Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Tuesday, 29 October 2019 5:20 PM
To: Adrienne Martin; Adam McRae
Cc: Lily.Chan[redacted]
Subject: 3rd fatal report for lamotrigine

Hi
I have some details for this now
This was a young man, cause of death unknown, they were found dead and therefore the case has been referred to coroner. Death occurred several weeks but less than a month after switch. Did not appear to be seizure free, but frequency not reported and start of anti-epileptic treatment not reported
Regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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My email address has changed to [redacted]

No Surprises – lamotrigine brand change

On Friday 18 October PHARMAC was advised by Medsafe that the Centre for Adverse Reactions Monitoring (CARM) had responded to two media queries (from TVNZ and RNZ) for data on adverse event reporting related to the lamotrigine brand change to Logem.

The RNZ journalist, [redacted], was advised by CARM that one of the adverse event reports it had received included a fatality. He has since contacted PHARMAC for comment.

Medsafe advised PHARMAC that the report involved a woman with epilepsy who had changed from the Logem brand to the Lamictal brand and then back to the Logem brand and had recently died. Medsafe advised that it would provide PHARMAC with more detail as it came to hand.

On late Monday afternoon, 21 October, Medsafe provided PHARMAC with a copy of a response from CARM to [redacted] that was sent at 4pm that day. See below.

On Tuesday 22 October we provided the below response and are expecting the story to run tomorrow, Wednesday 23 October.

Our Chief Executive Sarah Fitt and our Board Chair are attending the Health Select Committee (HSC) tomorrow to make submissions in response to a number of petitions, including the *Petition of Sarah Macrae Open a Public Inquiry in to PHARMAC's Patient Safety Protocols for Generic Meds*. We are expecting that there will be questions from the HSC on the lamotrigine brand change and possibly afterwards from media.

CARM Media response

In response to your query below:

Lamotrigine 1 May 2019 to 18 October 2019

Since 1 May 2019:

- Total Number of cases received for lamotrigine **31**
- Of 31 cases, number describing a brand switch **24**
- (Of 24 cases, number of brand switch to Logem brand) 21
- Of 31 cases, number of Logem but not reporting a brand switch **3**
- Of 31 cases, number of lamotrigine only (no brand identified) **4**

Fatalities: CARM has only received one case identifying a fatality.

Reactions reported:

17 cases describe Therapeutic effect decreased.

11 cases describe convulsions (4 patients had been seizure free prior to brand change).

Other reports describe combinations of tiredness, lethargy, headaches and psychiatric type reactions such as aggressiveness, irritability, mood swings, anxiety.

This information includes all cases up to Friday 18/10/2019.

PHARMAC Media response

PHARMAC provided the following statement to Guyon Espiner , attributed to Lisa Williams, our 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.

Next steps

PHARMAC will use the above messaging for any further media queries, with updated numbers as we receive them.

Post-mortem and toxicology review of sudden unexpected death in epilepsy (SUDEP) in New Zealand 2007-2016

Shona Scott[*1&2] & Peter Bergin[2]

[1] Department of Neurology Auckland City Hospital, New Zealand [2] DCN, Western General Hospital, Edinburgh

AUCKLAND DISTRICT HEALTH BOARD Te Toka Tumai

Background/ Introduction

Sudden unexpected death in epilepsy (SUDEP) is well recognised and widely reported but remains poorly understood[1,2]. It is the leading cause of death in many epilepsy populations[2].

SUDEP in young adults (aged 20-45) is 27 times more common than sudden death in control populations[1]. The rate of SUDEP is thought to be highest in young adult populations but SUDEP may be under reported in older population[2].

The risk of SUDEP in epilepsy clinic populations ranges from 1.1 - 5.9 per 1000 people and the pooled estimate from meta-analysis suggests there are 1.2 cases of SUDEP per 1000 people with epilepsy per year[1]. The incidence of SUDEP in New Zealand is not known but using this figure it is estimated that approximately 40 people with epilepsy in New Zealand die from SUDEP every year.

SUDEP has not been systematically studied in New Zealand.

