMAC gives people with bipolar affected by the brand change and if they are told before their brand is changed.

There is a shared responsibility across the health sector for patient safety and to ensure that patients are informed when changes to funded brands of medicines are made:

- Medsafe ensures generic medicines are bioequivalent (therapeutically the same) to the original brand and that the manufacturing process safety standards are met
- Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of medicines used and contribute to international knowledge of pharmacovigilance.
- PHARMAC liaises closely with Medsafe about brand changes and to ensure that we are aware of any increases in adverse event reporting.
- In general, primary care prescribers write prescriptions generically and may not be familiar with which brand of medicine a patient is taking.
- Pharmacists have a key role in counselling patients at the point when a new brand is dispensed to the patient

For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we:

- put in place a five-month transition period to allow people time to change brands
- created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients
- developed a mechanism for reimbursement of GP co-payments for patients to be able to discuss the change with their doctor
- developed a range of resources for prescribers and pharmacists which were circulated widely, including patient information leaflets they could give to consumers
- promoted an online 'Beyond the Brand' learning module for health professionals about brand changes
- put up to date information about brand changes on the PHARMAC website
- held an 'ask me anything' Facebook live event in June 2019 for consumers to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and
- supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to support consumers with the change.

We are always looking at how we communicate with prescribing doctors and pharmacists about upcoming funding changes, to see how we can improve our approach to this

Melanie, we are asking all media to ensure they include the following safety messages in their stories:

Safety key messages

- It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor. PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs.
- For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines

If you have any questions about why it is important to include the messages, please feel free to call me on 021863342 to discuss it further.

You can attribute any of the above to a PHARMAC spokesperson

Kind regards
Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

PHARMAC MEDIA ENQUIRY

Date Received	17 January 2020
Subject	Lamotrigine
Media outlet & contact details	Melanie Earley
Deadline	17 January 2020
Questions	"I have been contacted by a woman who was taking lamotrigine for bipolar disorder and was affected by the brand switch to Logem. She said the switch made her bipolar worse and her mood unstable, she is now being switched back to lamotrigine. Are these drugs often used to treat bipolar disorder? What is the advice PHARMAC is giving people with bipolar affected by the change? Why were they not told before being switched?"
Staff input	Adam McRae
Spokesperson as required	
Actions/response **Other information (include key messages)**	Hi Melanie, Thank you for your email concerning lamotrigine used for treating bipolar disorder. You have said that the woman who contacted is switching from Logem to lamotrigine I want to confirm for you that Logem is a brand of lamotrigine, so I imagine she was switching to one of the other two brands of lamotrigine, not switching back to lamotrigine. There are approximately 12,500 people taking lamotrigine and around 42% of patients are taking it for epilepsy with the other 58% taking it for mental health conditions (including bipolar) or other indication Since 1 October 2019, Logem is the sole subsidised brand of lamotrigine. Previously, there were three funded brands of lamotrigine: Arrow Lamotrigine, Lamictal, and Logem. You asked about advice PHARMAC gives people with bipolar affected by the brand change and if they are told before their brand is changed. There is a shared responsibility across the health sector for patient safety and to ensure that patients are informed when changes to funded brands of medicines are made: • Medsafe ensures generic medicines are bioequivalent (therapeutically the same) to the original brand and that the manufacturing process safety standards are met. • Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of medicines used and contribute to international knowledge of pharmacovigilance. • PHARMAC liaises closely with Medsafe about brand changes and to ensure that we are aware of any increases in adverse event reporting.

	• In general, primary care prescribers write prescriptions generically and may not be familiar with which brand of medicine a patient is taking. • Pharmacists have a key role in counselling patients at the point when a new brand is dispensed to the patient. For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we: • put in place a five month transition period to allow people time to change brands • created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients • developed a mechanism for reimbursement of GP co payments for patients to be able to discuss the change with their doctor • developed a range of resources for prescribers and pharmacists which were circulated widely, including patient information leaflets they could give to consumers • promoted an online 'Beyond the Brand' learning module for health professionals about brand changes • put up to date information about brand changes on the PHARMAC website • held an 'ask me anything' Facebook live event in June 2019 for consumers to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and • supported a training day and follow-up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to support consumers with the change. We are always looking at how we communicate with prescribing doctors and pharmacists about upcoming funding changes, to see how we can improve our approach to this. Melanie, we are asking all media to ensure they include the following safety messages in their stories: *Safety key messages* • It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor. PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs • For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. • Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines If you have any questions about why it is important to include the messages, please feel free to call me on 021863342 to discuss it further You can attribute any of the above to a PHARMAC spokesperson.

	Kind regards Jane

On 28/09/2019, at 3:54 PM, Miriam Harris <Withheld under section 9(2)(a)> wrote:

Hi there,

Epilepsy New Zealand has notified us that Pharmac's change to the funded brand of the antiepileptic medication, Lamotrigine comes into effect on Tuesday 1 October 2019

ENZ says a study should be conducted before any changeover is instituted. ENZ continue to believe that this trial should be undertaken, and would be happy to help facilitate such a trial.

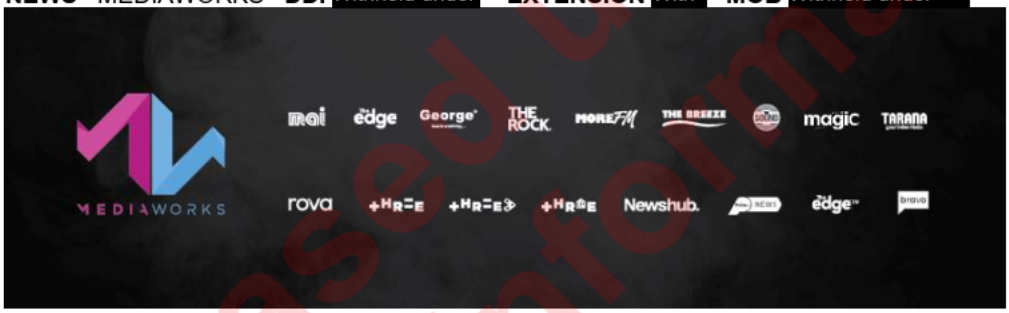
We are after comment from Pharmac on whether such a trial will go ahead, and if so, how?
Or if not, why not?

It would be great to have a brief phone interview this afternoon for our news bulletins tomorrow, or to receive a statement

You can call me directly on Withheld under

Warm regards,

--
MIRIAM HARRIS NEWSHUB BROADCAST JOURNALIST
NEWS MEDIAWORKS **DDI** Withheld under **EXTENSION** With **MOB** Withheld under



From: Media <Media@Pharmac.govt.nz>
Sent: Saturday, 28 September 2019 5:03 pm
To: Miriam Harris <Withheld under section 9(2)(a)>
Subject: Re: Newshub query

Hi Miriam, please see our statement which you can attribute to PHARMAC's spokesperson:

Logem works in the same way as the two other brands. Logem has the same active ingredient as the other brands and is delivered to the body in the same way This means it will have the same effect as the other brands.

Before deciding to change the funding arrangements for this medicine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine. If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change

Thanks!
Sent from my iPhone

From: Emma Stanford <Withheld under section 9(2)(a)>
Sent: Tuesday, 1 December 2020 12:47 pm
To: Media <media@pharmac.govt.nz>
Subject: Newshub Radio Logem inquiry

Hello

I am at the Lamotrigine inquest and have a few questions I would like to follow up with for my reporting. I understand Pharmac will itself present in February but would like this information for my records now.

How many people take Logem in New Zealand? Or the number of prescriptions written etc?

What is the rate of mortality of the drug?

Thank you

Emma
EMMA STANFORD NEWSHUB RADIO JOURNALIST
MOBILE: Withheld **NEWSROOM:** 09 360 0330
NEWSHUB RADIO THREE TV3.CO.NZ

From: Media
Sent: Tuesday, 1 December 2020 12:57 pm
To: 'Emma Stanford' <Withheld under section 9(2)(a)>
Subject: RE: Newshub Radio Logem inquiry.

Hi Emma,

Yes, that's right PHARMAC is scheduled to give evidence at the Coroner's inquest in late February 2021, so it is not appropriate for us to comment during the proceedings We are, however, asking media to use the following safety messages when reporting on lamotrigine:

- It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor.

- For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines

Of the 10,000 people who use funded lamotrigine, approximately 7,500 are taking the Logem brand. If you are looking for information on sudden unexplained death in epilepsy, this should be helpful https://www.nzma.org.nz/journal-articles/sudden-unexpected-death-in-epilepsy-sudep-in-new-zealand a retrospective review

Kind regards
Jane

PHARMAC MEDIA ENQUIRY

Date Received	06/12/2019
Subject	Lamotrigine study
Media outlet & contact details	Chelsea Daniels, Newstalk ZB and Guyon Espiner, RNZ
Deadline	06/12/2019
Questions	Following the Chief Coroner's media release on the joint inquiry into the 4 deaths of people on lamotrigine, we received requests from the above media outlets for a statement.
Staff input	Adam McRae
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	PHARMAC welcomes the news that the Chief Coroner has opened a joint inquiry into the four fatalities of people who were taking lamotrigine PHARMAC's medical director Dr Ken Clark wrote to the Chief Coroner in November to offer our full assistance Coroners investigating the deaths and to ask to have a full and early opportunity to have input into any investigation or inquiry where our actions or decisions may be relevant. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs. For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication I have attached it here in case you haven't seen it I have included a copy of Dr Clark's letter to the Chief Coroner for your information. If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

	Kind regards Jane

From: Media <Media@Pharmac.govt.nz>
Sent: 06 December 2019 12:00
To: Chelsea Daniels <Withheld under section 9(2)(a)>
Subject: Chief Coroner's joint inquiry

Hi Chelsea,

PHARMAC welcomes the news that the Chief Coroner has opened a joint inquiry into the four fatalities of people who were taking lamotrigine. PHARMAC's medical director Dr Ken Clark wrote to the Chief Coroner in November to offer our full assistance Coroners investigating the deaths and to ask to have a full and early opportunity to have input into any investigation or inquiry where our actions or decisions may be relevant.

Additional Information
I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs

For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication. I have attached it here in case you haven't seen it.

I have included a copy of Dr Clark's letter to the Chief Coroner for your information
If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams

Kind regards
Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Chelsea Daniels <Withheld under section 9(2)(a)>
Sent: Friday, 6 December 2019 12:14 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Re: Chief Coroner's joint inquiry

Fantastic, thanks Jane

Have just spoken to Epilepsy NZ and they say if anyone's concerned about switching, or wants to go back to taking Lamictal, they can go and speak to their GP at no cost about it is that correct?

I assume they mean there'll be no appointment fee charged?

Thanks again,

CHELSEA DANIELS
SENIOR JOURNALIST/NEWS DIRECTOR - NEWSTALK ZB

D: Withheld M: Withheld
: @CK Daniels

NewstalkZB

Ltd / GrabOne Ltd

From: Media
Sent: Friday, 6 December 2019 12:30 pm
To: 'Chelsea Daniels' <Withheld under section 9(2)(a)>
Subject: RE: Chief Coroner's joint inquiry

That is correct – check this out 😊 https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/lamotrigine epilepsy drug changes/

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Simon Maude <Withheld under section 9(2)(a)>
Sent: Wednesday, 13 November 2019 8:51 AM
To: Media <Media@Pharmac.govt.nz>
Subject: Suspected adverse reaction reports to lamotrigine after changing brands including 3 deaths

Hi,

Re this https://www.medsafe.govt.nz/safety/Alerts/Lamotrigine.asp

Can you please advise asap on what action Pharmac is taking around these medicines?

I am planning to publish a story by 2pm today.

Thanks,

Simon Maude
Journalist | New Zealand Doctor | nzdoctor.co.nz
The Health Media Ltd

Ph Withheld under | **Fax** 09 912 9257
Email Withheld under section 9(2)(a)
Post PO Box 31905, Milford, Auckland 0741
Street address 11 Omana Rd, Milford, Auckland, 0602

www.nzdoctor.co.nz | Twitter @NZDoctor News | Facebook/NewZealandDoctor

From: Media
Sent: Wednesday, 13 November 2019 10:42 am
To: Simon Maude <Withheld under section 9(2)(a)>
Subject: RE: Suspected adverse reaction reports to lamotrigine after changing brands including 3 deaths

HI Simon,

I haven't forgotten your other media query it is on my to do list!

But in the meantime, can you please attribute the following comment to our operations director Lisa Williams for your query below:

For many people, epilepsy is a condition which can be well managed and has little or no impact on their life. For others, ongoing seizures mean that epilepsy has a long-term impact. Like many medical

conditions epilepsy can be a cause of sudden death, although this is not common and is of course utterly devastating for family and whānau.

PHARMAC is having regular meetings with Medsafe about lamotrigine adverse event reports and Medsafe's analysis of them. At this time, we have very limited information about the reported fatalities, and we may not know the details until after the Coroner's investigations are completed

We want to emphasises that patients should not stop using lamotrigine. If people have any concerns, they should contact their healthcare professional.

Logem, the funded brand of lamotrigine, has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in a number of countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Jane Wright | senior communications advisor

_____

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	Wednesday 15 January 2020
Subject	Lamotrigine
Media outlet & contact details	Simon Maud NZ Doctor
Deadline	Monday 20 January @ midday, extended to Wednesday 22 January
Questions	"Given the deaths of five epileptics who reportedly switched from branded antiepileptics to generic Logem, I felt it was timely to revisit the broader topic asking whether Pharmac has reassessed how it responds to such events. 1 What is Pharmac's process when it is reported through reliable channels, such as CARM, that a person died after switching from a previously Pharmac funded branded to a now generic only equivalent drug? 2 In general, is Pharmac reviewing that process? 3. What changes is Pharmac considering? For instance, as a general rule, when a first death is reported (which may be linked to a drug switch) will Pharmac at least give branded drugs users the option to keep receiving funding for that brand until the drug switch has been ruled-out as a contributing to a person's cause of death? It would be good to interview someone like Lisa Williams about this. Also, has Pharmac appointed a permanent medical director and deputy medical director yet?"
Staff input	Adam McRae, Adrienne Martin, Dr Tristan Gardiner Murray, Sarah Fitt
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	Hi Simon, Thank you for your query on the lamotrigine brand change and our medical directorate staffing. **Lamotrigine** You asked about our process when fatalities are reported, and I thought it might be of interest to see our response to an OIA from another journalist last year on contingency planning. We have published it on our website. I note that all OIA responses relating to lamotrigine have been collated on our lamotrigine brand change web page. As you know there have been five reports to CARM made relating to deaths of patients using lamotrigine; at this stage there is no confirmed link between the death of these people and switching brands of lamotrigine. PHARMAC wrote to the Chief Coroner in late November 2019 offering to actively participate in any investigations by relevant Coroners and we look forward to contributing to the joint coronial investigation which was announced by the Chief Coroner in early December 2019.

