PHARMAC weekly key messages

Updated Thursday 7 November 2019

[redacted]

Overarching key messages

- [redacted]

Key issues overview

Current issues	Potential or ongoing issues
• Lamotrigine brand change • [redacted] • [redacted]	• [redacted] • [redacted]

Current issues

Lamotrigine

Background

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

Medsafe have informed us that the Centre for Adverse Reactions Monitoring (CARM) has been notified of three patients taking lamotrigine who have died. We understand all three cases have been referred to the Coroner.

Communications approach

Following our proactive media release on the lamotrigine brand change we are responding to media queries as they come in. Where appropriate our spokespeople are doing interviews. We are unable to comment about specific cases before the coroner.

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.
- 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.
- 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.

Specific to sudden deaths

- We understand that any sudden or unexpected death is referred to the Coroner for investigation and our thoughts go out to the families.
- 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.
- 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.
- 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.
- We have not received any direct reports of sentinel events attributed to the brand change.

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 report 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.
- 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.
- As of 4 November PHARMAC has received 76 lamotrigine Exceptional Circumstances applications since 1 May 2019:
    - 32 approved (can stay on their original brand of lamotrigine)
    - 10 withdrawn (no responses to requests for further information)
    - 11 declined (considered appropriate to trial Logem)
    - 23 currently under consideration.

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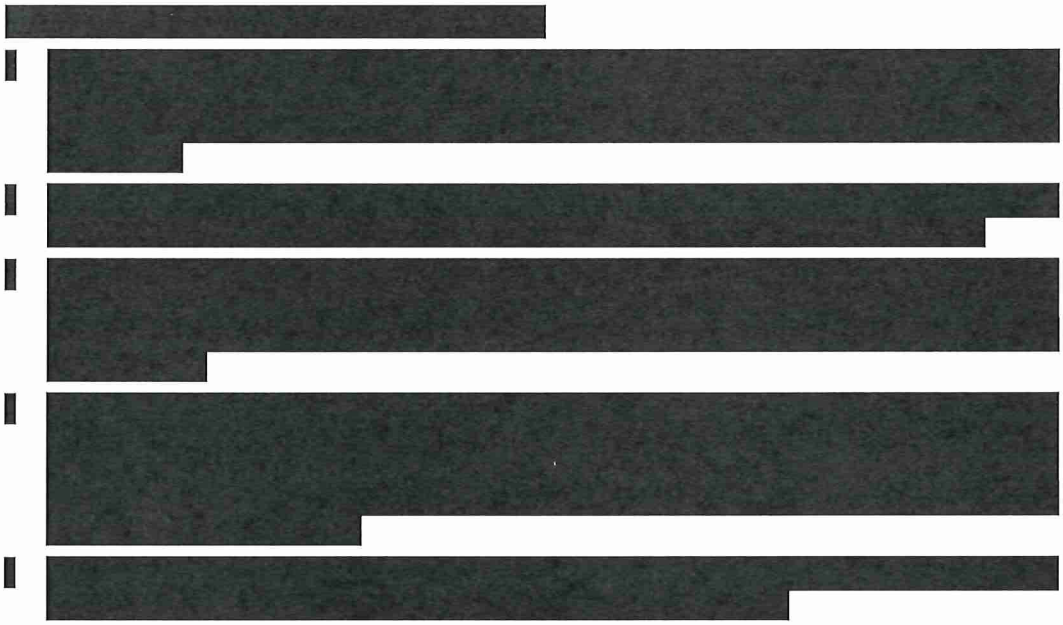