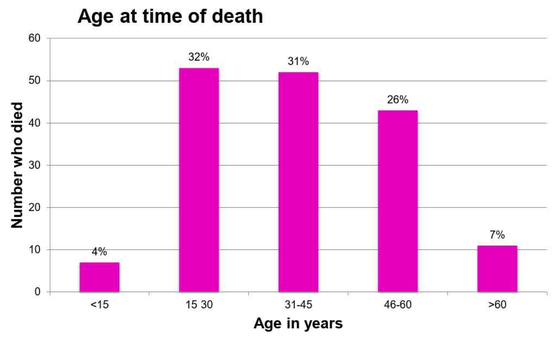
Aim

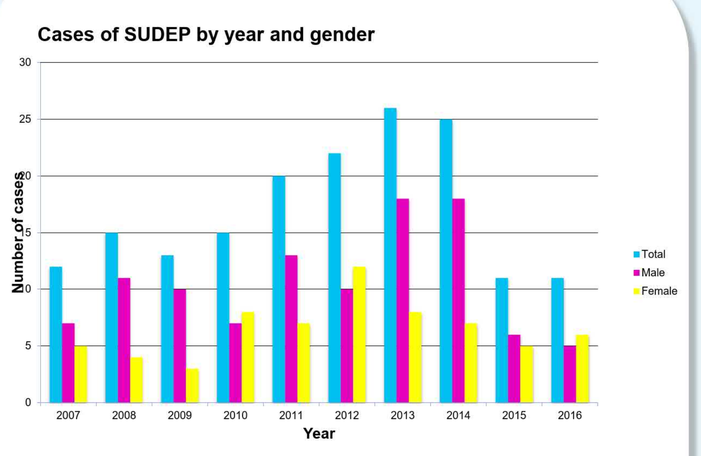
The post-mortem reports and post-mortem toxicology analysis were reviewed to establish if risk factors thought to be associated with SUDEP such as antiepileptic medication non compliance or alcohol and drug abuse[1,2,3] were associated with SUDEP in New Zealand.

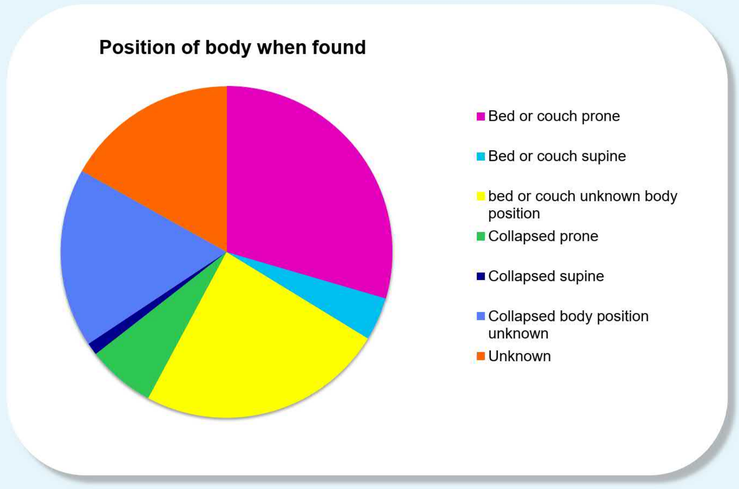
Methods

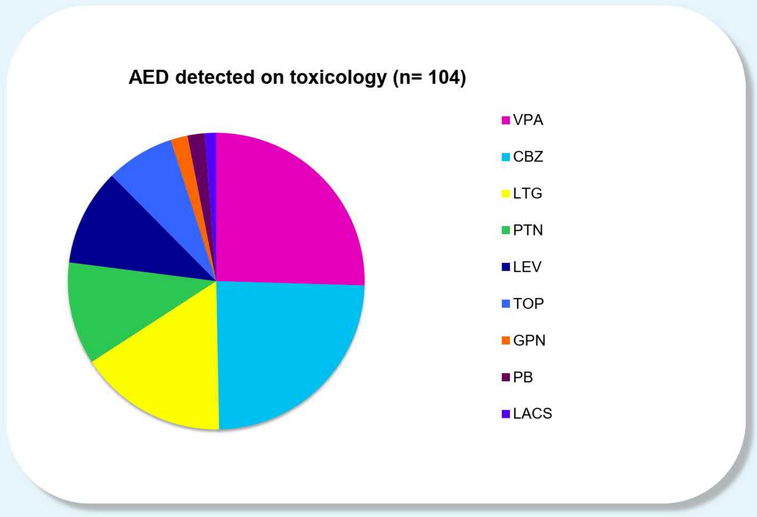
Epilepsy is consistently under documented on death certificates[1] and identifying all deaths in people with epilepsy is difficult. The Corner's office retrospectively identified all probable cases of SUDEP in New Zealand from 2007-2016 (n=190).