	I encourage you, if you haven't already, to look at the study co authored by Dr Peter Bergin recently published in the New Zealand Medical Journal and the media coverage on that from Friday Once the transition to the Logem brand is completed we intend to review this brand change process We do these types of reviews often after key transactions. Simon, we are asking all media to use the following safety messages when writing about lamotrigine: • It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor PHARMAC will refund the general practitioner for this visit, so the patient won't incur additional costs. • Logem has the same active ingredient and is delivered to the body in the same way as the other two lamotrigine brands This means it should have the same effect. • Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. You can attribute any of the above to our director of operations Lisa Williams **Medical directorate** Dr Ken Clark continues as our acting medical director until mid 2020 at this stage, and Dr Tristan Gardiner started at the end of last year as the primary care advisor, joining existing deputy medical directors Dr Peter Murray and Dr Scott Metcalfe who are both public health specialists I have attached a photo of Dr Gardiner. Dr Gardiner is a New Zealand trained general practitioner with Fellowship and almost 20 years primary care experience in New Zealand. Dr Gardiner is working at PHARMAC part time and is continuing to work part time in general practice. Please let me know if you have any further questions. Kind regards Jane

From: Media <Media@Pharmac.govt.nz>
Sent: Tuesday, 17 December 2019 11:25 AM
To: Boris Jancic <Withheld under section 9(2)(a)>
Subject: PHARMAC response

Hi Boris,

Just out of the office for an hour, will respond to you when back in. But happy to send you what we sent Guyon.

Kind regards
Jane

Get Outlook for iOS

From: Boris Jancic <Withheld under section 9(2)(a)>
Sent: Tuesday, 17 December 2019 12:58 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Re: PHARMAC response

Hey Jane,

Any luck on this?

Cheers,
Boris

Boris Jancic
POLITICAL REPORTER

D: Withheld under M: Withheld under
E: Withheld under section 9(2)

The New Zealand Herald

From: Media <Media@Pharmac.govt.nz>
Sent: Tuesday, 17 December 2019 1:17 PM
To: Boris Jancic <Withheld under section 9(2)(a)>
Subject: RE: PHARMAC response

Apologies for the delay! I was at my son's school farewell and they have zero internet coverage there!

You can see the OIA response that was sent to RNZ here https://www.pharmac.govt.nz/news/oia 2019-12-lamotrigine/

Our comment to Guyon following his question around the timing of the widening of the exceptional circumstances process was as follows:

You are correct that as of 29 October PHARMAC staff had been advised that there had been three CARM reports where there was a death of someone who was taking lamotrigine. As you will have seen in the email trails you received through OIA, PHARMAC has very limited information about the reported fatalities and we may not know the details, including whether there is any connection with the funded brand change, until after the Coroner's investigations are completed. You are also aware that PHARMAC proactively reached out to the Chief Coroner in November to offer input into any coronial investigations that occur and that subsequently the Chief Coroner has announced a joint inquiry Like many medical conditions, epilepsy can be a cause of sudden death, although this is not common.

PHARMAC was aware that there was a high level of anxiety among people on lamotrigine and their families, compounded by the amount of media coverage and social media commentary following the Medsafe monitoring alert published on 12 November. We already had in place our exceptional circumstances process to enable ongoing funding of previous brands for people unable to change and had received almost 90 applications before 15 November We considered that, in the context of the level of public concern being expressed, the volume of applications had been relatively low such that it needed to be more widely promoted and widened to make it easier for people on lamotrigine to stay on their current brand, if their doctor thinks they should

We have worked closely with our colleagues at Medsafe throughout the lamotrigine brand change Medsafe's advice that any brand switch should be "based on clinical judgement and consultation with patient and/ or carer" was a fundamental reason why PHARMAC extended the lead in time for the brand change and developed a range of resources for prescribers and pharmacists. There is a shared responsibility across the health sector for

patient safety and to ensure that patients are informed when changes to funded brands of medicines are made. Medsafe ensures generic medicines are bioequivalent (therapeutically the same) to the original brand and that the manufacturing process safety standards are met. Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of medicines used and contribute to international knowledge of pharmacovigilance PHARMAC liaises closely with Medsafe about brand changes and to ensure that we are aware of any increases in adverse event reporting. In general, primary care prescribers write prescriptions generically and may not be familiar with what brand of medicine a patient is taking Pharmacists have a key role in counselling patients at the point when a new brand is dispensed to the patient. PHARMAC, with input from our expert clinical advisers, considers the impact on patients and the sector and determines what is needed to support brand changes including communications and education. We know that the way that health care professionals explain brand changes to consumers can strongly influence how consumers react to a change of brand

For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we:

- put in place a five month transition period to allow people time to change brands
- created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients.
- developed a mechanism for reimbursement of GP co-payments for patients to be able to discuss the change with their doctor
- developed a range of resources for prescribers and pharmacists which were circulated widely, including patient information leaflets they could give to consumers
- promoted an online 'Beyond the Brand' learning module for health professionals about brand changes,
- put up-to-date information about brand changes on the PHARMAC website
- held an 'ask me anything' Facebook live event in June 2019 and consumers were able to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and
- supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to assist them with supporting consumers with the change

We are always looking at how we communicate with prescribing doctors and pharmacists, about upcoming funding changes, to see how we can improve our approach to this

I ask that you reiterate to your readers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs

For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams

Please let me know if you have any further questions

Kind regards
Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Boris Jancic <Withheld under section 9(2)(a) >
Sent: Tuesday, 17 December 2019 1:19 pm
To: Media <Media@Pharmac.govt.nz>
Subject: Re: PHARMAC response

No worries! Thanks a million! Hope the farewell went well!

Boris Jancic
POLITICAL REPORTER

D: Withheld under M: Withheld under
E: Withheld under section 9(2)

The New Zealand Herald

Ltd / GrabOne Ltd

From: Laura Beattie <Withheld under section 9(2)(a) >
Sent: Friday, 25 October 2019 3:54 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Statement Epilepsy drugs

Hi Cameron

could you please send through that statement on the epilepsy drugs?

Cheers
Laura

LAURA BEATTIE
EXECUTIVE PRODUCER - HEATHER DU PLESSIS-ALLAN DRIVE

M: Withheld under
E: Withheld under section 9(2)

NZ ME. INFORM ME.

From: Media
Sent: Friday, 25 October 2019 4:00 pm
To: Laura Beattie <Withheld under section 9(2)(a) >
Subject: RE: Statement Epilepsy drugs

Hi Laura,

Please see the below statement. Have a great long weekend.

We understand that any sudden or unexpected death would be referred to the Coroner for investigation and our thoughts go out to the family

PHARMAC is maintaining close contact with Medsafe about lamotrigine adverse event reports and its analysis of them

The brand change is continuing, and more than half of patients have made the change.
If people have concerns, we encourage them to talk to their doctor PHARMAC is covering the cost of a GP visit as part of the brand change.

From: Media
Sent: Thursday, 14 November 2019 3:44 pm
To: Withheld under section 9(2)(a)
Subject: lamotrigine

Hi Laura, you can attribute the statement to PHARMAC's operational director Lisa Williams
For many people, epilepsy is a condition which can be well-managed and has little or no impact on their life For others, ongoing seizures mean that epilepsy has a long-term impact Like many medical conditions' epilepsy can be a cause of sudden death, although this is not common and is of course utterly devastating for family and whānau.

If people on lamotrigine have concerns, we encourage them to talk to their doctor. Their doctor can apply to PHARMAC, through our exceptional circumstances programme, for continued funding of the brand they took before the funding change.

We want to emphasise that people should not stop using lamotrigine without talking with their doctor. PHARMAC is covering the cost of a GP visit as part of the brand change, so if people have any concerns they should contact their health professional.

Thanks!

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Laura Beattie <Withheld under section 9(2)(a)>
Sent: Friday, November 15, 2019 5:19 PM
To: media@pharmac.govt.nz
Subject: fourth death

Hi Jane

Can you please confirm you've been advised of a fourth death that may have been linked to the new epilepsy drug. What if anything does this mean for Pharmac?

Cheers
Laura

LAURA BEATTIE
EXECUTIVE PRODUCER - HEATHER DU PLESSIS-ALLAN DRIVE

M: Withheld under
E: Withheld under section 9(2)

NZ ME. INFORM ME.

From: Media <Media@Pharmac.govt.nz>
Sent: Friday, 15 November 2019 6:13 pm
To: Laura Beattie <Withheld under section 9(2)(a)>
Subject: Re: fourth death

Hi Laura

Medsafe advised PHARMAC early this afternoon of a report to CARM of a 4th fatality that was received yesterday. Medsafe has very limited details on the case, and advises us that CARM is currently seeking more information from the treating physician PHARMAC will continue to liaise with Medsafe on adverse event reports and Medsafe's analysis of them.

Kind regards
Jane

Get Outlook for iOS

From: Anan Zaki <Withheld under section >
Sent: Thursday, 2 January 2020 3:39 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Epilepsy medication

Good afternoon,

Anan here from RNZ hope you're well.

We're working a story about the death of Auckland man Andre Maddock (age 31) following a seizure He had recently switched to the Logem brand of lamotrigine taken for epilepsy prior to his death.

We just have a few questions following his death:

- Are Pharmac conducting any inquiries about the death of Andre Maddock following his switch to the Logem brand of lamotrigine?
- Medsafe has issued a safety alert advising people not to switch brands if their current medicine wasn't working, what is pharmac's stance on the switch of epilepsy medication? Does it believe it is safe?

We are hoping to run a piece about Mr Maddock on Summer Report tomorrow, if any statement could be provided this evening it would be much appreciated. I understand if it's not possible due to the public holidays

Kind regards
Anan

Anan Zaki | **Journalist**
RNZ | 332 Cashel Street | PO Box 1531 | Christchurch | New Zealand
T: Withheld under | M: Withheld under
E: Withheld under section | W: www.rnz.co.nz
@anan_zaki

From: Media
Sent: Thursday, 2 January 2020 11:25 pm

To: Anan Zaki <Withheld under section >
Subject: RE: Epilepsy medication

Hi Anan,

Here is some information that may be helpful

As per the Medsafe's media statement, nearly 90% of people are taking the Logem brand of lamotrigine. It is critical that people who have been prescribed Logem do not stop taking it. If they have concerns, they should talk about their options with their doctor.

PHARMAC has widened access to the exceptional circumstances process to make it easier for people on lamotrigine to stay on their current brand, if their doctor thinks they should.

Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Logem is used widely overseas.

I'm happy to talk to you about your first question if you'd like to give me a call on Withheld under .

Regards,
Jannel

Jannel Fisher | Manager Communications and External Relations

PHARMAC | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: Withheld under | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Emma Hatton <Withheld under section 9(2)(a) >
Sent: Thursday, 16 January 2020 5:19 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Media enq: Radio NZ Logem story

Kia ora,

Emma Hatton from Radio NZ here.

Sorry for the late in the day response but we've just had a story filed that the programme (Summer Report) wants to run in the morning

It's about a man who was on the epilepsy medication Lamictal (no issue with Lamictal), was switched to an arrow brand and then had 30 seizures in the space of 3 weeks. His doctor then switched him to Logem.

He wants to go back to Lamictal but says it's only prescribed for short periods of time and is being phased out

Some questions:
-Is Lamictal being phased out?
-Can a patient be put back on Lamictal? If so, how long for?

The man also says Logem is giving him side effects such as dizziness, he has fallen, got a twitch so is dropping a lot of things, has to sit a lot.
-what is Pharmac's response to these side effects?

-what options does this man have?
-what does Pharmac say to his situation, is this fair? He was on a medication that was working very well for him, but can't switch back (well, can but only for a short time).

Any questions please give me a call,
Thanks,

Emma Hatton
Reporter
DDI Withheld under | Mobile Withheld under section
www.radionz.co.nz

unwanted or unexpected inclusions. The views expressed in any non-business email are not necessarily the views of RNZ. www.rnz.co.nz

From: Media
Sent: Thursday, 16 January 2020 5:54 pm
To: 'Emma Hatton' <Withheld under section 9(2)(a) >
Subject: RE: Media end: Radio NZ Logem story

Hi Emma, best to call me with an after hours story as I won't always be checking my emails.

Some people may have difficulty changing brands due to medical reasons or other concerns For people who need it, we can continue to fund the same brand of medication, with no time limit, as long as it is available. Their doctor needs to apply to our exceptional circumstances process.
You can read more about it on our website

Emma, we are asking all media to use the following safety messages when writing about lamotrigine:

- It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor. PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs
- For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines.

If you need to attribute any of the above, you can just say a PHARMAC spokesperson.