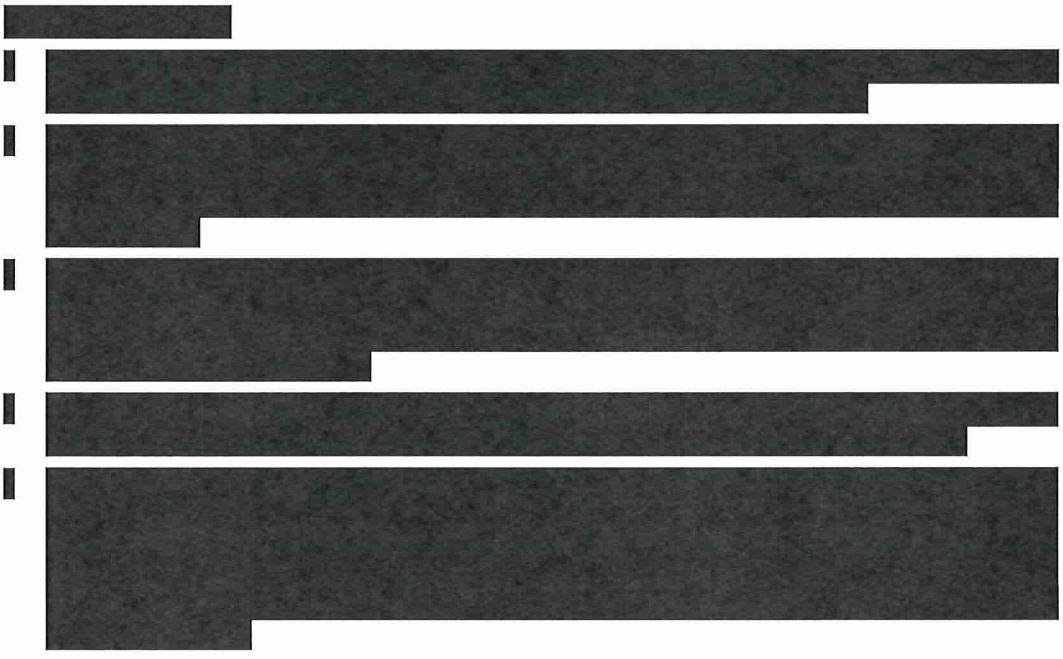

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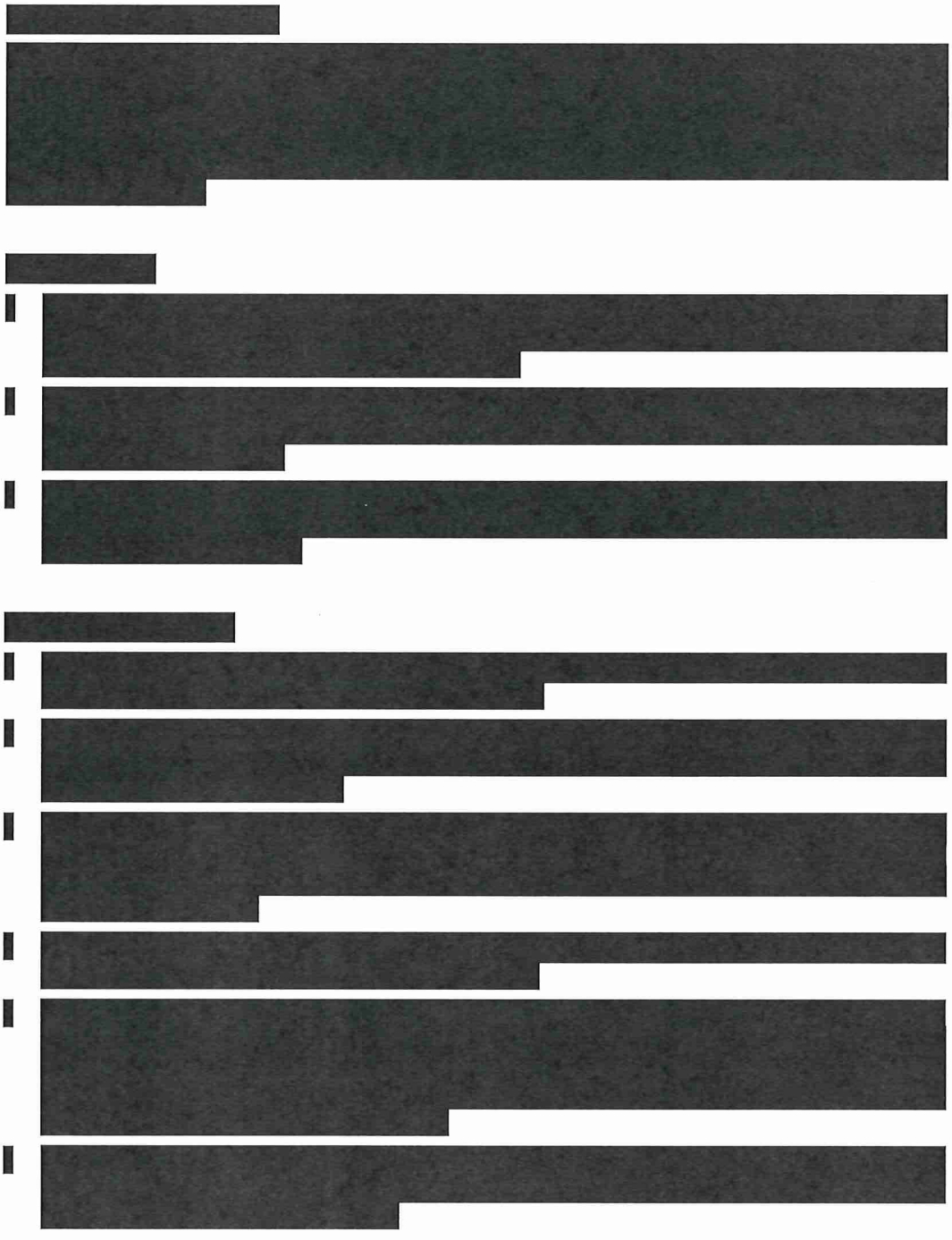