The post mortem reports were reviewed to categorise each case as definite SUDEP (n= 125), definite SUDEP plus (n=41), probable SUDEP (n=3),) or not SUDEP (n=21) using published criteria[2]. Toxicology results taken around the time of the post-mortem were reveiwed.









Results

The definite SUDEP and definite SUDEP plus cases (n=166) were aged 1.5 - 67 years (mean 37 years). 61% were male and 87% of the deaths occurred at home, with 74% found in their bed or the bedroom.

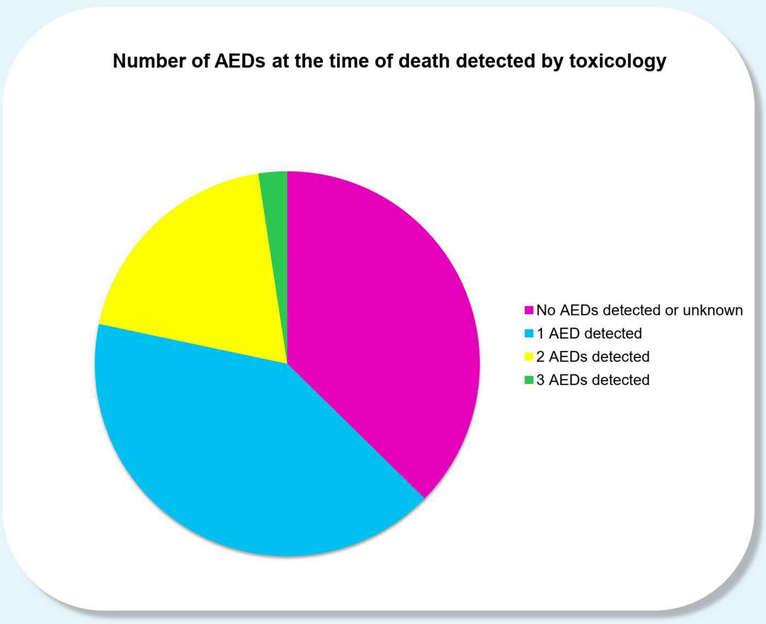
Toxicology reports were available for 155/166 and evidence of antiepileptic (AED) use was detected in 63% of cases.

68 (41%) people took a single AED, 32 (19%) took 2 AEDs and 4 (2%) took 3. (For 62 people (37%) AED use was not detected or not stated). Approximately half who took an AED were taking either Sodium Valproate or Carbamazepine.

The type of epilpesy that the person had was stated in less than a thrid of cases but in the cases where aetiology was stated epilepsy due genetic, structural brain lesions, remote brain infections and chromosomal abnormalities were all present. Information about seizure frequency was not available. Duration of epilepsy diagnosis was rarely stated. Evidence of a a seizure immediately prior to death was not consistently stated.

High alcohol levels were not identified. Recent cannabis use was detected in 20 people (12%) and other recreational drugs in 6 people. Antidepressants (n=11) and antipsychotic (n=9) medications were identified in small numbers.

The majority did not work: 30% were working or retired at the time of death, 15% were children or students and information regarding work status was not available for 11%.



Discussion

Each case of SUDEP represents a tragic premature loss of life. 67% of this cohort were younger than 46 years old at the time of death. Better understanding of who is at risk of SUDEP may allow strategies to be developed that will reduce premature mortality in epilepsy. Post-mortem cohorts may be a means of identifying associations. However the range of information that is recorded at post-mortem is often inconsistent.