Kind regards

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

PHARMAC MEDIA ENQUIRY

Date Received	10/09/2019
Subject	Lamotrigine
Media outlet & contact details	Guyon Espiner RNZ Stephanie Ockhuysen Taranaki Daily News (Stuff)
Deadline	12/09/2019
Questions	RNZ asked: • Requesting information on Lamotrigine: • Why the change? • How is it being managed? • Why are we going against Medsafe advice? • What about patients concerns? Taranaki Daily News (Stuff) asked: • Why is PHARMAC stopping funding Lamictal? • What is PHARMAC's responsibility if people have side effects from the drug switch? • Is PHARMAC aware of a petition has been started to keep the drug funded for those who need it? • Will PHARMAC consider the petition and continue to fund the drug?
Actions	Backgrounder – see below Media plan being drafted to answer the above style of questions on radio
Staff input	Adam McRae Adrienne Martin Jannel Fisher
Spokesperson as required	Our spokesperson is to be confirmed.
Actions/response Other information (include key messages)	We have provided the following link (on our website) as general background reading: https://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-06-generics and biosimilars/ The following are already approved background messages I would like to send to Guyon before we do the interview and to Stephanie as our final response. **About Logem and supporting the change** • Logem works in the same way as Lamictal and Arrow-Lamotrigine. Logem has the same active ingredient as the other brands and is delivered to the body in the same way. This means it will have the same effect as the other brands

	• Our dispensing data for 2018 shows that around 50% of all people who collected a funded prescription for lamotrigine, have changed brands at least once since they started on lamotrigine. Around 4,000 people have changed brands two or more times We are not aware of, nor have we been informed of, any significant clinical impacts for these people when they changed brands • Moving to a single funded brand of lamotrigine will avoid ongoing, potentially unmanaged, brand changes that can happen when there is more than one funded brand available Previously patients could chop and change at the discretion of the pharmacist without input from the doctor and often the patient might not be aware either. So brand changing was happening on an ad hoc basis all of the time When we move to sole supply with Logem, the transition will be obvious and managed and ad hoc changes will no longer happen • The chronic nature of epilepsy means that people, even on treatment, can have recurrent and spontaneous seizures. Expert advice based on a review of literature indicates that just over 1 in 5 people with epilepsy who are stable and have been seizure-free may experience a seizure within 2 years. In general, this is managed through medication review with a patient's doctor and by considering dosage adjustments or a change of medication. • We engaged with epilepsy support groups and health professionals before we made the decision to fund one brand of lamotrigine. We have used their feedback to help develop support materials for people changing brands of lamotrigine • To help prescribers and pharmacists to support people changing brands, we have developed a range of resources including patient information leaflets, access to the 'Beyond the Brand' learning module about brand changes and up to date information about the lamotrigine brand change on the PHARMAC website. • Some people may return to their GP with concerns following the change to the Logem brand and may need additional support to make a successful change. In these cases, the GP visit co-payment may be waived and PHARMAC will reimburse the GP clinic on invoice • PHARMAC will also consider applications from prescribers for continuation of funding for a specific brand of lamotrigine for a specific patient who, due to exceptional clinical difficulties, the prescriber thinks is unable to manage a change to Logem or who has tried to change and has not tolerated it • There have now been 15 exceptional circumstances applications for continued funding for Lamictal or Arrow Lamotrigine: 5 approved, 2 withdrawn, 2 where our clinical experts thought a trial of Logem was

	appropriate and 6 under assessment. Note 14 applications related to epilepsy, 1 to mental health indications. **Why have these changes been made?** • PHARMAC's job is to make sure New Zealanders have funded access to the medicines they need. We work within a fixed budget. Making brand changes helps us achieve that by freeing up money to fund other medicines. • Changing to Logem means we'll free up more than $30 million over the next five years, money that PHARMAC will use to fund other medicines for New Zealanders. • Before deciding to change the funding arrangements for this medicine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change, regardless of the savings we could achieve Consultation started on 28 August, and our original proposal was for the transition to start from 1 December 2018 with the sole supply commencing from 1 May 2019. We got all the feedback to consultation and as a result of it (including specifically the feedback from Medsafe) we decided to put a hold on the proposal and go back to our experts to get more advice See https://www.pharmac.govt.nz/news/notification-2019-04-11-lamotrigine/

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Tuesday, 10 September 2019 11:27 AM
To: Media <Media@Pharmac.govt.nz>
Subject: Espiner/lamotrigine/interview

Kia ora Pharmac media team

I spoke with you Jan today about this ...

I am doing a follow up story on the switch to the generic form of lamotrigine as this all rolls over at the end of the month

I want to coordinate the OIA information I am getting with an interview with Pharmac about the swtich and how it is going

Pharmac may also be able to give

So

Hopefully I can get the OIA maybe this week do the interview late this week or early next?

Let me know what suits

Nga mihi

Guyon Espiner
Withheld under

From: Media <Media@Pharmac.govt.nz>
Sent: Tuesday, 10 September 2019 2:26 PM
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE: Espiner/lamotrigine/interview

Hi Guyon.

Unfortunately we won't be able to get you the information requested under your OIA by next week as it is still being collated. I am working on your interview request and have been asked for a few specifics. Can you confirm that your questions will be on tips and information for patient safety and

also NPPA? Or fi you ahve any others, can you please send the general gist of them through? Are you interviewing anyone else? When is your interview going on the radio?

Many thanks!

Jane Wright | senior communications advisor

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PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Tuesday, 10 September 2019 2:29 PM
To: Media <Media@Pharmac.govt.nz>
Subject: RE: Espiner/lamotrigine/interview

Hi Jane,

Can you call me please? Might be easier to talk

From: Media <Media@Pharmac.govt.nz>
Sent: Tuesday, 10 September 2019 2:31 PM
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE: Espiner/lamotrigine/interview

Just running into a meeting, will call you after that if that suits? About half an hour

Jane Wright | senior communications advisor

_____

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www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a)>
Sent: Tuesday, 10 September 2019 2:33 PM
To: Media <Media@Pharmac.govt.nz>
Subject: RE: Espiner/lamotrigine/interview

Great – talk then

From: Media <Media@Pharmac govt.nz>
Sent: Thursday, 12 September 2019 11:53 AM
To: Guyon Espiner <Withheld under section 9(2)(a)>; Media <Media@Pharmac govt nz>
Subject: RE: Espiner/lamotrigine/interview

Hi Guyon,

I should be able to confirm an interview in the next day or so but in the meantime, here is some more background reading and general messages on the reasons for the change 😊

Logem works in the same way as Lamictal and Arrow-Lamotrigine. Logem has the same active ingredient as the other brands and is delivered to the body in the same way This means it will have the same effect as the other brands.

Our dispensing data for 2018 shows that around 50% of all people who collected a funded prescription for lamotrigine, have changed brands at least once since they started on lamotrigine Around 4,000 people have changed brands two or more times. We are not aware of, nor have we been informed of, any significant clinical impacts for these people when they changed brands. Moving to a single funded brand of lamotrigine will avoid ongoing, potentially unmanaged, brand changes that can happen when there is more than one funded brand available. Previously patients could chop and change at the discretion of the pharmacist without input from the doctor and often the patient might not be aware either. So brand changing was happening on an ad hoc basis all of the time As we move to sole supply with Logem, the transition will be obvious and managed and ad hoc changes will no longer happen.

The chronic nature of epilepsy means that people, even on treatment, can have recurrent and spontaneous seizures. Expert advice based on a review of literature indicates that just over 1 in 5

people with epilepsy who are stable and have been seizure-free may experience a seizure within 2 years. In general, this is managed through medication review with a patient's doctor and by considering dosage adjustments or a change of medication. We engaged with epilepsy support groups and health professionals before we made the decision to fund one brand of lamotrigine We have used their feedback to help develop a range of resources including patient information leaflets, access to the 'Beyond the Brand' learning module about brand changes and up to date information about the lamotrigine brand change on the PHARMAC website.

Some people may return to their GP with concerns following the change to the Logem brand and may need additional support to make a successful change. In these cases, the GP visit co-payment may be waived and PHARMAC will reimburse the GP clinic on invoice PHARMAC will also consider applications from prescribers for continuation of funding for a specific brand of lamotrigine for a specific patient who, due to exceptional clinical difficulties, the prescriber thinks is unable to manage a change to Logem or who has tried to change and has not tolerated it.

Why have these changes been made?

- PHARMAC's job is to make sure New Zealanders have funded access to the medicines they need. We work within a fixed budget. Making brand changes helps us achieve that by freeing up money to fund other medicines
- Changing to Logem means we'll free up more than $30 million over the next five years, money that PHARMAC will use to fund other medicines for New Zealanders.
- Before deciding to change the funding arrangements for this medicine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine. If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change, regardless of the savings we could achieve.
- Consultation started on 28 August, and our original proposal was for the transition to start from 1 December 2018 with the sole supply commencing from 1 May 2019. We got all the feedback to consultation and as a result of it (including specifically the feedback from Medsafe) we decided to put a hold on the proposal and go back to our experts to get more advice. See https://www pharmac.govt nz/news/notification 2019 04 11 lamotrigine/

Jane Wright | senior communications advisor

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www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Thursday, 12 September 2019 11:55 am
To: Media <Media@Pharmac govt nz>
Subject: RE: Espiner/lamotrigine/interview

Great – thanks so much for this

Look forward to locking in a date … and will take a closer look at this

Cheers

Guyon

From PHARMAC's perspective

Umbrella statement

Logem works in the same way as the other two Lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.

Core message 1
Before making this decision we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine

Core message 2
Changing to Logem means we'll free up more than $30 million over the next five years. All this money will be used to fund other medicines for New Zealanders.

Background Timeline:

14 June 2018 RFP for sole supply of lamotrigine

29 April 2018 consultation on proposal for sole supply to start from

1 December 2018 price changes
1 Feb 2019 – 30 April 2019 – 3-month transition
1 May 2019 sole supply commences

26 October 2018 update that we needed to take more time to consider feedback

7 February 2019 – meeting of Neuro & Mental Health SCs

11 April decision announced

1 May 2019 – 30 September 2019 – 5-month transition
1 October 2019 sole supply commences

It's about making the right decision 10 month delay lost savings of nearly $5m so it's not all about the money.

Guyon's questions:

How the switch is going?

- Our latest figures are that more than ¼ of consumers have already started taking Logem brand of lamotrigine.
- We know that at the end of August 3,225 patients were on Logem

- Any of the three brands can be dispensed up until 30 September (with a three month prescription), so we would expect most people will have changed to the Logem brand before the end of the year.

What monitoring you are doing?

- CARM monitors change processes like this and we are meeting frequently with Medsafe to monitor these reports
- We also get information through applications to our exceptional circumstances funding programme and through our general enquiries data (0800 line, website and email).

The numbers of CARM reports/switch backs?

- As at the last meeting held with Medsafe on 13 September 2019, there had been a total of seven adverse event reports for lamotrigine received by CARM. Many of these reports are not necessarily attributable to a change in brand from Lamictal to Logem. CARM will continue to monitor and investigate reports as required.
- There are a small number of people who aren't able to switch brands due to complicated medical reasons. PHARMAC will continue to fund the brand they are currently on through our exceptional circumstances programme.
- So far there have been eight applications approved for ongoing funding of other brands of lamotrigine through this process.

Issues people are having

- We have received 21 exceptional circumstances applications for continued funding for Lamictal or Arrow-Lamotrigine:
    - 8 approved
    - 2 withdrawn (due to no further information being received from applicant)
    - 4 where a trial of Logem was considered appropriate
    - 7 under assessment
- Note 19 applications related to epilepsy, 2 to mental health indications.
- Given the small numbers we wouldn't want to go into detail as this could identify the patient, however, likely to be people with clinically difficult circumstances (anxiety, autism, difficult family situations etc), those that have a previous reaction to a brand change or those experiencing a significant change to seizure frequency and rate
- When considering concerns around brand mixing the Neurological Subcommittee specifically considered the issue of brand and dosage mixing The Subcommittee could see no problem with having different suppliers for the adult strength and the paediatric strength preparations of lamotrigine tablets.
- Given that both brands have been assessed as being bioequivalent there is no clinical reason that this would be considered unsafe.
- It is not uncommon to mix different brands to achieve acceptable dose regimens, e.g. levothyroxine.

What did we do to engage with consumers?

- PHARMAC staff and a Subcommittee member ran a training session with field officers from Epilepsy New Zealand on the lamotrigine brand change, giving practical guidance on how to support consumers with the change.
- It is very hard for PHARMAC to engage with directly with consumers. All contact, quite rightly, is through their health professionals.
- We ran an "ask me anything" session on Facebook specifically on the lamotrigine brand change a few months ago.
    1. 13 individual Facebook users posted comments
    2 Seven of those actively commented during the session
    3. Five of those users were engaged in active dialogue during the AMA session
    4. AMA feed reached 2,213 individual Facebook users (this refers to reaching people within their News Feeds, on our page and as shared by friends)
    5. 304 reactions, comments and shares. Specifically, there were 199 comments (both before, during and after the allotted AMA time).
    6. PHARMAC staff provided 57 individual responses to questions posed
- Post the allotted time and during this we promoted the PHARMAC 0800 line and enquiry email on Facebook No lamotrigine enquires through these channels were received for the three days post the AMA.
- We recently had a teleconference with Epilepsy NZ field officers, to check in with them on how things are going and if there is anything we can do to help.

What options there are for people

- PHARMAC will consider applications from prescribers for continuation of funding for a specific brand of lamotrigine for a specific patient who, due to exceptional clinical difficulties, the prescriber thinks is unable to manage a change to Logem or who has tried to change and has not tolerated it.

People who are more vulnerable

- We know change can be difficult for some people, but clinical experts have told us people shouldn't notice a difference when changing to Logem
- They also told us it was really hard to proactively identify who those might people might be – that we needed to rely on prescribers (who know their patients best) to do this
- We have made this change gradually
- We started talking publicly about the possibility of this change more than 12 months ago, and starting from May 2019, patients have had five months to move to the new brand of their medicine

What information has gone out to pharmacies and GPs and neurologists?

- We have provided pharmacists with a leaflet specifically on the lamotrigine brand change to give to their patients.

- To help prescribers and pharmacists to support people changing brands, we have developed a range of resources including:
    - patient information leaflets specifically on lamotrogine
    - access to the 'Beyond the Brand' learning module about brand changes; and
    - up to date information about the lamotrigine brand change on the PHARMAC website;
    - payment of a special fee to pharmacists to reimburse them for the additional time they spend counselling patients about a change
    - Some people may return to their GP with concerns following the change to the Logem brand and may need additional support to make a successful change. In these cases, the GP visit co payment may be waived and PHARMAC will reimburse the GP clinic on invoice.
- Bpac NZ have developed clinical guidance to healthcare professionals to assist them in clinical decision-making and support for their patients who use lamotrigine.

Why PHARMAC is doing it?

- Changing the funded brand of medicines is one of the ways that PHARMAC can get good deals with suppliers and make more new medicines available
- Changing to Logem means we'll free up more than $30 million over the next five years All this money will be used to fund other medicines for New Zealanders
- Moving to a single funded brand of lamotrigine will avoid ongoing, potentially unmanaged, brand changes for patients We know that sometimes consumers are given whichever lamotrigine a pharmacy had in stock. Without knowing it they might have one brand one month, and a different brand the next.
- Dispensing data for 2018 shows that around half of all patients who collected a funded prescription for lamotrigine, have changed brands at least once since they started on lamotrigine. Around 4,000 patients have changed brands two or more times.

Why it went ahead despite the reservations from Medsafe?

- Medsafe's feedback cam as part of PHARMAC's public consultation on the proposed brand change.
- Medsafe reminded PHARMAC of international advice from medicines regulators on switching brands of antiepileptics. Medsafe also highlighted concerns about potential loss of seizure control or mood destabilisation.
- Medsafe did not provide advice on funding, as they know we need to remain independent, and these views were provided as part of the normal consultation process.
- Following careful consideration of Medsafe's feedback (and other feedback we'd received) we put the brakes on the proposal. We decided we needed to get more expert advice before making a decision about whether or not to go ahead.
- We set up a joint meeting of our Mental Health and Neurological advisory committees – these are made up of practising clinical specialists in New Zealand.

The Subcommittees reviewed all the evidence, including all the feedback received during consultation and they concluded that there was no pharmacological reason to suggest there would be a clinical problem for patients with epilepsy or mental health conditions to change the brand of lamotrigine they use. They gave further advice about the activities that PHARMAC should consider supporting implementation of the change.