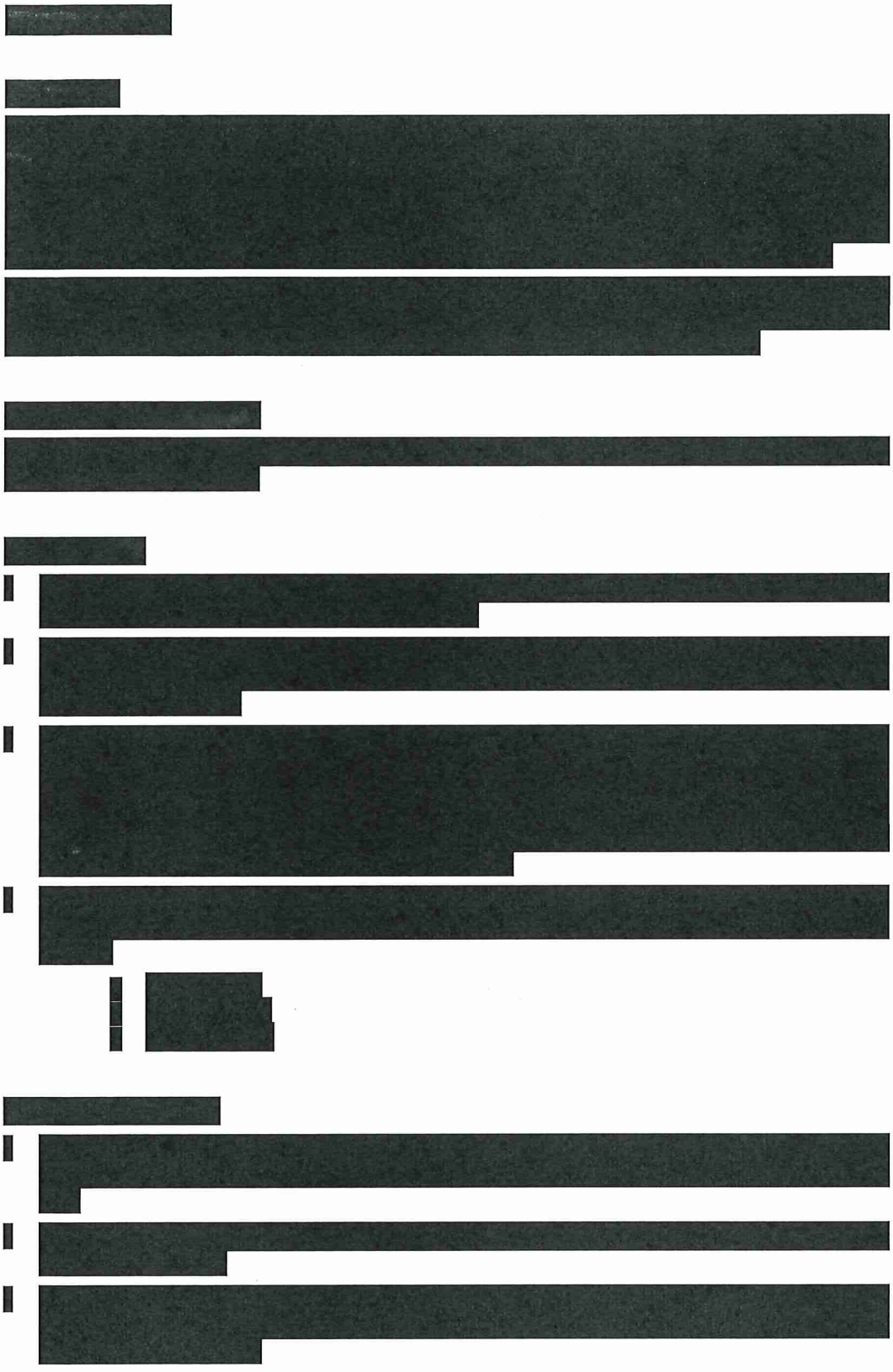

Lamotrigine exceptional circumstances FAQs

Question	Response
If a person changed brands but still wants to switch back to their original brand, can they change back?	Yes, their doctor can apply to PHARMAC, through our exceptional circumstances programme, for continued funding of the brand they took before the funding change.
If I am paying for Lamictal can I be refunded?	No but their doctor can apply to PHARMAC, through our exceptional circumstances programme, for continued funding of the brand.
Why do I need to wait for my doctor to apply, why can't I apply myself?	It has to be an application from your doctor. The
Before you said complicated medical reasons. What are the reasons now?	We recognise that some people may have difficulty changing brands due to medical reasons, other concerns or who have not tolerated the change. We will continue to fund the brand those people are currently on through our exceptional circumstances programme. This includes individuals that prescribers consider: o At risk of breakthrough seizures o At risk of mood destabilisation o That are significantly anxious about changing brands o That have concerns about their ability to drive o Have not tolerated the change
Why are you not just reversing the decision for everyone?	The brand change is continuing, with 8,000 people who have already switched to Logem.
Will there be penalties for changing the contract? Will GSK charge big prices for those getting their old brand through the exceptional circumstances?	We are working with our preferred supplier Mylan on this. GSK who supply Lamictal have committed to staying in the market and actually reduced their cost ….
Do I have to pay to see my doctor about this?	No, you can ask your doctor to fill in the attached form, requesting that PHARMAC cover the cost of the visit. https://www.pharmac.govt.nz/assets/PHARMAC-Lamotrigine-Proforma-invoice.pdf
Why are you making these changes now?	We understand that there is a lot of public concern in relation to this brand change.
Should patients stop taking Logem? Is it unsafe?	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. 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.

PHARMAC weekly key messages

Updated Friday 15 November 2019

[redacted]

Overarching key messages

- [redacted]

Key issues overview

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Current issues

Lamotrigine

Background

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.

This week Medsafe issued a Monitoring Alert on its website to summarise the range of adverse reaction reports that have been received by CARM, and this alert acknowledged the three fatalities.

Medsafe have informed us as of Friday 15 November that the Centre for Adverse Reactions Monitoring (CARM) has been notified of four patients taking lamotrigine who have died. We understand all four cases have been referred to the Coroner.

As of today, Friday 15 November, PHARMAC is making changes to the Exceptional Circumstances process.

Communications approach

Acting medical director Dr Ken Clark will be PHARMAC's spokesperson for media interviews on lamotrigine.

Specific to the exceptional circumstances process

- We understand that there is a high level of anxiety among people on lamotrigine and their families. Because of that we are widening the criteria for our lamotrigine exceptional circumstances process. This will allow those with concerns to stay on their current brand.
- Some people may have difficulty changing brands for medical reasons such as anxiety or may not tolerated the change. We will continue to fund the brand those people are currently on or were originally on before the change through our exceptional circumstances process.
- We have updated our application forms to make them simpler to use. These will be available on our website today.
- Reasons that doctors or other prescribers might consider when making an application to PHARMAC for ongoing funding will include people who are:
    - at risk of breakthrough seizures
    - at risk of mood destabilisation
    - significantly anxious about changing brands
    - concerned about their ability to drive
    - not tolerating the change
- If people have concerns, we encourage them to talk to their doctor. Their doctor can apply to PHARMAC, through our exceptional circumstances process, for continued funding of the brand they took before the funding change.

Specific to sudden deaths

- 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 cases 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.
- We understand that any sudden or unexpected death is referred to the Coroner for investigation and our thoughts go out to the families.
- 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.
- 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.
- The brand change is continuing. Over 8,000 patients have made the change, with around 4,000 who are yet to change.

Supporting information

- 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.
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- 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 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.

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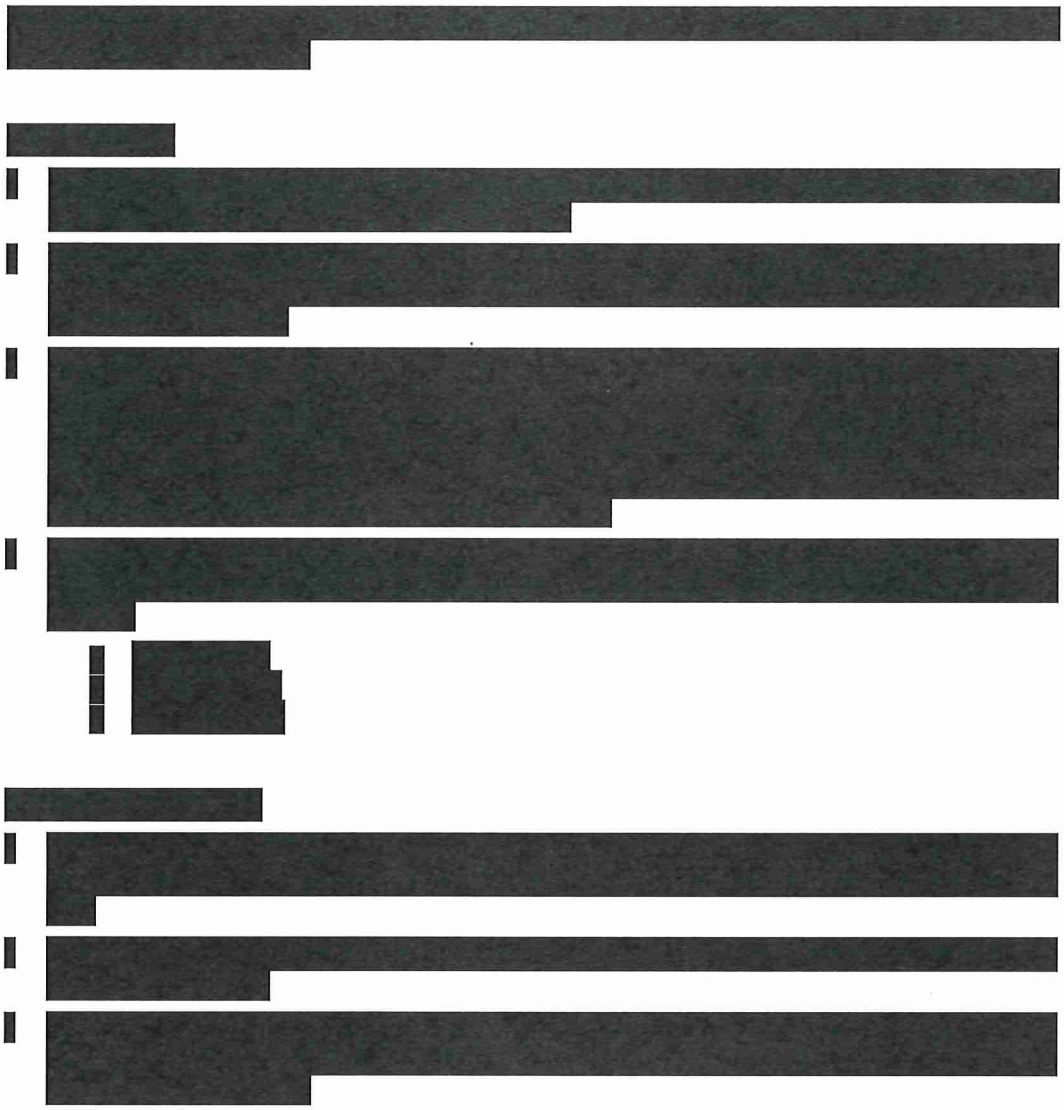
Key messages