References

1. Devensky O, Hesdorffer CD, Thruman DJ et al (2016) Sudden unexpected death in epilepsy: epidemiology, mechanisms and prevention. Lancet Neurology 15: 1075 88
2. SveinssonO, Anderson T, Carlsson S et al (2017) The Incidence of SUDEP: a nationwide population based cohort study. Neurology 89(2) 170-77
3. Middletone O, Atheton D, Bundock E et al (2018) Nationa; Assocoation of medical examoners position paper: Recommendations for the investigation and certification of deaths in people with epilpesy. *Epilepsia* 59:3 530 44

Conclusion

This cohort of Coroner identified cases of SUDEP has characteristics that are similar to other SUDEP cohorts but it is likely that some cases have been missed particularly in older people. This cohort does not support previous studies which have suggested SUDEP may be linked to AED non-compliance as in the majority of people at least one AED was present on toxicology analysis at the time of death. There is a suggestion of social disadvantage/isolation with only 30% working or retired at the time of death.

Standardisation of post-mortem documentation would increase the yield of this type of review[3]. If post-mortem information was documented in a more systematic manner more detailed analysis of risk factors that are associated with sudden death may be possible with the ultimate aim of identifying interventions to reduce premature deaths in epilepsy populations.

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Tuesday, 29 October 2019 5:43 PM
To: Adrienne Martin; Adam McRae
Cc: Lily.Chan[redacted]
Subject: Fw: Lamotrigine CARM reports as at 25/10/2019

Hi
Update on total number of reports
The number of lamotrigine reports as at 25/10/2019 was:

Total reports identifying lamotrigine	36 (+5)
Number of cases describing Brand Switch	29 (+5)
Number of cases of Brand Switch to Logem	25 (+4)

Of the 7 cases of lamotrigine which do not identify a Brand Switch, 3 are Logem brand and 4 do not state a Brand.

Regards
Susan

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

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My email address has changed to [redacted]
****

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Monday, 21 October 2019 4:49 PM
To: Adrienne Martin; Adam McRae
Subject: Fw: lamotrigine/RNZ

FYI
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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

My email address has changed to susan kenyon[redacted]

Sent: Monday, 21 October 2019 4:01 p.m.
To: [redacted]
Cc: [redacted]y
Subject: RE: lamotrigine/RNZ

Hello [redacted]
In response to your query below:

Lamotrigine 01 May 2019 to 18/10/2019:

Since 01 May 2019 - Total Number of cases received for lamotrigine	**31**
Of 31 cases, number describing a brand switch	**24**
(Of 24 cases, number of brand switch **to** Logem brand)	21
Of 31 cases, number of Logem but not reporting a brand switch	**3**
Of 31 cases, number of lamotrigine only (no brand identified)	**4**

Fatalities: CARM has only received one case identifying a fatality

Reactions reported: 17 cases describe Therapeutic effect decreased
11 cases describe convulsions (4 patients had been seizure free prior to brand change)
Other reports describe combinations of tiredness, lethargy, headaches and psychiatric type reactions such as aggressiveness, irritability, mood swings, anxiety.

This information includes all cases up to Friday 18/10/2019.

Regards
Janelle

Jane[redacted]nager Information Syst[redacted]covigilance
DDI: [redacted] | Fax: +64-3-479 7150 | [redacted]

****

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Tuesday, 17 September 2019 5:19 PM
To: Adam McRae; Adrienne Martin; Lily.Chan[redacted]
Subject: Fw: Pharmac change in funded Epilepsy Medication

FYI
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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M email address has chan ed to susan[redacted]

From: "Kim Hawe" <[redacted]
To: "Susan_Kenyon[redacted]
Date: 17/09/2019 05:16 p.m.
Subject: Pharmac change in funded Epilepsy Medication

Hi Susan

Thank you for your time today, as discussed here is our advice regarding Pharmac change in branded Epilepsy medication

In light of Medsafe's submission to PHARMAC on the change of epilepsy medication, the Transport Agency has now reviewed this policy with our Chief Medical Advisor and our position has not changed We will not be enforcing a mandatory stand down period from driving. We are basing this decision on the recommendation from the Neurological and Mental Health Subcommittees of the Pharmacology and Therapeutics Advisory Committee/PHARMAC who recommended that the change of medication would be unlikely to increase risks for people with epilepsy. While breakthrough seizures can result if a medication is absorbed differently or less effectively by a patient, between seven to 22 percent of people who are seizure free for two years or more experience a seizure even when continuing on the same medication, and the risk of a first seizure in the general population is about one percent.

The Transport Agency's primary concern is road safety, and while we will not be enforcing a mandatory stand-down period from driving as we do when licence holders undergo a withdrawal of treatment, as a precaution we will be 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.