- Medsafe have acknowledged that several changes were made by PHARMAC to the brand change process, and that PHARMAC followed an acceptable process in considering feedback on the consultation.
- Changes following the Medsafe feedback include:
  - we changed our exceptional circumstances approach to ensure people can be considered for funding on a case by case basis as we are targeting those unique individuals with clinically difficult circumstances
  - we put together an updated information package for healthcare professionals and patients to address any concerns.

What precautions were put in place?

- Before making this decision we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine
- To help prescribers and pharmacists to support people changing brands, we have developed a range of resources including patient information leaflets, access to the 'Beyond the Brand' learning module about brand changes and up to date information about the lamotrigine brand change on the PHARMAC website
- Some people may return to their GP with concerns following the change to the Logem brand and may need additional support to make a successful change. In these cases, the GP visit co payment may be waived and PHARMAC will reimburse the GP clinic on invoice.
- PHARMAC staff and a Subcommittee member ran a training session with Epilepsy New Zealand on the lamotrigine brand switch, giving practical guidance on how to support consumers with the switch.
- Bpac NZ have developed clinical guidance to healthcare professionals when dealing with lamotrigine consumers

Generic brand change key messages

- PHARMAC's job is to make sure New Zealanders have funded access to the medicines they need. We work within a fixed budget. Making brand changes helps us achieve our goal by freeing up money to fund other medicines.
- Before deciding to change the funding arrangements for this medicine we got expert advice from healthcare professionals to make sure it would be appropriate for people to change brands. If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change

- We rely on the evidence and advice of our expert clinical advisors for all medicine changes, including generics

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Monday, 21 October 2019 11:48 AM
To: Media <Media@Pharmac.govt.nz>
Subject: lamotrigine follow up

Hi Jane/Pharmac media team,

I am doing another follow up story on the lamotrigine brand switch.

Can you call me regarding this please?

There are three main aspects

* The number of CARM reports
* A report of a significant event in relation to lamotrigine
* The number of patients who have switched over so far

Would you do an interview on this?

I can ring and talk to you or give me a call Withheld under

Guyon

From: Media <Media@Pharmac.govt nz>
Sent: Monday, 21 October 2019 11:59 AM
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE: lamotrigine follow up

HI Guyon, just about to head into a meeting, but will be in touch later today.

Jane Wright | senior communications advisor
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PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
www pharmac govt nz

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From: Guyon Espiner <Withheld under section 9(2)(a)>
Sent: Tuesday, 22 October 2019 9:10 AM
To: Media <Media@Pharmac.govt.nz>
Subject: RE: lamotrigine follow up

Hi Jane,

Can we talk this morning I'm preparing this story for tomorrow and would like a response from Pharmac and some information please

From: Media <Media@Pharmac.govt.nz>
Sent: Tuesday, 22 October 2019 11:04 AM
To: Guyon Espiner <Withheld under section 9(2)(a)>
Subject: RE: lamotrigine follow up

Hi Guyon,

Lisa is unavailable to talk with you today, but you can attribute the following statement to her – Lisa Williams, Director of Operations.

PHARMAC was advised on Monday 21 October 2019 that there have been 31 reports about lamotrigine received by CARM since 1 May 2019, including one report of a fatality Of the 31 cases 21 identify the Logem brand.

For many people, epilepsy is a condition which can be well managed and has little or no impact on their life. For others, ongoing seizures mean that epilepsy has a long-term impact. Like many medical conditions epilepsy can be a cause of sudden death, although this is not common and is of

course utterly devastating for family and whānau. We understand that any sudden or unexpected death would be referred to the Coroner for investigation. PHARMAC is maintaining close contact with Medsafe about lamotrigine adverse event reports and its analysis of them.

As at 18 October 2019 approximately 6,000 people are taking Logem (more than 50% of people using lamotrigine) Around 5,180 of those people have changed from one of the other two brands

PHARMAC has received 59 applications for exceptional circumstances funding for people to remain on their previous brands. So far 27 of those requests have been approved, six have been closed because additional information requested was not provided, 10 have been declined because the advice of external clinical experts was that there is no clinical reason why the particular patients should not try Logem, and 16 are currently being assessed.

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www pharmac govt nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Tuesday, 22 October 2019 11:43 AM
To: Media <Media@Pharmac.govt.nz>
Subject: RE: lamotrigine follow up

Thanks Jane

So is Pharmac treating this as a "serious sentinel event"?

What action has been taken as a result of it?

From: Media
Sent: Tuesday, 22 October 2019 1:10 pm
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE: lamotrigine follow up

Hi Guyon,

we understand that any sudden or unexpected death would be referred to the Coroner for investigation. While it is with the Coroner we can't comment, but PHARMAC is maintaining close contact with Medsafe about lamotrigine adverse event reports and its analysis of them.

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	21/10/2019
Subject	Lamotrigine
Media outlet & contact details	Guyon Espiner RNZ
Deadline	21/10/2019
Questions	There are three main aspects * The number of CARM reports * A report of a significant event in relation to lamotrigine * The number of patients who have switched over so far
Staff input	Adrienne Martin, Lisa Williams
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	Hi Guyon, Lisa is unavailable to talk with you today, but you can attribute the following statement to her Lisa Williams, Director of Operations PHARMAC was advised on Monday 21 October 2019 that there have been 31 reports about lamotrigine received by CARM since 1 May 2019, including one report of a fatality. Of the 31 cases 21 identify the Logem brand. For many people, epilepsy is a condition which can be well managed and has little or no impact on their life. For others, ongoing seizures mean that epilepsy has a long-term impact. Like many medical conditions epilepsy can be a cause of sudden death, although this is not common and is of course utterly devastating for family and whānau. We understand that any sudden or unexpected death would be referred to the Coroner for investigation PHARMAC is maintaining close contact with Medsafe about lamotrigine adverse event reports and its analysis of them. As at 18 October 2019 approximately 6,000 people are taking Logem (more than 50% of people using lamotrigine). Around 5,180 of those people have changed from one of the other two brands. PHARMAC has received 59 applications for exceptional circumstances funding for people to remain on their previous brands. So far 27 of those requests have been approved, six have been closed because additional information requested was not provided, 10 have been declined because the advice of external clinical experts was that there is no clinical reason why the particular patients should not try Logem, and 16 are currently being assessed.

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Wednesday, 30 October 2019 1:43 PM
To: Media <Media@Pharmac.govt.nz>
Subject: Espiner/lamotriginne/sentinel event

Hi Jane,

Guyon here again,

Clould you please tell me whether Pharmac has triggered a sentinel event in relation to the lamotrigine switch?

The risk scenario outlined in the OIA documents then lists a number of actions that this sets in train

Has this risk scenario (No2) in the Pharmac's lamotrigine brand change contigency plan eventuated?

Does Pharmac consider there has been "reports of serious sentinel event causing patient harm being attributed to the brand change" ?

Thanks

Guyon

From: Media
Sent: Wednesday, 30 October 2019 2:12 pm
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE: Espiner/lamotrigine/sentinel event

Hi Guyon, hope you had a lovely long weekend.

PHARMAC doesn't lodge sentinel events. The coroner will provide advice to Medsafe, and that will be shared with the appropriate healthcare agencies. We have activated our contingency plans.

Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	30/10/2019
Subject	Lamotrigine
Media outlet & contact details	Guyon Espiner RNZ
Deadline	None given
Questions	• Clould you please tell me whether Pharmac has triggered a sentinel event in relation to the lamotrigine switch? • The risk scenario outlined in the OIA documents then lists a number of actions that this sets in train Has this risk scenario (No2) in the Pharmac's lamotrigine brand change contigency plan eventuated? • Does Pharmac consider there has been "reports of serious sentinel event causing patient harm being attributed to the brand change" ?
Staff input	Janet and Jannel
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	Hi Guyon, PHARMAC doesn't lodge sentinel events. The coroner will provide advice to Medsafe, and that will be shared with the appropriate healthcare agencies. We have activated our contingency plans.

From: Jonathan Mitchell <Withheld under section 9(2)(a)>
Sent: Wednesday, 13 November 2019 10:49 AM
To: Media <Media@Pharmac.govt.nz>
Subject: Guyon Espiner follow

Hello,

Following up on Guyon's piece yesterday - https://www.rnz.co.nz/news/national/403116/three-deaths-following-epilepsy-drug-brand-switch

Interested to know what Pharmac plans to do now given the switch is only halfway through?

Can you back out of the switch?

As well, do you have to pay out if there's an issue?

If there's any other comment to make, please send through to.

I'm on Withheld for any questions.

Cheers,

Jonathan

Jonathan Mitchell | **Journalist**
RNZ News | Level 2 | 155 The Terrace
PO Box 123 | Wellington | New Zealand 6140 | www.rnz.co.nz
Mobile Withheld under (w) Withheld
@RNZjonathan

From: Media
Sent: Wednesday, 13 November 2019 11:01 am
To: Jonathan Mitchell <Withheld under section 9(2)(a)>
Subject: RE: Guyon Espiner follow

Hi Jonathan, thank you for your email. You can attribute the statement to PHARMAC's operational director Lisa Williams.

For many people, epilepsy is a condition which can be well managed and has little or no impact on their life For others, ongoing seizures mean that epilepsy has a long-term impact Like many medical

conditions epilepsy can be a cause of sudden death, although this is not common and is of course utterly devastating for family and whānau.

PHARMAC is having regular meetings with Medsafe about lamotrigine adverse event reports and Medsafe's analysis of them. At this time, we have very limited information about the reported fatalities, and we may not know the details until after the Coroner's investigations are completed

The brand change is continuing, and more than half of patients have made the change.

We want to emphasises that patients should not stop using lamotrigine. If people have any concerns, they should contact their healthcare professional PHARMAC is covering the cost of a GP visit as part of the brand change.

Logem, the funded brand of lamotrigine, has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in a number of countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands

Jane Wright | senior communications advisor

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www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	21/11/2019
Subject	Lamotrigine
Media outlet & contact details	Guyon Espiner RNZ
Deadline	21/11/2019
Questions	As discussed we are running a story tonight on Checkpoint The main focus is that there have been two complaints to the Health and Disability Commissioner which relate to the switch of the anti-epilepsy drug lamotrigine Health and Disability Commissioner Anthony Hill has provided the following written statement: "This matter raises significant issues and I will be following this up with Pharmac. It is important patients have the information they need to make informed choices, including understanding the risks and benefits of treatment options. Communication regarding the risks and benefits of medication (including contraindications, adverse reactions, and side effects) is an integral part of the informed consent process." So I am seeking a response from Pharmac to this issue of whether patients got adequate information and communication And also • Whether people will be asked to trial Logem again – I have seen an NPPA form which says under some circumstances patients who go back to their original brand may have to trial Logem in the future if things are not working well • Do people who have self-funded Lamictal or Arrow – are they eligible for funding now – or only the patients who had switched to Logem and want to switch • Could you also provide figures about how many people have now been approved to switch back under exceptional circumstances? How many are on Logem now?
Staff input	Adam Macrae, Lauren Ramonos, Pete Murray
Spokesperson as required	Lisa Williams

Actions/response Other information (include key messages)	Hi Guyon, You have asked if patients got adequate information and communication on the brand change Dr Clark told you during his interview that we could have done more to reassure and inform people about Logem. We will be looking at how we can work more closely with prescribers because we acknowledge that there is a shared responsibility across the health sector to ensure patient safety is considered when changes to brands are made For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we: • put in place a five-month transition period to allow people time to change brands • created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients • developed a range of resources for health professionals which were circulated widely, including patient information leaflets they could give to consumers • promoted an online 'Beyond the Brand' learning module for health professionals about brand changes, • put up-to date information about brand changes on the PHARMAC website. • held an 'ask me anything' Facebook live event in June 2019 and consumers were able to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and • supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to assist them with supporting consumers with the change. You asked whether people will be asked to trial Logem again and I believe you are referring a sentence in an exceptional circumstances approval letter. My understanding is that was included in approvals prior to our decision to widen access via this process You also asked if the exceptional circumstances process will be opened up to all on lamotrigine, and the answer is yes, any person using lamotrigine can talk with their prescribing doctor about applying for funding to stay on their current brand of lamotrigine. As at the beginning of November there were approximately 10,000 patients on the Logem brand of lamotrigine. As of midday Thursday 21 November 2019 we have received 409 exceptional circumstances applications. 100 of these were received before we widened access to the exceptional circumstances process. 113 of these have been approved so far, with the rest being processed As you can appreciate this is a significant increase in application numbers within a short timeframe, so

	we have brought in additional temporary resource to ensure we can make decisions as quickly as possible. I ask that you reiterate to your listeners that it is critical that people who have been prescribed Logem do NOT stop taking it and that if they have concerns they should be talking about their options with their prescriber PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in a number of countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the communication that Dr Peter Bergin, Epilepsy New Zealand, put out to ENZ members about Logem. I attach it here in case you haven't seen it If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams. Kind regards Jane

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Thursday, 21 November 2019 10:39 AM
To: Media <Media@Pharmac.govt.nz>
Subject:

As discussed we are running a story tonight on Checkpoint

The main focus is that there have been two complaints to the Health and Disability Commissioner which relate to the switch of the anti-epilepsy drug lamotrigine.

Health and Disability Commissioner Anthony Hill

He has provided the following written statement:

"This matter raises significant issues and I will be following this up with Pharmac. It is important patients have the information they need to make informed choices, including understanding the risks and benefits of treatment options. Communication regarding the risks and benefits of medication (including contraindications, adverse reactions, and side effects) is an integral part of the informed consent process."

So I am seeking a response from Pharmac to this issue of whether patients got adequate information and communication

And also

- Whether people will be asked to trial Logem again I have seen an NPPA form which says under some circumstances patients who go back to their original brand may have to trial Logem in the future if things are not working well
- Do people who have self funded Lamictal or Arrow – are they eligible for funding now or only the patients who had switched to Logem and want to switch
- Could you also provide figures about how many people have now been approved to switch back under exceptional circumstances? How many are on Logem now?

Quick phone interview with Lisa would be ideal

Thanks

Guyon

From: Media <Media@Pharmac.govt.nz>
Sent: Thursday, 21 November 2019 10:50 AM

To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE:

Thanks Guyon, will be back in touch shortly

Jane Wright | senior communications advisor

_____

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Thursday, 21 November 2019 1:42 PM
To: Media <Media@Pharmac.govt.nz>
Subject: RE:

Hi – is it just going to be a statement?

Or will you do an interview?