- [redacted]

Potential or ongoing issues

[redacted]



From: Lizzy Cohen
Sent: Friday, 15 November 2019 10:15 AM
To: PHARMAC Board Members
Subject: PHARMAC No surprises update - widening criteria for lamotrigine exceptional circumstances
Attachments: 2019-11-15 Web content for lamotrigine Exceptional Circumstances funding.docx

Kia ora all,

Please see below for your information a no surprises to the Minister sent this morning regarding widening the criteria for the exceptional circumstances process for lamotrigine.

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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

From: Rachel Read
Sent: Friday, 15 November 2019 9:43 AM
To: 'Michael Roberts' [redacted]
Cc: 'Peter.Jane@[redacted] <[redacted]
Subject: No surprises update - widening criteria for lamotrigine exceptional circumstances

Hi Michael

In response to the high level of public concern around the lamotrigine brand change, PHARMAC is widening the criteria for the exceptional circumstances process for lamotrigine. This will allow those with concerns about the brand change to stay on their current brand of lamotrigine.

We will be encouraging people with any concerns about the brand change 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 understand that there is a high level of anxiety among many people taking lamotrigine, and their families. Some people may have difficulty changing brands for medical reasons, such as anxiety, or have not tolerated the change. We will continue to fund the brand those people are currently taking, or allow them to change back to the brand they were previously taking, through our exceptional circumstances programme.

Criteria that PHARMAC will consider include people who are:

- at risk of breakthrough seizures
- at risk of mood destabilisation
- significantly anxious about changing brands
- concerned about their ability to drive

- not tolerating the change

We have arranged media interviews with RNZ, TVNZ and Newstalk ZB for today. Following those interviews we will be updating our information on our website, letting our key stakeholders know and putting out a media release to all media advising them of the widened access to the exceptional circumstances process for lamotrigine.

The criteria for applying exceptional circumstances to people seeking to remain on the same brand of lamotrigine is slightly different to our normal NPPA programme. PHARMAC's website outlines the details for this under the information for health professionals section https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/lamotrigine-epilepsy-drug-changes/ Note that the information and application form are in the process of being updated. I've attached the revised text that will be published on this website link later today.

Applications should take no more than 5 to 10 days to process. PHARMAC's Director of Operations, makes the final decisions on exceptional circumstances applications for lamotrigine, based on recommendations from the NPPA team, supported by clinical advice.

The updated figures for the number of applications that have been received for patients seeking funding to remain on their current brand of lamotrigine are as follows:

- 100 applications received
- 59 approved
- 10 declined
- 10 withdrawn
- 21 under assessment

I hope this information is helpful. Please let me know if you need anything further

Regards Rachel

Rachel Read| Policy Manager, Engagement and Implementation

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www.pharmac.govt.nz

From: Steve Maharey [redacted]
Sent: Friday, 15 November 2019 10:40 AM
To: Lizzy Cohen
Subject: Re: PHARMAC No surprises update - widening criteria for lamotrigine exceptional circumstances

Very good to see this proactive approach to the brand switch. Please pass on my thanks. Steve

Sent from my iPhone

On 15/11/2019, at 10:15 AM, Lizzy Cohen <[redacted]> wrote:

> Kia ora all,
>
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>
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We will be encouraging people with any concerns about the brand change 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 understand that there is a high level of anxiety among many people taking lamotrigine, and their families. Some people may have difficulty changing brands for medical reasons, such as anxiety, or have not tolerated the change. We will continue to fund the brand those people are currently taking, or allow them to change back to the brand they were previously taking, through our exceptional circumstances programme.

Criteria that PHARMAC will consider include people who are:

- at risk of breakthrough seizures

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- significantly anxious about changing brands
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Regards Rachel

Rachel Read| Policy Manager, Engagement and Implementation

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<2019-11-15 Web content for lamotrigine Exceptional Circumstances funding.docx>

Funding for Lamictal or Arrow-Lamotrigine

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. Prescribers need to apply via our exceptional circumstances process.

Application for funding for alternative brands of lamotrigine

PHARMAC will consider a funding application made by a prescriber for the Lamictal or Arrow-Lamotrigine brands of lamotrigine. We'll consider funding these brands for people who:

- may have difficulty managing a change of brand to Logem for medical reasons or other concerns, or
- have tried to change and have not tolerated it.

Duration of funding for the requested lamotrigine brand will, if granted, be determined by PHARMAC on a case by case basis. This may mean that you would need to submit a renewal application for ongoing funding. This would need to indicate why a change to Logem would not be clinically appropriate. All approvals will indicate the duration of funding.