Additionally, we encourage anyone with concerns about the potential side effects as a consequence of changing brands to consult with their health practitioner or specialist before continuing to drive. Health professionals are often best placed to make a determination in respect of a person's driving ability, by considering the patient's medical history and other relevant factors that may only be known by their health practitioner.

Kind regards

Kim Hawe /Manager Medical Reviews
E[redacted] W nzta.govt.nz

Palmerston North Office Private Bag 11777, Palmerston North 4442, New Zealand

Find the latest transport news, information, and advice on our website:
www nzta govt nz

Deirdre McCullough

From: Lily_Chan[redacted]
Sent: Friday, 18 October 2019 3:07 PM
To: Adam McRae; Adrienne Martin
Cc: Susan.Kenyon[redacted]
Subject: Lamotrigine media queries

Hi Adam and Adrienne

CARM has received two media queries in the last week or so:
1. [redacted]): Number of cases received for lamotrigine since 1 May 2019 (n=26). Of the 26 cases 19 identify the Logem brand
2. [redacted] The number of lamotrigine cases. CARM has also informed him of a fatal case and it seems [redacted] is in contact with the family.

Thought it best to keep you both in the loop.

Thank you,
Lily

Lily Chan | Principal Technical Specialist (Pharmacovigilance) | Clinical Risk Management | Medsafe | Ministry of Health [redacted] |

Deirdre McCullough

From: Susan_Kenyon[redacted]z
Sent: Tuesday, 29 October 2019 9:17 AM
To: Adrienne Martin; Adam McRae
Cc: Lily.Chan[redacted]
Subject: Lamotrigine

Hi
Found an email this morning from CARM telling me they have received another fatal case for a young man taking lamotrigine
Cause of death unknown, brand unknown but appears to have switched. Case has been referred to the coroner.
Kind regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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Deirdre McCullough

From: Lily_Chan[redacted]
Sent: Friday, 11 October 2019 2:41 PM
To: Adrienne Martin; Adam McRae
Subject: Notes from PHARMAC / Medsafe meeting

Hi Adrienne and Adam

Thank you for coming over today. Below is a summary of what we discussed. Please feel free to make any changes.

Date: 11 October 2019
Present: Adam McRae, Adrienne Martin, Lily Chan

- Ongoing efforts by PHARMAC to clarify NZTA's recommendation
- Information on accessing exceptional circumstances funding is being provided by CARM.
- About 37 exceptional circumstances applications received of which 21 are approved
- 6 reports to CARM since last month: 3 of increase in seizure frequency after switch, 2 of other reactions, 1 where Medsafe can't access the report
- Medsafe to send a link to PHARMAC on any communication about mixing brands to achieve the necessary dose.
- About 45% of patients have changed brands.
- To meet again in a month subject to events.

Have a good weekend!

Lily

Lily Chan | Principal Technical Specialist (Pharmacovigilance) | Clinical Risk Management | Medsafe | Ministry of Health [redacted]

Deirdre McCullough

From: Lizzy Cohen
Sent: Tuesday, 22 October 2019 1:14 PM
To: Michael Roberts
Subject: PHARMAC - No Surprises to the Minister of Health
Attachments: 2019 10 22 No surprises lamotrigine.pdf

Hi Michael,

Please find attached a No Surprises to the Minister regarding Lamotrigine.

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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

Deirdre McCullough

From: Lizzy Cohen
Sent: Tuesday, 29 October 2019 3:32 PM
To: Michael Roberts
Cc: Rachel Read
Subject: PHARMAC No Surprises death of two patients taking lamotrigine

Good afternoon,

No surprises to the Minister death of two patients taking lamotrigine

Following the no surprises briefing on lamotrigine we sent you last week, Medsafe has today advised PHARMAC that the Centre of Adverse Reactions Monitoring (CARM) has received notice of two more fatalities of patients taking lamotrigine The details provided are that one patient was a young man taking lamotrigine, brand unknown, and that he appears to have changed brands. The cause of death is unknown and the case has been referred to the coroner. No information has yet been provided on the second fatality.