From: Media <Media@Pharmac govt nz>
Sent: Thursday, 21 November 2019 1:43 PM
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE:

Hi Guyon, we are sending a statement Will have it to you shortly

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Thursday, 21 November 2019 1:47 PM
To: Media <Media@Pharmac.govt.nz>
Subject: RE:

Great – thanks

From: Media
Sent: Thursday, 21 November 2019 3:24 pm
To: Guyon Espiner <Withheld under section 9(2)(a) >
Subject: RE:

Hi Guyon,

You have asked if patients got adequate information and communication on the brand change Dr Clark told you during his interview that we could have done more to reassure and inform people about Logem. We will be looking at how we can work more closely with prescribers because we acknowledge that there is a shared responsibility across the health sector to ensure patient safety is considered when changes to brands are made.

For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we:

- put in place a five month transition period to allow people time to change brands
- created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients.
- developed a range of resources for health professionals which were circulated widely, including patient information leaflets they could give to consumers
- promoted an online 'Beyond the Brand' learning module for health professionals about brand changes,
- put up to date information about brand changes on the PHARMAC website.

- held an 'ask me anything' Facebook live event in June 2019 and consumers were able to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and
- supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to assist them with supporting consumers with the change

You asked whether people will be asked to trial Logem again and I believe you are referring a sentence in an exceptional circumstances approval letter. My understanding is that was included in approvals prior to our decision to widen access via this process

You also asked if the exceptional circumstances process will be opened up to all on lamotrigine, and the answer is yes, any person using lamotrigine can talk with their prescribing doctor about applying for funding to stay on their current brand of lamotrigine.

As at the beginning of November there were approximately 10,000 patients on the Logem brand of lamotrigine. As of midday Thursday 21 November 2019 we have received 409 exceptional circumstances applications. 100 of these were received before we widened access to the exceptional circumstances process. 113 of these have been approved so far, with the rest being processed. As you can appreciate this is a significant increase in application numbers within a short timeframe, so we have brought in additional temporary resource to ensure we can make decisions as quickly as possible

I ask that you reiterate to your listeners that it is critical that people who have been prescribed Logem do NOT stop taking it and that if they have concerns they should be talking about their options with their prescriber. PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs

For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in a number of countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Please also take note of the communication that Dr Peter Bergin, Epilepsy New Zealand, put out to ENZ members about Logem. I believe it is on their Facebook page and their website.

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

Kind regards
Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Monday, 25 November 2019 4:08 PM
To: Media <Media@Pharmac.govt.nz>
Subject:

Hey there Jane,

Do you know whether Pharmac (or MedSafe?) have done any testing on the levels of lamotrigine in the blood for patients who have switched to Logem?

Are there plans to do this?

Or any other studies which seek to find out why people appear – or at least are reporting – adverse reactions to the change?

No story imminent on this but something I am interested in looking into further we have had a number of people get in touch saying their personal blood levels of lamotrigine had been lower with the switch

Be interested to see if you have anything on this

Cheers

Guyon

From: Media
Sent: Monday, 25 November 2019 4:28 PM
To: 'Guyon Espiner' <Withheld under section 9(2)(a) >
Subject: RE:

Hi Guyon,

This is from our website that might help 😊 https://www pharmac govt nz/assets/ptac neurological and mental health subcommittee lamotrigine minute 2019-02 .pdf

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Media
Sent: Monday, 25 November 2019 4:34 pm
To: 'Guyon Espiner' <Withheld under section 9(2)(a) >
Subject: RE:

In particular check out 1 24 and 1 25

Jane Wright | senior communications advisor

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www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	05/12/2019
Subject	Lamotrigine study
Media outlet & contact details	Guyon Espiner RNZ
Deadline	05/12/2019
Questions	I understand that Pharmac has ceased its nocebo research and pulled a video describing the effect after concerns from the epilepsy community. We are looking at doing the story for Checkpoint tonight. As discussed here are the questions on the Nocebo research issue 1) I understand this study was the Generic Switch Information Study by Keith Petrie. Please outline briefly what the research was, how many people participated, what was the cost to Pharmac, the dates the survey was run, whether there was an extension 2) Why was the research stopped? 3) How has the suspension affected the research – is it still of use – and if so for what? 4) Why did the researchers say it was not funded by Pharmac as per this link https://auckland.au1.qualtrics.com/jfe/form/SV_eeMsviiUNYol3FP 5) Why does the ethics approval form say 18 – but the release above say 16 as the minimum age? 6) Given questions four and five is Pharmac satisfied patients have been given correct information about this and it has met ethical standards? 7) Does Pharmac accept that even if the number of cases is small there may be some patients who have 'clinical' rather than Nocebo affects and if so shouldn't that have been mentioned in the video? 8) When was the video first put out? 9) Does Pharmac consider that presenting the video in this way posed any safety risks – in that it may have led people to believe that any symptoms were just Nocebo related 10) Does Pharmac still believe that any side effects with this brand switch are Nocebo and not pharmacological/medical
Staff input	Adam McRae
Spokesperson as required	Lisa Williams

Actions/response Other information (include key messages)	Hi Guyon, Thank you for your questions on lamotrigine and the University of Auckland Faculty of Health and Medical Science's research project on brand changes PHARMAC is an evidence based organisation and we use research to inform our work, including improvements we can make to the support we provide consumers and health professionals. We commissioned research via the University of Auckland Faculty of Health and Medical Science in March 2019 to support the lamotrigine brand change and also to gain insights about how best to support future brand changes. The research has ethics approval and was looking at looking at whether a text message to patients, informing them of an upcoming change to their funded brand of medicine, has a positive impact on their acceptance of the change in brand. Some study participants were provided a link to a video to watch. The video was not intended to be widely distributed in the public domain, rather it was aimed at people who had provided informed consent to participate in the study. However, in the context of significant public concern around the lamotrigine brand change, including the recent media coverage, and information PHARMAC received that a link to the video had been broadly shared amongst patient groups, the research activity was ceased and the video content removed earlier this week by the research provider. With regards to the survey that you included in your questions, https://auckland.au1.qualtrics.com/jfe/form/SV_eeMsviiUNYol3FP this was not part of the same research project, and was not funded or designed by PHARMAC. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication I have attach it here in case you haven't seen it If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams If you have further questions about University of Auckland Faculty of Health and Medical Science's research project you are best to talk directly

	with Keith Petrie. He is not a PHARMAC employee and it is for him to decide if he wishes to talk with you. Kind regards Jane

PHARMAC MEDIA ENQUIRY

Date Received	06/12/2019
Subject	Lamotrigine study
Media outlet & contact details	Chelsea Daniels, Newstalk ZB and Guyon Espiner, RNZ
Deadline	06/12/2019
Questions	Following the Chief Coroner's media release on the joint inquiry into the 4 deaths of people on lamotrigine, we received requests from the above media outlets for a statement.
Staff input	Adam McRae
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	PHARMAC welcomes the news that the Chief Coroner has opened a joint inquiry into the four fatalities of people who were taking lamotrigine PHARMAC's medical director Dr Ken Clark wrote to the Chief Coroner in November to offer our full assistance Coroners investigating the deaths and to ask to have a full and early opportunity to have input into any investigation or inquiry where our actions or decisions may be relevant. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs. For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attached it here in case you haven't seen it. I have included a copy of Dr Clark's letter to the Chief Coroner for your information. If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

	Kind regards Jane

From: Media
Sent: Friday, 6 December 2019 12:00 pm
To: 'Guyon Espiner' <Withheld under section 9(2)(a)>
Subject: Chief Coroner's joint inquiry
Attachments:

Hi Guyon,

PHARMAC welcomes the news that the Chief Coroner has opened a joint inquiry into the four fatalities of people who were taking lamotrigine. PHARMAC's medical director Dr Ken Clark wrote to the Chief Coroner in November to offer our full assistance Coroners investigating the deaths and to ask to have a full and early opportunity to have input into any investigation or inquiry where our actions or decisions may be relevant

Additional Information
I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs.

For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands

Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication. I have attached it here in case you haven't seen it.

I have included a copy of Dr Clark's letter to the Chief Coroner for your information.

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

Kind regards
Jane

Jane Wright | senior communications advisor
_____
PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.

Email: *media@pharmac.govt.nz*
Phone: Withheld under

PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
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www.pharmac.govt.nz

20 November 2019

Judge Deborah Marshall
Chief Coroner
Office of the Chief Coroner
By email: OfficeoftheChiefCoroner@justice govt nz

Dear Judge Marshall

RECENT DEATHS OF PATIENTS TAKING LAMOTRIGINE

As you may be aware there have been some recent reports of epileptic patients who have been taking the medicine lamotrigine who have died suddenly It has been suggested in some media reports that these deaths may be connected to a change in the funded brand of lamotrigine as the result of a decision made by PHARMAC.

Medsafe recently issued an alert advising of suspected adverse reactions that have been reported to the Centre for Adverse Reactions Monitoring (CARM) since the transition to the new funded brand began; this includes some reports of sudden deaths in patients using lamotrigine https://www.medsafe.govt.nz/safety/Alerts/Lamotrigine.asp. We understand that these deaths have been reported to the Coroner.

I write to offer PHARMAC's full assistance to Coroners investigating these deaths, and also to confirm our expectation that PHARMAC will have a full and early opportunity to have input into any investigation or inquiry where our actions or decisions may be relevant

As we are not aware of the details of these deaths, or which Coroners they have been referred to, I would appreciate you passing this letter on to the relevant Coroners and inviting them to make contact with PHARMAC, in the first instance via our General Counsel, Graham Beever on [redacted]

Yours sincerely

Dr Ken Clark
Acting Medical Director MBChB FRANZCOG FRCOG FRACMA

A1329787

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Thursday, 5 December 2019 12:02 PM
To: Media <Media@Pharmac.govt.nz>
Subject: ten questions

Hi Jane

As discussed here are the questions on the Nocebo research issue

1) I understand this study was the Generic Switch Information Study by Keith Petrie. Please outline briefly what the research was, how many people participated, what was the cost to Pharmac, the dates the survey was run, whether there was an extension

2) Why was the research stopped?

3) How has the suspension affected the research – is it still of use – and if so for what?

4) Why did the researchers say it was not funded by Pharmac as per this link https://auckland au1 qualtrics com/jfe/form/SV_eeMsviiUNYol3FP

5) Why does the ethics approval form say 18 but the release above say 16 as the minimum age?

6) Given questions four and five is Pharmac satisfied patients have been given correct information about this and it has met ethical standards?

7) Does Pharmac accept that – even if the number of cases is small – there may be some patients who have 'clinical' rather than Nocebo affects and if so shouldn't that have been mentioned in the video?

8) When was the video first put out?

9) Does Pharmac consider that presenting the video in this way posed any safety risks in that it may have led people to believe that any symptoms were just Nocebo related

10) Does Pharmac still believe that any side effects with this brand switch are Nocebo and not pharmacological/medical

From: Media
Sent: Thursday, 5 December 2019 3:40 pm
To: 'Guyon Espiner' <Withheld under section 9(2)(a) >
Subject: RE: ten questions ...

Hi Guyon,

Thank you for your questions on lamotrigine and the University of Auckland Faculty of Health and Medical Science's research project on brand changes.

PHARMAC is an evidence based organisation and we use research to inform our work, including improvements we can make to the support we provide consumers and health professionals. We commissioned research via the University of Auckland Faculty of Health and Medical Science in March 2019 to support the lamotrigine brand change and also to gain insights about how best to support future brand changes.

The research has ethics approval and was looking at looking at whether a text message to patients, informing them of an upcoming change to their funded brand of medicine, has a positive impact on their acceptance of the change in brand. Some study participants were provided a link to a video to watch The video was not intended to be widely distributed in the public domain, rather it was aimed at people who had provided informed consent to participate in the study.

However, in the context of significant public concern around the lamotrigine brand change, including the recent media coverage, and information PHARMAC received that a link to the video had been broadly shared amongst patient groups, the research activity was ceased and the video content removed earlier this week by the research provider.

With regards to the survey that you included in your questions, https://auckland.au1.qualtrics.com/jfe/form/SV_eeMsviiUNYol3FP this was not part of the same research project, and was not funded or designed by PHARMAC.

Additional Information
I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs.

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Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attach it here in case you haven't seen it.

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

If you have further questions about University of Auckland Faculty of Health and Medical Science's research project you are best to talk directly with Keith Petrie. He is not a PHARMAC employee and it is for him to decide if he wishes to talk with you

Kind regards
Jane

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

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We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

PHARMAC MEDIA ENQUIRY

Date Received	12/12/2019
Subject	Lamotrigine
Media outlet & contact details	Guyon Espiner RNZ
Deadline	14/12/2019
Questions	Guyon's questions are: • The OIA email trail shows that Pharmac found out that three deaths had been linked to the brand switch on October 29 What was the reason that the agency waited until November 15 to make its policy change on this issue? • The MedSafe prescriber advisory of December 6 says prescribers should "follow the UK MHRA advice" … which is that any brand switch should be "based on clinical judgement and consultation with patient and or carer" taking into account patient history etc – does Pharmac agree with this or do we have two differing views between MedSafe and Pharmac? • There were also significant differences between Pharmac and NZTA over whether the brand switch would be a danger for drivers – have these been resolved? • I'd also like an update on how many are taking Logem now, how many NPPA applications have been received and approved and what the latest CARM figures show
Staff input **External input**	Adam McRae, Adrienne Martin, Pete Murray MoH media advisor Blair Cunningham NZTA media manager Andrew Knackstedt
Spokesperson as required	Lisa Williams
Actions/response **Other information (include key messages)**	Hi Guyon, Thank you for your questions on lamotrigine. I have spoken with the Ministry of Health and NZTA to ensure I answer questions two and three accurately To get the latest CARM figures you are best to talk to CARM directly or to Medsafe who receive the reports from CARM. I understand you have asked for an interview, but we think a statement will provide answers to your questions. You are correct that as of 29 October PHARMAC staff had been advised that there had been three CARM reports where there was a death of someone who was taking lamotrigine. As you will have seen in the email trails you received through OIA, PHARMAC has very limited information about the reported fatalities and we may not know the details, including whether there is any connection with the funded brand change, until after the Coroner's investigations are completed. You are also aware that PHARMAC proactively reached out to the Chief Coroner in November to offer input

	into any coronial investigations that occur and that subsequently the Chief Coroner has announced a joint inquiry. Like many medical conditions, epilepsy can be a cause of sudden death, although this is not common. (You might want to refer back to your interview with Dr John Fink and the poster you were sent in the most recent OIA response for more clarity around this). PHARMAC was aware that there was a high level of anxiety among people on lamotrigine and their families, compounded by the amount of media coverage and social media commentary following the Medsafe monitoring alert published on 12 November We already had in place our exceptional circumstances process to enable ongoing funding of previous brands for people unable to change and had received almost 90 applications before 15 November. We considered that, in the context of the level of public concern being expressed, the volume of applications had been relatively low such that it needed to be more widely promoted and widened to make it easier for people on lamotrigine to stay on their current brand, if their doctor thinks they should. We have worked closely with our colleagues at Medsafe throughout the lamotrigine brand change and both agencies are concerned that the media has portrayed that we are at odds. Medsafe's advice - that any brand switch should be "based on clinical judgement and consultation with patient and/ or carer" – was a fundamental reason why PHARMAC extended the lead in time for the brand change and developed a range of resources for prescribers and pharmacists. There is a shared responsibility across the health sector for patient safety and to ensure that patients are informed when changes to funded brands of medicines are made. Medsafe ensures generic medicines are bioequivalent (therapeutically the same) to the original brand and that the manufacturing process safety standards are met Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of medicines used and contribute to international knowledge of pharmacovigilance. PHARMAC liaises closely with Medsafe about brand changes and to ensure that we are aware of any increases in adverse event reporting. In general, primary care prescribers write prescriptions generically and may not be familiar with what brand of medicine a patient is taking. Pharmacists have a key role in counselling patients at the point when a new brand is dispensed to the patient. PHARMAC, with input from our expert clinical advisers, considers the impact on patients and the sector and determines what is needed to support brand changes including communications and education. We know that the way that health care professionals explain brand changes to consumers can strongly influence how consumers react to a change of brand