PHARMAC has no contractual arrangements for supply of other brands of lamotrigine. As such, even if PHARMAC approves your funding application for a specific brand, we can't guarantee there will be ongoing supply of the specific lamotrigine brand.

Application process

Complete the application form for your patient/s (a separate form will need to be submitted for each patient) and submit it via the PHARMAC website.

PHARMAC's secure form submission portal (external link)
Exceptional circumstances application form for funding of an alternative brand of lamotrigine [DOC, 213 KB]

- You will receive a confirmation email that we have received the application and we may ask you some further questions to clarify your patient's situation.
- We will contact you as soon as possible to let you know the outcome of the application. You will need to let your patient know the outcome of any application.
- You can call 0800 66 00 50 or email NPPA@pharmac.govt.nz if you have any questions about the process.

Types of applications for alternative brand funding

Applications for funding will be considered from prescribers for individuals:

- Have not tolerated the change
- Have had breakthrough seizures
- Have had mood destabilisation
- The prescriber has clinical concerns about the individual's ability to manage the change (e.g. previous issues with medication changes, severe anxiety around this brand change)
- That have concerns about their ability to drive

Davina Carpenter

From: Lizzy Cohen
Sent: Monday, 4 November 2019 9:19 AM
To: PHARMAC Board Members; [redacted]
Subject: PHARMAC - Minister's Report for Quarter 1
Attachments: PHARMAC - Minister's Report for Quarter 1 2019-20.pdf

Good morning,

Please find attached for your interest, PHARMAC's quarterly report to the Minister for Quarter 1 2019/20, incorporating the monthly report for October 2019. This was sent this morning.

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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PHARMAC
TE PĀTAKA WHAIORANGA

14 November 2019

Media release

PHARMAC to widen access to the exceptional circumstances process

Patients taking lamotrigine who have concerns about the change can talk with their doctor about remaining on their current brand as PHARMAC has widened the criteria for lamotrigine exceptional circumstances.

"We know that there is a high level of anxiety among people on lamotrigine and their families," explains Dr Ken Clark, PHARMAC's medical director.

"We understand the news of the three deaths of patients taking lamotrigine will concern people. We don't know if this linked to the brand change – and we don't want people to stop taking their medication out of fear so we're making it easier for people to stay on their current brand if their doctor believes it is the right thing for them."

PHARMAC will continue to fund the brand those people are currently on or were originally on before the change through the exceptional circumstances process.

"I want to reassure those people who have already changed to Logem – over 8,000 people – that Logem works in the same way as the other two lamotrigine brands.

"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."

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.

"If people have concerns, we encourage them to talk to their doctor. Their doctor can apply to PHARMAC, through our exceptional circumstances process, for continued funding of the brand they took before the funding change," concludes Dr Clark.

Ends

For more information please contact Jane Wright on media@pharmac.govt.nz or 021863342.

Additional information

Reasons that doctors or other prescribers might consider when making an application to PHARMAC for ongoing funding will include people who:

- have not tolerated the change
- have had breakthrough seizures
- have had mood destabilisation
- have concerns about their ability to drive

- The prescriber has clinical concerns about the individual's ability to manage the change (e.g. previous issues with medication changes, severe anxiety around this brand change)

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Updated Friday 15 November 2019

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- 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.
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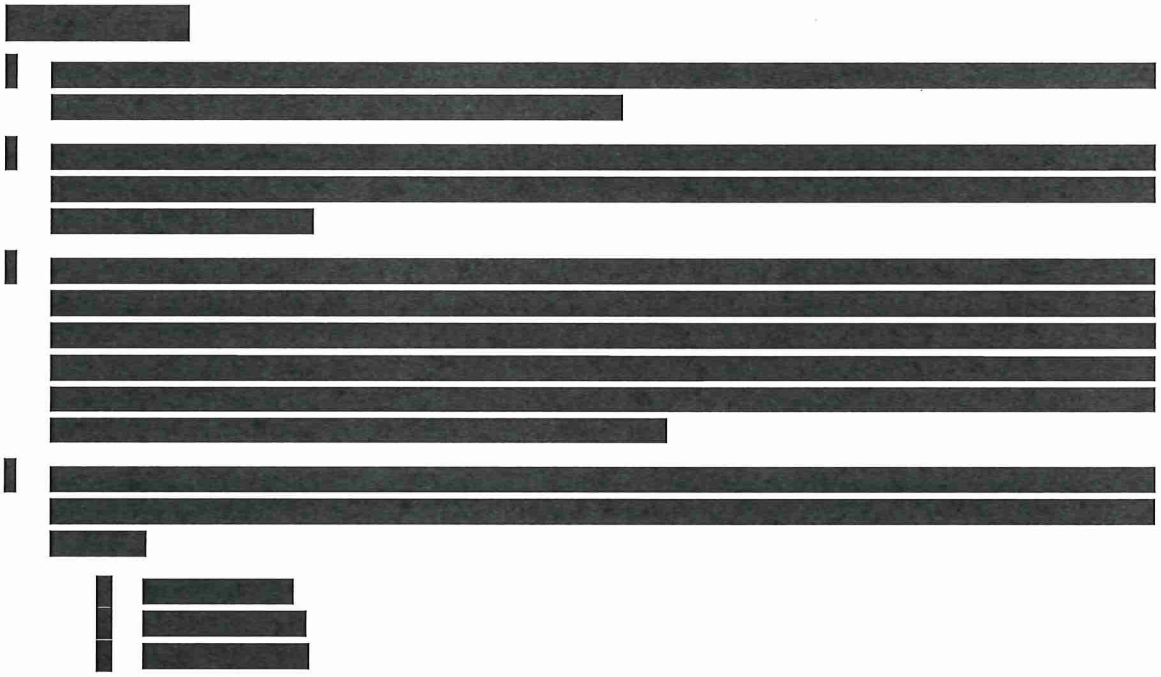

Davina Carpenter

From: Rachel Read
Sent: Friday, 15 November 2019 9:43 AM
To: 'Michael Roberts'
Cc: 'Peter.Jane[redacted]'
Subject: No surprises update - widening criteria for lamotrigine exceptional circumstances
Attachments: 2019-11-15 Web content for lamotrigine Exceptional Circumstances funding.docx

Hi Michael

In response to the high level of public concern around the lamotrigine brand change, PHARMAC is widening the criteria for the exceptional circumstances process for lamotrigine. This will allow those with concerns about the brand change to stay on their current brand of lamotrigine.