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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

Deirdre McCullough

From: Adam McRae
Sent: Monday, 21 October 2019 4:11 PM
To: Adrienne Martin
Subject: Please review

2019-10 21 File note Teleconference with Medsafe

Present from PHARMAC: Adrienne and Adam
Present from Medsafe: Susan Kenyon

Susan had been in contact with CARM. Initial update suggests that the patient had both Logem and Lamictal brands and had previously been on Logem brand. CARM likely to follow up with prescriber to gain additional information and context.

At this stage the information on reports had not been released It is likely that CARM would categorise reports where patients were uncontrolled. Likely to be released to media on Wednesday. Noted that in other brand changes media reporting directly corelated to the frequency and type of reports received

Weekly teleconferences to be updated, particularly if any serious or sentinel events are reported to CARM, and Susan in turn will inform PHARMAC

Noted as at 23 September over half of patients were on Logem Noted that a number of patients had received more than 30 days supply the implication being CARM could to continue to receive reports potentially attributed to the brand change into the New Year

---

From: Adrienne Martin <[redacted]>
Sent: Friday, 18 October 2019 4:11 PM
To: Adam McRae <[redacted]
Subject: please review

2019 10 18 File note Teleconference with Medsafe

Present from PHARMAC: Adrienne and Adam
Present from Medsafe: Susan Kenyon

We called Susan to discuss an email sent to PHARMAC noting that CARM has informed the media of a fatal lamotrigine case

Susan noted that she does not have a copy of the report and will need to look at CARMs assessment of it. Adrienne asked if Medsafe have any details on the case and Susan noted that there had been a report involved a patient who switched from the Logem brand to the Lamictal brand and then back to the Logem brand and had recently died. Susan noted that the person has epilepsy and therefore it is possible that the person died from a seizure related cause.

Susan noted that Michael Tatley is currently out of the office and she would therefore follow up with him on Monday. Susan said she would get back in contact with us on Monday when she had further details.

Adrienne asked why the reported CARM reports to the media appeared higher than the number Medsafe had reported to us Susan noted that the additional reports are likely still in progress so wouldn't have been processed when we last met.

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHARMAC, PO B[redacted] 10254, L[redacted] L9, 40 Mercer Street, Wellington
DDI:[redacted] | F: +64 4 460 4995 | www.pharmac.govt.nz
[redacted]

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Thursday, 31 October 2019 9:30 AM
To: Adrienne Martin; Adam McRae
Cc: Lily.Chan[redacted]
Subject: possibly helpful info
Attachments: abn_poster_sudep1_pb_003_.pdf

Hi
found this and thought it might be useful for you

thanks
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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My email address has changed to [redacted]

Deirdre McCullough

From: Adrienne Martin
Sent: Wednesday, 30 October 2019 1:35 PM
To: 'Susan_Kenyon[redacted]
Cc: Adam McRae; Lily.Chan[redacted]
Subject: RE: 2rd fatal report for lamotrigine

Thanks for the update Susan

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHARMAC PO B[redacted]10254 | Level 9, 40 Mercer Street, Wellington
DDI: +[redacted] P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan Kenyon[redacted]>
Sent: Wednesday, 30 October 2019 9:36 AM
To: Adrienne Martin <[redacted]
Cc: Adam McRae <[redacted]>; Lily Chan[redacted]
Subject: 2rd fatal report for lamotrigine

Hi
I have further details for the second fatal case.
This was another young man. He started lamotrigine in May this year and yet still had a brand switch...
He died around 1 month after changing brands (not stated which were taken), not thought to have had a seizure since starting lamotrigine.
Cause of death unknown

To summarise we have three reports of death in patients taking lamotrigine. Since the cause is unknown CARM have assigned the causality as unascertained
All three cases have been referred to the coroner. Our normal process is not to take any action at this point as we would not wish to prejudice the coroner investigation.
The coroner will contact us if they determine there are actions that Medsafe needs to take. In any case we will follow up with the coroner to get the final report as we have done in similar situations
Until then I do not expect to get any further information and I note that it usually takes months to years for coroners to complete their investigation
Kind regards
Susan

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

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

My email address has changed to [redacted]

From: "Adrienne Ma[redacted]" <[redacted]>, "Adam McRae" <[redacted]>,
To: "Susan_K[redacted]
Cc: "Lily.Chan[redacted]z"

Date: 30/10/2019 07:56 a.m
Subject: RE: 3rd fatal report for lamotrigine

Hi Susan

Thanks for the update If you could let me know further details for the 3rd case once you have them that would be much appreciated.