	For the lamotrigine brand change we identified the need for additional support for consumers and health professionals, so we: • put in place a five-month transition period to allow people time to change brands • created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients • developed a mechanism for reimbursement of GP co payments for patients to be able to discuss the change with their doctor • developed a range of resources for prescribers and pharmacists which were circulated widely, including patient information leaflets they could give to consumers • promoted an online 'Beyond the Brand' learning module for health professionals about brand changes, • put up-to-date information about brand changes on the PHARMAC website • held an 'ask me anything' Facebook live event in June 2019 and consumers were able to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine; and • supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to assist them with supporting consumers with the change. We are always looking at how we communicate with prescribing doctors and pharmacists, about upcoming funding changes, to see how we can improve our approach to this We had been talking with NZTA to understand the change that they made to their advice to drivers going through the brand change of lamotrigine, but now that the exceptional circumstances process has been widened to include those who are concerned about their ability to drive we consider this to no longer be an issue With regards to your question on numbers, as at 18 November there were approximately 10,800 people on Logem As of 11 December, we have received 1,129 exceptional circumstances applications with 849 approved. The turnaround time for decisions is currently 4-5 working days. We are publishing application numbers on our website (https://www.pharmac.govt.nz/medicines/my medicine has changed/lamotrigine epilepsy-drug changes/) **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs.

	For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams. Kind regards Jane

From: Media <Media@Pharmac.govt.nz>
Sent: Wednesday, 18 December 2019 11:25 AM
To: Guyon Espiner <Withheld under section 9(2)(a)>
Subject: lamotrigine

Hi Guyon,

As discussed the other day it is really important that people on Logem aren't listening to your stories and panicking without reason about their medication. I know your written stories are including the message about contacting their doctor if they have any concerns, and not just stopping their medication, but it is not being included in the audio The ramifications of someone simply stopping taking their medication could be huge and I know that you care about your listeners and would hate to put anyone at risk Please talk with your producers and ENSURE that the message is included that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs.

I am guessing there will be a third story tomorrow, so fingers crossed that safety message will make it in.

Thanks Guyon
Jane

Jane Wright | senior communications advisor
_____
PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Guyon Espiner <Withheld under section 9(2)(a)>
Sent: Wednesday, 18 December 2019 11:33 AM
To: Media <Media@Pharmac.govt.nz>
Subject: RE: lamotrigine

Thanks Jane,

It was in the audio story broadcast Tuesday and in the written versions of the Tuesday and Wednesday stories but yes not in the audio version today

We have broadcast and written this message many times but just to be clear: are you requesting that EVERY story we do should contain this message?

From: Media <Media@Pharmac.govt.nz>
Sent: Wednesday, 18 December 2019 11:39 AM
To: Guyon Espiner <Withheld under section 9(2)(a)>
Subject: RE: lamotrigine

Yes please 😊 The logic is that for those people who have just tuned in or who have listened before but grow more and more concerned as the stories continue, they need that information.

Jane Wright | senior communications advisor

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www.pharmac.govt.nz

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We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Guyon Espiner <Withheld under section 9(2)(a)>
Sent: Wednesday, 18 December 2019 11:48 AM
To: Media <Media@Pharmac govt nz>
Subject: RE: lamotrigine

Ok Jane,

I will make sure that happens.

Thanks again

Guyon

From: Media <Media@Pharmac govt nz>
Sent: Wednesday, 18 December 2019 11:49 am
To: Guyon Espiner <Withheld under section 9(2)(a) >; Media <Media@Pharmac.govt.nz>
Subject: RE: lamotrigine

Really appreciate that, thanks Guyon

Jane Wright | senior communications advisor
_____
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www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

PHARMAC MEDIA ENQUIRY

Date Received	27 November 2020
Subject	Epilepsy meds
Media outlet & contact details	Guyon Espiner RNZ
Deadline	ASAPR
Who else is involved in the story?	Epilepsy NZ who provided their consultation feedback and our response
Questions	Hi Jane, As discussed I am reporting that Pharmac considered brand switches for two AEDs in August 2020 and then removed them from the tender schedule after a submission from ENZ. Here are the letters underpinning my reporting. Please advise if there is any other context I need to be aware of?
Staff input	Adam, Craig, Chippy, Chloe
Spokesperson as required	Lisa Williams
Actions/response **Other information (include key messages)**	Kia ora Guyon, Please attribute the below to PHARMAC's director of operations Lisa Williams. PHARMAC's role is to decide which medicines are publicly funded for New Zealanders. We have a robust, evidence based approach and seek expert clinical advice and ask the healthcare sector and wider public for their thoughts through consultation, to help us make these decisions. When medicine sole supply arrangements end (whether due to patent expiry or contractual conditions) PHARMAC aims to comply with Government Procurement Rules, which encourage open competitive processes and fairness to all suppliers Medicines used to manage epilepsy, clonazepam and phenobarbitone, were included in the **draft** 2020/2021 Invitation to Tender (ITT) product list which was issued for consultation in August 2020. This year, we created a new consultation webpage targeted at patients, with clearer language in order to better support engagement Public information on the tender cycle was developed to support the public in better understanding the process Following public consultation, PHARMAC seeks clinical advice from the Tender Medical Evaluation Subcommittee who review the proposed tender list and consultation feedback received. Every year, the list of tendered pharmaceuticals is changed prior to the final tender release in November Items are added, amended and removed

	following consideration of the consultation feedback and clinical advice received - this is why consultation feedback is so important. For the 2020/21 ITT, subsequent to the process described above, PHARMAC removed clonazepam and phenobarbitone from the final tender product list As discussed on the phone, PHARMAC is scheduled to give evidence at the Coroner's inquest in late February 2021, so it is not appropriate for us to comment during the proceedings We are, however, asking all media to use the following safety messages when writing about lamotrigine: • It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor. • For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. • Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Kind regards Jane

From: Jane Wright <Withheld under section 9(2)(a)>
Sent: 06 March 2020 09:57
To: Karoline Tuckey <Withheld under section 9(2)(a)>
Subject: Lamotrigine

Lovely talking with you – here are our safety messages which I urge you to use please 😊

Safety key messages

- It is critical that people who have been prescribed Logem do NOT stop taking it and that, if they have concerns, they talk about their options with their doctor PHARMAC will refund the prescriber for this visit, so the patient won't incur additional costs.
- For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands.
- Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines
- If people have concerns, we encourage them to talk to their doctor. Their doctor can apply to PHARMAC, through our Exceptional Circumstances Framework, for continued funding of the brand they took before the funding change

Jane Wright | senior communications advisor

_____

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Karoline Tuckey <Withheld under section 9(2)(a)>
Sent: Friday, 6 March 2020 10:31 AM
To: Jane Wright <Withheld under section 9(2)(a)>
Subject: Re: Lamotrigine

Hi Jane, Thanks for this info!

I've talked further with Bella, I would be keen to find out responses to a few of her points:

She says while Logem has the same active ingredient, the concentration can vary by 20%, and the drug is absorbed differently - she says some of their members blood tests have shown levels of the drug has dropped 50 or 60 per cent

She also says Pharmac had previously said that this type of drug should not be given to pts without their drs being involved in the decision - but that the switch was made at the pharmacy dispensing level, and many doctors - and pts weren't initially aware their medication had been switched

Could you tell me the month the switch was made, and who the switch was made with - all pts receiving lamotrigine? How many?
Was the switch made at the pharmacy dispensing level?

At this point, have all NZ pts who receive lamotrigine been switched to logem unless their drs have specified they should receive another brand? Or most? Is the process continuing?

Thanks!

Karoline Tuckey

Reporter
Phone Withheld under
www radionz co nz

From: Jane Wright
Sent: Friday, 6 March 2020 10:46 am
To: Karoline Tuckey <Withheld under section 9(2)(a)>
Subject: RE: Lamotrigine

Thanks Karoline,

I will have a look at her points but in the meantime, check out our website https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/lamotrigine-epilepsy-drug-changes/ which should give you the answers to the second part of your email

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Jane Wright
Sent: Friday, 6 March 2020 10:51 am
To: Karoline Tuckey <Withheld under section 9(2)(a)>
Subject: FW:

Hi Karoline, this might also be helpful, particularly to Bella's first point

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Media
Sent: Monday, 25 November 2019 4:34 PM
To: 'Guyon Espiner' <Withheld under section 9(2)(a)>
Subject: RE:

In particular check out 1.24 and 1.25

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Media
Sent: Monday, 25 November 2019 4:28 PM
To: 'Guyon Espiner' <Withheld under section 9(2)(a)>
Subject: RE:

Hi Guyon,

This is from our website that might help 😊 https://www pharmac govt nz/assets/ptac neurological-and-mental-health subcommittee lamotrigine minute 2019-02 .pdf

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Guyon Espiner <Withheld under section 9(2)(a) >
Sent: Monday, 25 November 2019 4:08 PM
To: Media <Media@Pharmac.govt.nz>
Subject:

Hey there Jane,

Do you know whether Pharmac (or MedSafe?) have done any testing on the levels of lamotrigine in the blood for patients who have switched to Logem?

Are there plans to do this?

Or any other studies which seek to find out why people appear – or at least are reporting – adverse reactions to the change?

No story imminent on this but something I am interested in looking into further we have had a number of people get in touch saying their personal blood levels of lamotrigine had been lower with the switch

Be interested to see if you have anything on this

Cheers

Guyon

PHARMAC MEDIA ENQUIRY

Date Received	16 July 2020
Subject	Lamotrigine
Media outlet & contact details	Hannah Martin Stuff
Deadline	End of Friday
Questions	I'm seeking comment from Pharmac for a piece on the lamotrigine brand switch and the effects people have reported as a result. I understand some of this will be going over old ground, given RNZ reporting last year, but wanted to give Pharmac the opportunity to address these concerns again which patients and their whanau continue to raise. 1 Why was the decision made to switch to the one funded brand of Logem? 2 What consultation and clinical advice did Pharmac receive before making its decision? Over what period of time was this carried out? 3. Why did not Pharmac not heed Medsafe's warnings against switching the drug, given it was posed as potentially "extremely detrimental" and went "against international consensus"? 4 Does Pharmac stand by its decision not to fully inform patients about the brand switch ahead of time? 5. If the Coroner's joint inquiry finds the drug switch was implemented in the deaths of those first five patients, will Pharmac permanently reverse the switch? 6 How does Pharmac respond to the fact that there have been 175 adverse events reports made to CARM specifically relating to the Logem switch, including 63 reported increased convulsions and more than 120 reporting decrease in therapeutic response?
Staff input	Adam McRae, Janet Mackay
Spokesperson as required	Sarah Fitt

Actions/response Other information (include key messages)	Hi Hannah, The funded brand of lamotrigine changed from Lamictal, Arrow-Lamotrigine and Logem to Logem only in October 2019 PHARMAC works to get the best health outcomes for New Zealanders we can by funding medicines from within the available budget Having a fixed budget means we need to make careful and considered funding choices in the interests of all New Zealanders. Brand changes and sole supply arrangements with suppliers have been key to PHARMAC being able to invest in more medicines for more New Zealanders. Before deciding to change the funding arrangements for lamotrigine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine. If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change, regardless of the savings we could achieve. PHARMAC does not have access to individual patient information and rely on healthcare professionals to support patients as they are in the most appropriate position to do so. For the lamotrigine brand change we identified the need for additional support for those taking the medicine and health professionals, so we: • put in place a five-month transition period to allow people time to change brands created a separate exceptions process to enable continued funding for previous brands to be considered for individual patients • developed a mechanism for reimbursement of GP co payments for patients to be able to discuss the change with their doctor • developed a range of resources for health professionals which were circulated widely, including patient information leaflets they could give to consumers • promoted an online 'Beyond the Brand' learning module for health professionals about brand changes • put up to-date information about brand changes on the PHARMAC website • held an 'ask me anything' Facebook live event in June 2019 and consumers were able to ask us questions about any PHARMAC issue, including the then upcoming change to one funded brand of lamotrigine, and • supported a training day and follow up video conference for Epilepsy New Zealand field officers, to ensure they had sufficient information to assist them with supporting consumers with the change. It would not be appropriate for PHARMAC to comment about an ongoing coronial investigation. There is a shared responsibility across the health sector for patient safety Medsafe ensures generic medicines are bioequivalent (therapeutically the same) to the original brand and that the manufacturing process safety standards are met. They did this with Logem. Medsafe uses the Centre for Adverse Reactions Monitoring (CARM) as a way to improve the safety of

	medicines used and contribute to international knowledge of pharmacovigilance. You might want to refer your last question to Medsafe. **Additional Information** I ask that you reiterate to your readers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attached it here in case you haven't seen it. Please attribute the above to PHARMAC's Chief Executive Sarah Fitt Kind regards

From: Stephanie Ockhuysen <Withheld under section 9(2)(a)>
Sent: Wednesday, 11 September 2019 1:50 pm
To: Media <Media@Pharmac.govt.nz>
Subject: Stuff co nz story Lamictal

Hi,

I am writing a story about a New Plymouth man currently on Lamictal which I understand Pharmac plans to stop funding and switching those on it to Logem

Below are some questions If you could please get back to me by 2pm tomorrow.

Why is Pharmac stopping funding Lamictal a drug that helps 10,000 New Zealanders live normal lives?
What is Pharmac's responsibility if people have side effects from the drug switch?
Is Pharmac aware a petition has been started to keep the drug funded for those who need it?
Will Pharmac consider the petition and continue to fund the drug?