We will be encouraging people with any concerns about the brand change 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 understand that there is a high level of anxiety among many people taking lamotrigine, and their families. Some people may have difficulty changing brands for medical reasons, such as anxiety, or have not tolerated the change. We will continue to fund the brand those people are currently taking, or allow them to change back to the brand they were previously taking, through our exceptional circumstances programme.

Criteria that PHARMAC will consider include people who are:

- at risk of breakthrough seizures
- at risk of mood destabilisation
- significantly anxious about changing brands
- concerned about their ability to drive
- not tolerating the change

We have arranged media interviews with RNZ, TVNZ and Newstalk ZB for tomorrow. Following those interviews we will be updating our information on our website, letting our key stakeholders know and putting out a media release to all media advising them of the widened access to the exceptional circumstances process for lamotrigine.

The criteria for applying exceptional circumstances to people seeking to remain on the same brand of lamotrigine is slightly different to our normal NPPA programme. PHARMAC's website outlines the details for this under the information for health professionals section https://www.pharmac.govt.nz/medicines/my-medicine-has-changed/lamotrigine-epilepsy-drug-changes/ Note that the information and application form are in the process of being updated. I've attached the revised text that will be published on this website link later today.

Applications should take no more than 5 to 10 days to process. PHARMAC's Director of Operations, makes the final decisions on exceptional circumstances applications for lamotrigine, based on recommendations from the NPPA team, supported by clinical advice.

The updated figures for the number of applications that have been received for patients seeking funding to remain on their current brand of lamotrigine are as follows:

- 100 applications received
- 59 approved
- 10 declined
- 10 withdrawn
- 21 under assessment

I hope this information is helpful. Please let me know if you need anything further

Regards Rachel

Rachel Read| Policy Manager, Engagement and Implementation

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www.pharmac.govt.nz [redacted]

From: Michael Roberts [redacted]
Sent: Wednesday, 13 November 2019 1:32 PM
To: Rachel Read [redacted]
Cc: Lizzy Cohen <[redacted]Jane Wallace [redacted]
Subject: Query: NPPA / Exceptional Circumstances funding process

Hi Rachel,

We've received a number of inquiries following media reporting yesterday afternoon regarding Logem.

Previously you've advised us of the process available for patients to seek an exception via their GP to remain on a particular medicine. Could you please provide some notes for the office regarding how that process occurs and the volume?

We'd appreciate knowing how a patient can request this occur, how the process works, who determines whether it is agreed or declined, and what the criteria would be, and of course roughly how long this would take?

An earlier No Surprises brief (18/10) included the following:
"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."

Ideally we're after an expansion on that detail please.

Kind regards,
Michael

Michael Roberts | Private Secretary Health
Office of Hon Dr David Clark
Minister of Health | Associate Minister of Finance

Mobile [redacted] | DDI [redacted] | Email [redacted]

PHARMAC
TE PĀTAKA WHAIORANGA

15 November 2019

Media release

PHARMAC to widen access to the exceptional circumstances process

Patients taking lamotrigine who have concerns about the change can talk with their doctor about remaining on their current brand as PHARMAC has widened the criteria for lamotrigine exceptional circumstances.

"We know that there is a high level of anxiety among people on lamotrigine and their families," explains Dr Ken Clark, PHARMAC's medical director.

"We understand the news of the three deaths of patients taking lamotrigine will concern people. We don't know if this linked to the brand change – and we don't want people to stop taking their medication out of fear so we're making it easier for people to stay on their current brand if their doctor believes it is the right thing for them."

PHARMAC will continue to fund the brand those people are currently on or were originally on before the change through the exceptional circumstances process.

"I want to reassure those people who have already changed to Logem – over 8,000 people – that Logem works in the same way as the other two lamotrigine brands.

"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."

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.

"If people have concerns, we encourage them to talk to their doctor. Their doctor can apply to PHARMAC, through our exceptional circumstances process, for continued funding of the brand they took before the funding change," concludes Dr Clark.

Ends

For more information please contact Jane Wright on media@pharmac.govt.nz or 021863342.

Additional information

Reasons that doctors or other prescribers might consider when making an application to PHARMAC for ongoing funding will include people who:

- have not tolerated the change
- have had breakthrough seizures
- have had mood destabilisation
- have concerns about their ability to drive

- The prescriber has clinical concerns about the individual's ability to manage the change (e.g. previous issues with medication changes, severe anxiety around this brand change)

Staying on your current brand (exceptional circumstances for lamotrigine)

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. Your prescriber needs to apply to our exceptional circumstances process.

If you don't think the Logem brand is working for you, talk to your doctor, nurse or pharmacist.

Application for funding for alternative brands of lamotrigine

Your prescriber can apply to PHARMAC to fund the Lamictal or Arrow-Lamotrigine brands of lamotrigine. We'll consider funding these brands for people who:

- may have difficulty managing a change of brand to Logem for medical reasons or other concerns, or
- have tried to change and have not tolerated it.

PHARMAC will also decide how long you can continue to get the other brand of lamotrigine. Your prescriber may need to renew the application for ongoing funding. They will need to explain why a change to Logem would not be clinically appropriate.

PHARMAC has no contractual arrangements for supply of other brands of lamotrigine. As such, even if PHARMAC funds your application for a specific brand, we can't guarantee there will be a supply for the specific lamotrigine brand.

Application process

- Your prescriber will complete the application form on your behalf and submit it through PHARMAC's website.
- Your prescriber will get a confirmation email to say we received the application.
- We will contact your prescriber with the outcome as soon as possible. They will let you know.

If you or your prescriber have questions:

- call 0800 66 00 50

- email NPPA@pharmac.govt.nz

Funding for Lamictal or Arrow-Lamotrigine

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. Prescribers need to apply via our exceptional circumstances process.

Application for funding for alternative brands of lamotrigine

PHARMAC will consider a funding application made by a prescriber for the Lamictal or Arrow-Lamotrigine brands of lamotrigine. We'll consider funding these brands for people who:

- may have difficulty managing a change of brand to Logem for medical reasons or other concerns, or
- have tried to change and have not tolerated it.

Duration of funding for the requested lamotrigine brand will, if granted, be determined by PHARMAC on a case by case basis. This may mean that you would need to submit a renewal application for ongoing funding. This would need to indicate why a change to Logem would not be clinically appropriate. All approvals will indicate the duration of funding.