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHAR[redacted]10254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan Kenyon [redacted]>
Sent: Tuesday, 29 October 2019 5:20 PM
To: Adrienne Martin <[redacted]; Adam McRae [redacted]
Cc: Lily Chan [redacted]
Subject: 3rd fatal report for lamotrigine

Hi
I have some details for this now
This was a young man, cause of death unknown, they were found dead and therefore the case has been referred to coroner
Death occurred several weeks but less than a month after switch Did not appear to be seizure free, but frequency not reported and start of anti epileptic treatment not reported.
Regards
Susan

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

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New Zealand Medicines and Medical Devices Safety Authority

My email address has changed to [redacted]

Deirdre McCullough

From: Adrienne Martin
Sent: Wednesday, 30 October 2019 7:56 AM
To: Susan_Kenyon [redacted]; Adam McRae
Cc: Lily.Chan [redacted]
Subject: RE: 3rd fatal report for lamotrigine

Hi Susan

Thanks for the update. If you could let me know further details for the 3rd case once you have them that would be much appreciated.

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHARMAC, PO B... 10254 | Level 9, 40 Mercer Street, Wellington
DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan_Kenyon [redacted]>
Sent: Tuesday, 29 October 2019 5:20 PM
To: Adrienne Martin [redacted]>; Adam McRae [redacted]>
Cc: Lily.Chan [redacted]
Subject: 3rd fatal report for lamotrigine

Hi
I have some details for this now
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Regards
Susan

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

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

My email address has changed to [redacted]

Deirdre McCullough

From: Nicole Anderson [redacted]>
Sent: Tuesday, 29 October 2019 3:44 PM
To: Lizzy Cohen; PHARMAC Board Members
Subject: RE: For your information - PHARMAC No Surprises to the Minister

Kia ora Steve,

No doubt you are in the thick of this and will update us as soon as any further information available

I'm keen to understand what our response to this will be and what action if any we need to take.

Ngā Mihi,

Nicole Anderson
[redacted]

From: Lizzy Cohen <[redacted]>
Sent: Tuesday, 29 October 2019 3:35 p.m.
To: PHARMAC Board Members [redacted]>
Subject: For your information PHARMAC No Surprises to the Minister

Good afternoon,

Please see below for your information a no surprises to the Minister of Health sent today.

No surprises to the Minister - death of two patients taking lamotrigine

Following the no surprises briefing on lamotrigine we sent you last week, Medsafe has today advised PHARMAC that the Centre of Adverse Reactions Monitoring (CARM) has received notice of two more fatalities of patients taking lamotrigine. The details provided are that one patient was a young man taking lamotrigine, brand unknown, and that he appears to have changed brands The cause of death is unknown and the case has been referred to the coroner. No information has yet been provided on the second fatality.

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Wednesday, 18 September 2019 9:31 AM
To: Adrienne Martin
Cc: Adam McRae; Lily.Chan[redacted]
Subject: Re: FW: notes from PHARMAC / Medsafe meeting

Follow Up Flag: Follow up
Flag Status: Flagged

Thanks Adrienne good to document that
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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

My email address has changed to [redacted]

From: "Adrienne Ma[redacted]"
To: "Susan_Kenyon[redacted]
Cc: "Adam McRae"[redacted], "Lily.Chan[redacted]
Date: 18/09/2019 09:03 a.m.
Subject: FW: notes from PHARMAC / Medsafe meeting

Thanks Susan

Have just added once paragraph re 'brand mixing'

Kind regards
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

[redacted]0254 | Level 9, 40 Mercer Street, Wellington
P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan_Kenyon[redacted]
Sent: Tuesday, 17 September 2019 9:30 AM
To: Adam McRae <[redacted]; Adrienne Martin [redacted]
Cc: Lily Chan[redacted]
Subject: notes from PHARMAC / Medsafe meeting