Thanks,
Steph

Stephanie Ockhuysen
Reporter

E Withheld under section 9(2)(a) | **M** Withheld under
Taranaki Daily News, 25 Gill Street, New Plymouth, 4310, New Zealand
PO Box 444, New Plymouth 4340

On Wed, 11 Sep 2019 at 15:20, Media <Media@pharmac.govt.nz> wrote:
Hey Steph,

This should be useful background reading for you 😊
https://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-06-generics-and-biosimilars/

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Stephanie Ockhuysen <Withheld under section 9(2)(a)>
Sent: Thursday, 12 September 2019 10:58 AM
To: Media <Media@Pharmac govt nz>
Subject: Re: Stuff.co.nz story Lamictal

Thanks Jane.

Will I still get a response to my questions?

Also wondering how much Lamictal will cost if people wanted to continue on it once it is no longer funded?

Stephanie Ockhuysen
Reporter

E Withheld under section 9(2)(a) | **M** Withheld under
Taranaki Daily News, 25 Gill Street, New Plymouth, 4310, New Zealand
PO Box 444, New Plymouth 4340

On Thu, 12 Sep 2019 at 11:50, Media <Media@pharmac.govt.nz> wrote:

Hi Steph,

Thanks for your questions on Lamotrigine of which Lamictal is one of the brands. As you know PHARMAC is just funding Logem as of 1 October Logem works in the same way as Lamictal and Arrow Lamotrigine. Logem has the same active ingredient as the other brands and is delivered to the body in the same way. This means it will have the same effect as the other brands.

Our dispensing data for 2018 shows that around 50% of all people who collected a funded prescription for lamotrigine, have changed brands at least once since they started on lamotrigine Around 4,000 people have changed brands two or more times. We are not aware of, nor have we been informed of, any significant clinical impacts for these people when they changed

brands. Moving to a single funded brand of lamotrigine will avoid ongoing, potentially unmanaged, brand changes that can happen when there is more than one funded brand available. Previously patients could chop and change at the discretion of the pharmacist without input from the doctor and often the patient might not be aware either So brand changing was happening on an ad hoc basis all of the time. As we move to sole supply with Logem, the transition will be obvious and managed and ad hoc changes will no longer happen

The chronic nature of epilepsy means that people, even on treatment, can have recurrent and spontaneous seizures. Expert advice based on a review of literature indicates that just over 1 in 5 people with epilepsy who are stable and have been seizure-free may experience a seizure within 2 years In general, this is managed through medication review with a patient's doctor and by considering dosage adjustments or a change of medication. We engaged with epilepsy support groups and health professionals before we made the decision to fund one brand of lamotrigine. We have used their feedback to help develop a range of resources including patient information leaflets, access to the 'Beyond the Brand' learning module about brand changes and up to date information about the lamotrigine brand change on the PHARMAC website

Some people may return to their GP with concerns following the change to the Logem brand and may need additional support to make a successful change. In these cases, the GP visit co payment may be waived and PHARMAC will reimburse the GP clinic on invoice PHARMAC will also consider applications from prescribers for continuation of funding for a specific brand of lamotrigine for a specific patient who, due to exceptional clinical difficulties, the prescriber thinks is unable to manage a change to Logem or who has tried to change and has not tolerated it.

Why have these changes been made?

- PHARMAC's job is to make sure New Zealanders have funded access to the medicines they need We work within a fixed budget Making brand changes helps us achieve that by freeing up money to fund other medicines.
- Changing to Logem means we'll free up more than $30 million over the next five years, money that PHARMAC will use to fund other medicines for New Zealanders.
- Before deciding to change the funding arrangements for this medicine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine. If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change, regardless of the savings we could achieve.
- Consultation started on 28 August, and our original proposal was for the transition to start from 1 December 2018 with the sole supply commencing from 1 May 2019 We got all the feedback to consultation and as a result of it (including specifically the feedback from Medsafe) we decided to put a hold on the proposal and go back to our experts to get more advice. See https://www.pharmac.govt.nz/news/notification_2019_04_11_lamotrigine/

Please let me know if you have any further questions

Kind regards

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Stephanie Ockhuysen <Withheld under section 9(2)(a)>
Sent: Thursday, 12 September 2019 1:00 PM
To: Media <Media@Pharmac govt nz>
Subject: Re: Stuff.co.nz story Lamictal

Thanks for this. Shall I just attribute to Pharmac spokesperson or is there someone in particular?

Stephanie Ockhuysen
Reporter

E Withheld under section 9(2)(a) | **M** Withheld under
Taranaki Daily News, 25 Gill Street, New Plymouth, 4310, New Zealand
PO Box 444, New Plymouth 4340

From: Media
Sent: Thursday, 12 September 2019 1:26 pm
To: Stephanie Ockhuysen <Withheld under section 9(2)(a)>
Subject: RE: Stuff.co.nz story - Lamictal

A spokesperson is fine 😊

Jane Wright | senior communications advisor
_____
PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	22 July 2020
Subject	Lamotrigine
Media outlet & contact details	Cushla Norman TV1
Deadline	4 pm today
Questions	Patient Voice Aotearoa is making a submission today at the health select committee regarding the epilepsy drug brand switch. They have had Logem tested at an international testing agency and found significant differences between it and the brand it replaced. The testing found differences in dose and dissolution rates of between 3.6 – 11.7%. Experts say the differences are enough to be fatal. I would like a response from Pharmac regarding these findings.
Staff input	Lisa Williams
Spokesperson as required	N/S
Actions/response Other information (include key messages)	Hi Cushla, Questions about the medicine should be directed to Medsafe An independent review on the lamotrigine sole supply decision found that PHARMAC's processes were evidence based and robust, and of a high standard. You can read that here and the related media release. You may also be interested to read PHARMAC's submission in response to the petition. You can read that here. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication I have attached it here in case you haven't seen it

PHARMAC MEDIA ENQUIRY

Date Received	16 July 2020
Subject	Lamotrigine
Media outlet & contact details	Rosie Gordon TV3
Deadline	3pm today
Questions	As you may be aware, a petition is being presented to a Parliamentary Health Select Committee today calling for Lamictal to be publicly funded again for epilepsy patients. Among the issues patients and their families argue the medication present are: - Seven lives have potentially been lost due to the brand switch to Logem last year Lamictal is safer for young patients in particular Cost cutting by PHARMAC has potentially come at the hands of patient safety. Could you please provide a response to these points and please answer the question 'will PHARMAC consider reversing its branding switch decision and fund Logem again and stop funding Lamictal?' The petition group will also publish some embargoed evidence about the medications at 1pm. I will also be seeking a response from PHARMAC to this once it is published. This is a matter we intend to broadcast on tonight's 6pm news. I would like to offer PHARMAC an interview to respond for fairness and balance. Should you wish to respond in statement instead please let me know
Staff input	Adam McRae, Janet Mackay, Lisa Williams
Spokesperson as required	Ken Clark
Actions/response Other information (include key messages)	Hi Rosie, PHARMAC works to get the best health outcomes for New Zealanders we can by funding medicines from within the available budget. Having a fixed budget means we need to make careful and considered funding choices in the interests of all New Zealanders. Brand changes and sole supply arrangements with suppliers have been key to PHARMAC being able to invest in more medicines for more New Zealanders. Before deciding to change the funding arrangements for lamotrigine we got expert advice from healthcare professionals who work directly with people with epilepsy and people with mental health conditions to make sure it would be appropriate for people to change brands of lamotrigine If our expert clinical advisors said it wasn't appropriate, we wouldn't have made the change, regardless of the savings we could achieve An independent review on the lamotrigine sole supply decision found that PHARMAC's processes were evidence based and robust, and of a high standard. You can read that here and the related media release.

	You may also be interested to read PHARMAC's submission in response to the petition. You can read that here. As we haven't seen the embargoed evidence you refer to, I am afraid I can't comment on that. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it. If they have concerns, they should talk about their options with their doctor For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attached it here in case you haven't seen it. Please attribute the above to PHARMAC's Medical Director Dr Ken Clark. Kind regards

From PHARMAC's perspective

Umbrella statement

Logem works in the same way as the other two Lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands.

Core message 1

Before making this decision we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine

Core message 2

Changing to Logem means we'll free up more than $30 million over the next five years. All this money will be used to fund other medicines for New Zealanders

It's about making the right decision - 10 month delay – lost savings of nearly $5m … so it's not all about the money

If asked about why we didn't accept Dr Bergin's offer of a study

Before making this decision we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine. We believe that Dr Bergin's proposal for funding to study the two different brands would have limited benefits

If asked why we are going ahead without the support of Epilepsy NZ or Medsafe

Logem works in the same way as the other two Lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Before making this decision we got expert advice from healthcare professionals who work directly with people with epilepsy and mental health conditions to make sure it's appropriate for people to change brands of lamotrigine.

Is it all about the money?

Changing to Logem means we'll free up more than $30 million over the next five years. All this money will be used to fund other medicines for New Zealanders But we know that it's about making the right decision 10 month delay lost savings of nearly $5m … so it's not all about the money.

From: Nicole Bremner <Withheld under section 9(2)(a)>
Sent: Wednesday, 13 November 2019 10:36 AM
To: Media <Media@Pharmac.govt.nz>
Subject: 1 News query

Hi Jane

How are you going re an iv about Medsafe alert?

Cheers
Nicole

Nicole Bremner
Journalist

d. Withheld under
m. Withheld under
e. Withheld under section 9(2)(a)

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From: Media
Sent: Wednesday, 13 November 2019 10:46 am
To: Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query

In the meantime, I understand you already have the statement I sent Jess last night, can you add the below to it…

We want to emphasises that patients should not stop using lamotrigine. If people have any concerns, they should contact their healthcare professional. Logem, the funded brand of lamotrigine, has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines Approximately 80 million doses per annum of Logem are used in a number of countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

PHARMAC MEDIA ENQUIRY

Date Received	27/11/2019
Subject	Lamotrigine and Enlafax
Media outlet & contact details	Nicole Bremner TVNZ
Deadline	03/12/2019
Questions	I'm doing some checks on the lamotrigine brand switch. Would you please let me know: • How many CARM reports have now been received and are there any more deaths (than 4) under coronial investigation? • How many GP's have applied for their patients to go back onto their original meds? • How many have actually switched back? • How much money has Pharmac spent in the the last 5 years on research about anti epileptic drugs – specifically patients views on generics and the nocebo effect? Is any underway and what is the methodology? • What local research, if any, did Pharmac use or refer to in its decision to switch to Logem? Finally, as you're aware, I have done a number of stories on the Enlafax brand switch. There have been a significantly higher number of adverse reaction reports about Enlafax than Logem - yet there has not been the same level of 'patient concession.' • Can you please explain why? • Also, what effect, if any, the four unexplained deaths had on Pharmac's decision to fund patients back on previous meds?
Staff input	Adam McRae, Sarah Le Leu, Adrienne Martin, Pete Murray, Legal team (for the value of the research)
Spokesperson as required	Lisa Williams

Actions/response **Other information (include key messages)**	Hi Nicole, Thank you for your questions on lamotrigine. You are best to contact Medsafe for the most up to date figures on adverse event reports to CARM. As at the beginning of November 2019 dispensing data shows there were approximately 10,000 patients on the Logem brand of lamotrigine. As of today, Tuesday 3 December 2019, we have received 921 exceptional circumstances applications from prescribers These are a mix of people who had not yet tried the new brand and those whose prescribers felt it clinically appropriate that they return to using their original brand – Lamictal or Arrow lamotrigine. 812 of these were received after 15 November 2019, when we announced that PHARMAC had widened the criteria for lamotrigine exceptional circumstances 481 applications have been approved, the remainder are being processed. PHARMAC has brought in additional resource so we can ensure decisions are made as quickly as possible. PHARMAC has engaged the University of Auckland to conduct two studies that are currently underway to look at psychological influences on the efficacy and side-effects associated with brand changes. The value of the research is $72,683 plus GST. The research is not about anti epileptic drugs per se, but the lamotrigine brand change is being used to look at whether a text message to patients, from their community pharmacy, informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. Research results will be used by PHARMAC to help us to design and continuously improve our approaches to support any future brand changes Questions about research methodology are best referred to the lead researcher, Professor Keith Petrie, at the University of Auckland PHARMAC considered a broad range of published research and information about dispensing data before making the decision to change the funded brand of lamotrigine • A list, including full citations, of all publications that were considered is set out in the subcommittee minutes. This included some local research (Lessing et al Appl Health Econ Health Policy 2014;12:537-46) The subcommittee minutes sets out our expert's advice on all the evidence including the local research. • New Zealand specific dispensing data was also examined. Data for 2018 showed that around 50% of all patients who collected a funded prescription for lamotrigine in 2018, had changed brands at least once since they started on lamotrigine Around 4,000 patients had changed brands two or more times. PHARMAC was not aware of, nor had we been informed of, any significant clinical impacts for these people when they changed brands.

	See our media release of 15 November 2019 for information on why we decided to widened the criteria for lamotrigine exceptional circumstances: https://www pharmac govt nz/news/pharmac-to-widen access to the exceptional circumstances process/ PHARMAC is continuously looking to improve our work by listening to people impacted by our decisions. You might be interested in our submission to the Health Select Committee in response to the *Petition of Sarah Macrae concerning PHARMAC's patient safety protocols for brand changes* which sets out PHARMAC's commitment to continuously improving our work to support healthcare professionals and consumers who are impacts by changes to brands that are funded (https://www.parliament.nz/resource/en NZ/52SCHE_EVI_80397_HE6396/c6b8acfc4db8d9cb8d47dbec1f51379c403d7ed5). **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs. For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands. Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication. I have attach it here in case you haven't seen it. If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams. Kind regards Cam

From: Nicole Bremner <Withheld under section 9(2)(a)>
Sent: Wednesday, 27 November 2019 9:33 AM
To: Media <Media@Pharmac.govt.nz>
Subject: 1 News query lamotrigine

Hi Jane

I'm doing some checks on the lamotrigine brand switch.

Would you please let me know:

How many CARM reports have now been received and are there any more deaths (than 4) under coronial investigation?
How many GP's have applied for their patients to go back onto their original meds?
How many have actually switched back?

- How much money has Pharmac spent in the the last 5 years on research about anti-epileptic drugs – specifically patients views on generics and the nocebo effect? Is any underway and what is the methodology?
- What local research, if any, did Pharmac use or refer to in its decision to switch to Logem?

Finally, as you're aware, I have done a number of stories on the Enlafax brand switch.

There have been a significantly higher number of adverse reaction reports about Enlafax than Logem - yet there has not been the same level of 'patient concession.'

Can you please explain why?