PHARMAC has no contractual arrangements for supply of other brands of lamotrigine. As such, even if PHARMAC approves your funding application for a specific brand, we can't guarantee there will be ongoing supply of the specific lamotrigine brand.

Application process

Complete the application form for your patient/s (a separate form will need to be submitted for each patient) and submit it via the PHARMAC website.

PHARMAC's secure form submission portal (external link)
Exceptional circumstances application form for funding of an alternative brand of lamotrigine [DOC, 213 KB]

- You will receive a confirmation email that we have received the application and we may ask you some further questions to clarify your patient's situation.
- We will contact you as soon as possible to let you know the outcome of the application. You will need to let your patient know the outcome of any application.
- You can call 0800 66 00 50 or email NPPA@pharmac.govt.nz if you have any questions about the process.

Types of applications for alternative brand funding

Applications for funding will be considered from prescribers for individuals:

- Have not tolerated the change
- Have had breakthrough seizures
- Have had mood destabilisation
- The prescriber has clinical concerns about the individual's ability to manage the change (e.g. previous issues with medication changes, severe anxiety around this brand change)
- That have concerns about their ability to drive

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Contact details:
Phone: 0800 66 00 50 option 2
Fax: 09 523 6870 (09 is correct)
Email: nppa@pharmac.govt.nz

Exceptional Circumstances application for funding of an alternative brand of lamotrigine

PHARMAC will consider a funding application for a specific brand of lamotrigine for patients who, due to medical difficulties or concerns, are unable to manage a change to the Logem brand of lamotrigine, or who have not tolerated the change.

Duration of ongoing funding for the requested lamotrigine brand will, if granted, be determined by PHARMAC on a case by case basis. Some people need a longer period of time to transition and we have generally been granting funding for such people for 26 weeks. For other people, who are unlikely to be able to attempt a change, we have been granting approvals for 156 weeks (the sole supply period).

Funding approval will not guarantee ongoing continuity of supply for the specific lamotrigine brand. PHARMAC has no contractual arrangements for supply of other brands of lamotrigine.

Please note: this form should be completed electronically and should not be handwritten. Boxes will expand as text is entered.

Patient

NHI			
Date of birth		Age	
Gender			
Last name			
First name			
Middle name			
DHB of domicile			

Applicant

NZMC number			
Title			
Last name			
First name			
Department or practice address			
DHB			
Email address			
Phone		Pager or extension	
Facsimile			

Are there any others who need to be informed about this application? Eg patient's GP

Contact name			
Contact email		Contact facsimile	

Brand of lamotrigine sought

Brand name			
Strength			
Dosage regimen			
Duration of funding	☐ 26 weeks	☐ 156 weeks	☐ Other _____ weeks
Reason for duration			

Where will treatment be dispensed (pharmacy details)?

Name		Contact name	
Address			
Facsimile		Phone	
Email			
DHB			

Reason for application

Indication	☐ Epilepsy	☐ Mental health
Clinical concern	☐ Break through seizures ☐ Mood destabilisation ☐ Concerns regarding driving motor vehicles	☐ Clinical concerns around the patient's ability to manage a brand change (eg. previous difficulty with medicine changes, severe anxiety around change)
Other (please specify)	☐	

Declaration

By submitting this form

- I confirm that all information provided is correct to the best of my knowledge.
- I agree to provide PHARMAC, or its agent, all additional information they reasonably request.
- I acknowledge that I am responsible for obtaining any patient consent required for that additional information.

Applicant's signature

(Insert electronic signature or sign.)

Submitting the application

Once the form has been completed, submit it to PHARMAC:

Upload at: https://www.pharmac.govt.nz/upload

We will contact you as soon as possible with the outcome. You can call 0800-66-00-50 (option 2) or email: NPPA@pharmac.govt.nz for an update on progress of our assessment

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Exceptional Circumstances applications for Lamotrigine

An Exceptional Circumstances (EC) form and process has been set up to access applications for patients who, due to medical difficulties or concerns, are unable to manage a change to the funded lamotrigine (Logem).

The revised process

This process has been revised, and from 15 November 2019 all the applications for lamotrigine no longer need to meet the threshold of "exceptionally difficult to manage" clinical circumstances. Instead, applications will need to meet one of the following criteria, as outlined on the revised lamotrigine EC form.

E x c e p t i o n a l
c i r c u m s t a n c e s a p p l i c

Clinical concern	☐ Break through seizures ☐ Mood destabilisation ☐ Concerns regarding driving motor vehicles	☐ Clinical concerns around the patient's ability to manage a brand change (eg. previous difficulty with medicine changes, severe anxiety around change)
Other (please specify)	☐	

Applications that meet one of the above four criteria can be processed as an automatic approval without further review or documentation. The process for this as is follows:

1. Enter the application into MAD under the NPPA Panel.
2. Once entered, if at least one of the above "Clinical concern" criteria is met, approve the application using the automatic approval options.
3. Send approval fax to Sector Service.
4. Email the applicant notifying of approval using the lamotrigine approval letter template.

For applications where the "Other" criterion has been ticked and a message written, these will need to be reviewed by a medical staff member in the Medical Directorate. Once the application has been reviewed, there may be three possible outcomes:

1. More information is required
    a. An email should be written and sent to the applicant (Doctor) requesting the additional information that we require in order to consider the application further.

2. The request is not progressed
    a. A letter is sent to the applicant, via email, notifying them that their application is not being progressed and why. Please note that this is an unlikely outcome, and should only be used in extreme situations, after

clinical advice is sought and the applicant is first asked for additional information.

3. The application is recommended for approval
    a. The application is progressed for a decision by the DoO, this is done in the form of an email which contains a table, example below:

2019-11-05 DOO approval alias.obr

    b. If the application is approved, the approval should then be processed in MAD.
        i. Approve the application in MAD using the option approved by Director Operations.
        ii. Send approval fax to Sector Service.
        iii. Email the applicant notifying of approval using the lamotrigine approval letter template.

Approval Details

Please note that all approvals should be generated for 156 weeks (three years) and the cost should be calculated using the lamotrigine calculator.

2019-11-21 cost calculator for lamotr

The following renewal criteria should also be used for all approvals:

For Epilepsy

- Demonstrate no change in patient's seizure frequency; and
- Ongoing tolerance of Lamictal/ Arrow-lamotrigine without undue side effects.