Also, what effect, if any, the four unexplained deaths had on Pharmac's decision to fund patients back on previous meds?

Look forward to hearing from you.

Thanks
Nicole

Nicole Bremner
Journalist

d. Withheld under
m. Withheld under
e. Withheld under section 9(2)(a)

From: Media
Sent: Tuesday, 3 December 2019 10:07 am
To: Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Hi Nicole,

Thank you for your questions on lamotrigine.

You are best to contact Medsafe for the most up to date figures on adverse event reports to CARM. As at the beginning of November 2019 dispensing data shows there were approximately 10,000 patients on the Logem brand of lamotrigine.

As of this morning, Tuesday 3 December 2019, we had received 921 exceptional circumstances applications from prescribers. These are a mix of people who had not yet tried the new brand and those whose prescribers felt it clinically appropriate that they return to using their original brand – Lamictal or Arrow-lamotrigine.

> 812 of these were received after 15 November 2019, when we announced that PHARMAC had widened the criteria for lamotrigine exceptional circumstances
> 481 applications have been approved, the remainder are being processed.

PHARMAC has brought in additional resource so we can ensure decisions are made as quickly as possible

PHARMAC has engaged the University of Auckland to conduct two studies that are currently underway to look at psychological influences on the efficacy and side-effects associated with brand changes. The value of the research is $72,683 plus GST.

The research is not about anti-epileptic drugs per se, but the lamotrigine brand change is being used to look at whether a text message to patients, from their community pharmacy, informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. Research results will be used by PHARMAC to help us to design and continuously improve our approaches to support any future brand changes Questions about research methodology are best referred to the lead researcher, Professor Keith Petrie, at the University of Auckland

PHARMAC considered a broad range of published research and information about dispensing data before making the decision to change the funded brand of lamotrigine.

- A list, including full citations, of all publications that were considered is set out in the subcommittee minutes This included some local research (Lessing et al Appl Health Econ Health Policy 2014;12:537-46). The subcommittee minutes sets out our expert's advice on all the evidence including the local research
- New Zealand specific dispensing data was also examined Data for 2018 showed that around 50% of all patients who collected a funded prescription for lamotrigine in 2018, had changed brands at least once since they started on lamotrigine. Around 4,000 patients had changed brands two or more times. PHARMAC was not aware of, nor had we been informed of, any significant clinical impacts for these people when they changed brands.

See our media release of 15 November 2019 for information on why we decided to widened the criteria for lamotrigine exceptional circumstances: https://www pharmac govt nz/news/pharmac-to widen access to-the exceptional circumstances process/

PHARMAC is continuously looking to improve our work by listening to people impacted by our decisions.

You might be interested in our submission to the Health Select Committee in response to the *Petition of Sarah Macrae concerning PHARMAC's patient safety protocols for brand changes* which sets out PHARMAC's commitment to continuously improving our work to support healthcare professionals and consumers who are impacts by changes to brands that are funded (https://www.parliament.nz/resource/en-NZ/52SCHE_EVI_80397_HE6396/c6b8acfc4db8d9cb8d47dbec1f51379c403d7ed5).

Additional Information
I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs.

For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attach it here in case you haven't seen it

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

Kind regards
Cam

From: Christina Campbell <Withheld under section 9(2)(a)>
Sent: Wednesday, 4 December 2019 6:05 PM
To: Media <Media@Pharmac govt nz>
Subject: RE: 1 News query - lamotrigine

Hi there,

My name is Christina and I'm Nicole's producer on this story.

Can you please confirm if the text message below and the video it linked to is part of the studies highlighted in the text in yellow (which is taken from your email sent yesterday)?

PHARMAC has engaged the University of Auckland to conduct two studies that are currently underway to look at psychological influences on the efficacy and side-effects associated with brand changes The value of the research is $72,683 plus GST

The research is not about anti epileptic drugs per se, but the lamotrigine brand change is being used to look at whether a text message to patients, from their community pharmacy, informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. Research results will be used by PHARMAC to help us to design and continuously improve our approaches to support any future brand changes. Questions about research methodology are best referred to the lead researcher, Professor Keith Petrie, at the University of Auckland.

If so, we request an on camera interview tomorrow to discuss both the nature of the video and the timing of the text. It would be helpful to hear from you by 10.30am.

Many thanks,

Christina

From: Media <Media@Pharmac.govt.nz>
Sent: Thursday, 5 December 2019 9:55 a.m.
To: Christina Campbell <Withheld under section 9(2)(a)>; Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Hi

We won't be able to do an interview today, but will send you a response to your questions. You are best to contact Keith on any questions around his research

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Christina Campbell <Withheld under section 9(2)(a)>
Sent: Thursday, 5 December 2019 10:30 AM
To: Media <Media@Pharmac.govt.nz>; Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Thanks for letting us know – we'll send some questions through soon

In the meantime, can you please confirm if the text message below and the video it linked to is part of the studies highlighted in the text in yellow (which is taken from your email sent Tuesday)?

PHARMAC has engaged the University of Auckland to conduct two studies that are currently underway to look at psychological influences on the efficacy and side-effects associated with brand changes. The value of the research is $72,683 plus GST.

The research is not about anti-epileptic drugs per se, but the lamotrigine brand change is being used to look at whether a text message to patients, from their community pharmacy, informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. Research results will be used by PHARMAC to help us to design and continuously improve our approaches to support any future brand changes Questions about research methodology are best referred to the lead researcher, Professor Keith Petrie, at the University of Auckland

Thanks,

Christina

From: Media <Media@Pharmac.govt.nz>
Sent: Thursday, 5 December 2019 11:16 a.m.
To: Christina Campbell <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Hi Christina, do you have a number I can call to discuss this?

Jane Wright | senior communications advisor

_____

PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Christina Campbell <Withheld under section 9(2)(a)>
Sent: Thursday, 5 December 2019 12:27 PM
To: Media <Media@Pharmac govt nz>
Cc: Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Hi Jane,

I understand you've already spoken to Nicole. She's since had a response from Keith saying he's not aware Pharmac wants him to talk to TVNZ and that he doesn't work for Pharmac

With regards to the Nocebo video, our questions are:

1. Please confirm the text containing the link to the video was part of the research funded by Pharmac (referenced in your response below).
2. Given the situation with Logem, what is Pharmac's view of the messaging and timing of the video's release?
3. A number of effected patients are angry at this video and the timing of its release do you stand by it?
4. Why was it removed?
5. It's unclear how the research team obtained the cellphone numbers of the patients who received the messages – what are Pharmac's protocols for research teams gathering private data?

Please email a response by 2pm and let us know how you're getting on with Keith.

Many thanks,

Christina

From: Media <Media@Pharmac.govt.nz>
Sent: Thursday, 5 December 2019 12:45 p.m.
To: Christina Campbell <Withheld under section 9(2)(a)>; Media <Media@Pharmac govt nz>
Cc: Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Thanks Christina, working on your questions now.

Jane Wright | senior communications advisor

PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

From: Christina Campbell <Withheld under section 9(2)(a)>
Sent: Thursday, 5 December 2019 2:32 PM
To: Media <Media@Pharmac govt nz>
Cc: Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query lamotrigine

Hi there,

Just following up on the below request. Can you please get a response to us?

Many thanks,

Christina

From: Media
Sent: Thursday, 5 December 2019 2:49 pm
To: 'Christina Campbell' <Withheld under section 9(2)(a)>; Nicole Bremner <Withheld under section 9(2)(a)>
Subject: RE: 1 News query - lamotrigine

Hi Christina and Nicole, statement below 😊

Thank you for your questions on lamotrigine and the University of Auckland Faculty of Health and Medical Science's research project on brand changes.

PHARMAC is an evidence based organisation and we use research to inform our work, including improvements we can make to the support we provide consumers and health professionals. We commissioned research via the University of Auckland Faculty of Health and Medical Science in March 2019 to support the lamotrigine brand change and also to gain insights about how best to support future brand changes

The research has ethics approval and was looking at looking at whether a text message to patients, informing them of an upcoming change to their funded brand of medicine, has a positive impact on their acceptance of the change in brand. Some study participants were provided a link to a video to

watch. The video was not intended to be widely distributed in the public domain, rather it was aimed at people who had provided informed consent to participate in the study.

However, in the context of significant public concern around the lamotrigine brand change, including the recent media coverage, and information PHARMAC received that a link to the video had been broadly shared amongst patient groups, the research activity was ceased and the video content removed earlier this week by the research provider.

Additional Information
I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs

For most people taking it, Logem works in the same way as the other two lamotrigine brands. Logem has the same active ingredient and is delivered to the body in the same way This means it will have the same effect as the other brands. Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands.

Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti-seizure medication. I have attach it here in case you haven't seen it

If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams.

If you have further questions about University of Auckland Faculty of Health and Medical Science's research project you are best to talk directly with Keith Petrie. He is not a PHARMAC employee and it is for him to decide if he wishes to talk with you

Kind regards
Jane

Jane Wright | senior communications advisor
PHARMAC | Te Pātaka Whaioranga | Withheld
www.pharmac.govt.nz

PHARMAC will be closed from 25 December 2019 to 2 January 2020 inclusive.

We will monitor the media email throughout the holiday period. If your request is urgent, call the media phone. Because the office is closed, the information and spokespeople we can provide over the summer holiday period will be limited.
Email: media@pharmac.govt.nz
Phone: Withheld under

PHARMAC MEDIA ENQUIRY

Date Received	05/12/2019
Subject	Lamotrigine study
Media outlet & contact details	Nicole Bremner TVNZ
Deadline	05/12/2019
Questions	Can you please confirm if the text message below and the video it linked to is part of the studies highlighted in the text in yellow (which is taken from your email sent yesterday)?  PHARMAC has engaged the University of Auckland to conduct two studies that are currently underway to look at psychological influences on the efficacy and side-effects associated with brand changes. The value of the research is $72,683 plus GST. The research is not about anti epileptic drugs per se, but the lamotrigine brand change is being used to look at whether a text message to patients, from their community pharmacy, informing them of an upcoming change to their funded brand of medicine has a positive impact on their acceptance of the change in brand. Research results will be used by PHARMAC to help us to design and continuously improve our approaches to support any future brand changes Questions about research methodology are best referred to the lead researcher, Professor Keith Petrie, at the University of Auckland If so, we request an on camera interview tomorrow to discuss both the nature of the video and the timing of the text. It would be helpful to hear from you by 10.30am. Follow up questions: With regards to the Nocebo video, our questions are:

	1. Please confirm the text containing the link to the video was part of the research funded by Pharmac (referenced in your response below) 2. Given the situation with Logem, what is Pharmac's view of the messaging and timing of the video's release? 3. A number of effected patients are angry at this video and the timing of its release – do you stand by it? 4 Why was it removed? 5. It's unclear how the research team obtained the cellphone numbers of the patients who received the messages – what are Pharmac's protocols for research teams gathering private data?
Staff input	Adam McRae
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	Hi Nicole, Thank you for your questions on lamotrigine and the University of Auckland Faculty of Health and Medical Science's research project on brand changes PHARMAC is an evidence-based organisation and we use research to inform our work, including improvements we can make to the support we provide consumers and health professionals. We commissioned research via the University of Auckland Faculty of Health and Medical Science in March 2019 to support the lamotrigine brand change and also to gain insights about how best to support future brand changes. The research has ethics approval and was looking at looking at whether a text message to patients, informing them of an upcoming change to their funded brand of medicine, has a positive impact on their acceptance of the change in brand. Some study participants were provided a link to a video to watch. The video was not intended to be widely distributed in the public domain, rather it was aimed at people who had provided informed consent to participate in the study. However, in the context of significant public concern around the lamotrigine brand change, including the recent media coverage, and information PHARMAC received that a link to the video had been broadly shared amongst patient groups, the research activity was ceased and the video content removed earlier this week by the research provider. **Additional Information** I ask that you reiterate to your viewers that it is critical that people who have been prescribed Logem do NOT stop taking it If they have concerns, they should talk about their options with their doctor. PHARMAC will refund general practitioners for this visit, so the patient won't incur additional costs. For most people taking it, Logem works in the same way as the other two lamotrigine brands Logem has the same active ingredient and is delivered to the body in the same way. This means it will have the same effect as the other brands Logem has been approved for use in New Zealand by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, who are responsible for ensuring the quality, safety and

	efficacy of medicines. Approximately 80 million doses per annum of Logem are used in several countries, including Australia, Canada, Germany, UK, Spain, France, and the Netherlands Please also take note of the press release that Dr Peter Bergin, Epilepsy New Zealand, put out emphasising that Logem remains a good anti seizure medication. I have attach it here in case you haven't seen it. If you need to attribute any of the above to a spokesperson, please attribute to our director of operations Lisa Williams If you have further questions about University of Auckland Faculty of Health and Medical Science's research project you are best to talk directly with Keith Petrie. He is not a PHARMAC employee and it is for him to decide if he wishes to talk with you Kind regards Jane

PHARMAC MEDIA ENQUIRY

Date Received	21 July 2020
Subject	Lamotrigine Exceptional Circumstances
Media outlet & contact details	Nicole Bremner TV1 News
Deadline	ASAP
Questions	Hi team I'm seeking clarification of the current situation with funded anti-epilepsy medication. 1 News has been under the impression that since the deaths currently under coronial investigation, patients have been able to switch back to their previous medication. However, we have been informed this is not the case Please let me know asap what the situation is – happy to discuss on the phone if this is easier So does that mean anyone who wanted to switch back to Lamictal or Arrow-Lamotrigine has done so? Would you please let me know numbers that have switched back Also, the situation with paediatric epilepsy medication – is a low dose option for children available?
Staff input	Janye Watkins
Spokesperson as required	Lisa Williams
Actions/response Other information (include key messages)	Hi Nicole, Prescribers treating people taking lamotrigine are still able to apply to PHARMAC through our exceptional circumstances processes for funded access to the Arrow and Lamictal brands of lamotrigine. The criteria for exceptional circumstances funding of the Arrow-Lamotrigine and Lamictal brands of lamotrigine are on our website. Our latest figures on our website show that we have had 2526 exceptional circumstances lamotrigine funding applications Of those, we have approved 2418 and declined 78. Nine were withdrawn for a variety of reasons. The number of declined applications has increased because dispensing data indicated that these applications were for people who: • were not previously on Lamictal or Arrow-Lamotrigine and for who Logem is an appropriate treatment option; or • had not been prescribed lamotrigine for mental health or epilepsy indications. Teva, the supplier of Arrow-Lamotrigine, is discontinuing its 5 mg presentation. People who have been using the Arrow-Lamotrigine 5 mg presentation will need to change to the funded 5 mg dose of Lamictal. See here for more information Please attribute the above to director of operations Lisa Williams