For Mental Health

- Demonstrate ongoing treatment benefit in regard to mental state; and
- Ongoing tolerance of Lamictal/ Arrow-lamotrigine without undue side effects

Reporting

Updates regarding the number of lamotrigine applications will need to be circulated via email on a regular basis to the members of the lamotrigine project team, specifically Adrienne Martin, Adam McRae, Peter Murray and Lisa Williams. Template for reporting is:

XX applications received
XX approved
XX declined
XX withdrawn

XX under assessment

Dear [redacted]

We recently wrote to you regarding support for the lamotrigine brand change. We understand that there is a lot of public concern in relation to this brand change. As a result of the feedback we have received, we have streamlined the application process for funding for a specific brand of lamotrigine. We will consider funding applications from prescribers for patients who may have difficulty changing brands due to medical reasons or other concerns.

This includes for individuals that prescribers consider:

- Have not tolerated the change
- Have had breakthrough seizures
- Have had mood destabilisation
- There are clinical concerns about the individual's ability to manage the change (e.g. previous issues with medication changes, severe anxiety around this brand change)
- That have concerns about their ability to drive

Additional information is available on PHARMAC's website under applying for exceptional circumstances funding this includes updated, simpler to use, downloadable application forms.

We would appreciate your support in distributing this information to your networks.

If you have any questions you can contact PHARMAC on 0800 66 00 50 or e-mail enquiry@pharmac.govt.nz

Regards
Ken Clark
Medical Director

[reply to previous proactive communication]

Davina Carpenter

From: Lisa Williams
Sent: Monday, 18 November 2019 6:21 PM
To: Lisa Williams
Subject: 2019-11-15 File note of phone call with Mylan re widening of approach to EC for lamotrigine

I phoned Sean Stewart to discuss lamotrigine and advised him that PHARMAC's medical director would be doing media interviews with Radio NZ and TVNZ today to discuss a decision that PHARMAC had made to relax its approach to assessment of applications under the EC process. I noted that this would likely mean [redacted] that we had negotiated with Mylan [redacted] approved already.

I commented that nearly 9,000 people were on Logem now (from our data) and that we did not expect a huge number to seek ongoing funding for previous brands or seek to change back, but that it was difficult to make any predictions in this regard. I noted that, given the impact of anxiety on epilepsy patients (i.e. could trigger seizures) and the level of public concern, PHARMAC thought it was the right thing to do and that I hoped Mylan would agree it was the best thing for NZ patients and for their brand also. I told Sean that I would hope we wouldn't see a claim from them [redacted], and suggested we could keep in touch to share information on uptake of the EC approvals.

Sean advised that Mylan had no problem with the information I'd given him and wanted to support any decisions PHARMAC made in this space.

Lisa Williams | Director of Operations

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[redacted]

Davina Carpenter

From: Adam McRae
Sent: Wednesday, 20 November 2019 8:31 AM
To: 'Susan.Kenyon@[redacted]
Cc: Lily.Chan@[redacted] Peter Murray
Subject: RE: PHARMAC Medsafe meeting -lamotrigine
Attachments: 2019-11-15 Letter Follow-Up fm KenClark to Primary Care re Lamotrigine.pdf

Thanks Susan
E-mail communication sent to health professionals below and letter from Ken Clark outlining the EC process attached.
Any questions please let me know.
Kind regards
Adam

"In response to the high level of public concern around the lamotrigine brand change, PHARMAC is widening the criteria for the exceptional circumstances process for lamotrigine, and we have updated the forms to make them simpler to use. These are available on our website. This will allow prescribers to make an application to PHARMAC for ongoing funding for individuals:

- Who have not tolerated the change
- Who have breakthrough seizures
- Who have had mood destabilisation
- The prescriber has clinical concerns about the individuals ability to manage the change (eg previous issues with medication changes, severe anxiety around this brand change)
- That have concerns about their ability to drive.

Please direct any enquires you get about the process to our website, all of the details are there. We will be encouraging people with any concerns about the brand change to talk to their doctor if they have concerns.

We understand that there is a high level of anxiety among many people taking lamotrigine, and their families. Some people may have difficulty changing brands for medical reasons, such as anxiety, or have not tolerated the change.

I have attached a letter from our Ken Clark our Medical Director which we have distributed to health professionals today."

From: Susan.Kenyon@[redacted]
Sent: Tuesday, 19 November 2019 3:57 PM
To: Adam McRae [redacted]@[redacted] Peter Murray [redacted]
Geraldine.Hill[redacted]
Cc: Lily.Chan@[redacted] Adrienne Martin <[redacted]
Subject: PHARMAC Medsafe meeting -lamotrigine

Draft minutes

19 Nov 2019
Present: Adam McRae, Peter Murray, Geraldine Hill & Susan Kenyon

Overview of CARM data

As of 25 Oct - total 36 reports
29 brand switch reports of which 25 were definitely to Logem

From the data transferred to Medsafe
26 reports in October. Five reports in children <18.
22/23 reports in patients with epilepsy
9 reports of seizures (change in frequency)
1 suicidal ideation in a patient taking lamotrigine for epilepsy
Reports state brand change date range from June to October

Information on 4th fatal case still very vague, CARM still trying to contact GP. Likely that the coronial process will take a long time and may not determine the cause of death.

Update from PHARMAC

Media release and interview last Friday
Criteria were loosened and form made simpler (copy to be provided to Medsafe)
Currently getting 80 exceptional circumstances applications per day-arranging resource to meet demand

No further information from NZTA on the advice they provided which was confusing to the sector and different to their initial advice to PHARMAC.

Actions
PHARMAC wish to emphasise that Logem is safe and effective and bioequivalent
Suggest that media release to medical press would be helpful.
Would like to explore the option of a joint release with Medsafe.
PHARMAC to send key messages to Medsafe for review.

Suggested that PHARMAC get Mylan to support their product with GPs.

PHARMAC have had meetings with Guild and Pharm Soc and clinical pharmacists in GP practices to help improve knowledge of the issue.
Discussed investigating ways of improving relationships between pharmacists and GPs so that pharmacists can make GPs aware when new funded brands are in stock so that GPs can discuss with patients before they get to the pharmacy.

Noted that 10 years ago after the Losec brand change PHARMAC and Medsafe set up a road show to talk to GPs and pharmacists about bioequivalence which was successful.
Could be time to repeat.

Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | (04) [redacted]

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

take & tell
Together for safer medicines

Think you've had an adverse reaction to a medicine?

Report it here https://nzphvc.otago.ac.nz/reporting/

My email address has changed to [redacted]