Date 13 Sept 2019
Present Adam McRae, Adrienne Martin, Lily Chan, Susan Kenyon

Medsafe had contacted NZTA regarding a media release where they stated they were considering whether the lamotrigine brand switch should be considered a change in treatment No response has been received
PHARMAC have not had contact either
Update on CARM reports, 3 more reports for lamotrigine last month, one was an increase in seizure frequency after switch, one was a product complaint and one was not brand related.
PHARMAC noted that 1/4 of patients have now changed brands.
There have been 15 exceptional circumstances applications, 5 approved, 2 withdrawn, 2 where a trial of Logem was considered appropriate and 6 under assessment
PHARMAC noted concerns raised by a consumer and an Epilepsy NZ field Officer about brand mixing with lamotrigine during dose titrations. PHARMAC noted that we had taken clinical advice on this and our experts did not perceive a problem. Medsafe noted that it wasn't aware of a problem with mixing brands for purposes of dose titration. Medsafe highlighted that there is similar confusion about the ability to mix brands of levothyroxine for dose titration and Medsafe are considering providing guidance to the sector on this.

Agreed to meet in another month

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

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immediately and delete this message.
****

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Thursday, 31 October 2019 4:08 PM
To: Adrienne Martin
Cc: Adam McRae; Lily.Chan[redacted]
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

Sorry the numbers in brackets are the increase from the previous week
Regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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

My email address has changed to [redacted]

From: "Adrienne Ma[redacted]"
To: "Susan K[redacted]"
Cc: "Lily.Chan[redacted]" "Adam McRae"[redacted]
Date: 31/10/2019 03:59 p.m.
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

Hi Susan

Sorry, just a bit confused about what the (+5), (+5), (+4) means?

Do you mean there are now a total of 41 reports identifying lamotrigine?

Also does this include the 2 recent fatalities that you emailed me about?

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHAR[redacted]10254 | Level 9, 40 Mercer Street, Wellington
DDI: +[redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www pharmac.govt nz

From: Susan_Kenyon[redacted]>
Sent: Tuesday, 29 October 2019 5:43 PM
To: Adrienne Martin [redacted]; Adam McRae <[redacted]
Cc: Lily.Chan[redacted]
Subject: Fw: Lamotrigine CARM reports as at 25/10/2019

Hi
Update on total number of reports
The number of lamotrigine reports as at 25/10/2019 was:
Total reports identifying lamotrigine 36 (+5)
Number of cases describing Brand Switch 29 (+5)
Number of cases of Brand Switch to Logem 25 (+4)

Of the 7 cases of lamotrigine which do not identify a Brand Switch, 3 are Logem brand and 4 do not state a Brand

Regards
Susan

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

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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]

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Thursday, 31 October 2019 4:22 PM
To: Adrienne Martin
Cc: Adam McRae; Lily.Chan[redacted]
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

No I don't think so
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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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]

From: "Adrienne Ma[redacted]"
To: "Susan Kenyon[redacted]
Cc: "Adam McRae"[redacted] "Lily Chan[redacted]
Date: 31/10/2019 04:12 p.m.
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

Got it thanks! Do those numbers include the additional 2 fatalities?

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHA[redacted]10254 | Level 9, 40 Mercer Street, Wellington
DDI[redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz
[redacted]

From: Susan_Kenyon[redacted]
Sent: Thursday, 31 October 2019 4:08 PM
To: Adrienne Martin[redacted]
Cc: Adam McRae[redacted]; Lily.Chan[redacted]
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

Sorry the numbers in brackets are the increase from the previous week
Regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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

My email address has changed to [redacted]

From: "Adrienne Martin" [redacted]
To: "Susan Ken on [redacted]>,
Cc: "Lily Chan [redacted]>, "Adam McRae" <[redacted]
Date: 31/10/2019 03:59 p.m.
Subject: RE: Lamotrigine CARM reports as at 25/10/2019

Hi Susan

Sorry, just a bit confused about what the (+5), (+5), (+4) means?

Do you mean there are now a total of 41 reports identifying lamotrigine?

Also does this include the 2 recent fatalities that you emailed me about?

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHARMAC PO Box 10254 | Level 9, 40 Mercer Street, Wellington
DDI [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan Kenyon [redacted]
Sent: Tuesday, 29 October 2019 5:43 PM
To: Adrienne Martin [redacted]>; Adam McRae [redacted]
Cc: Lily Chan [redacted]
Subject: Fw: Lamotrigine CARM reports as at 25/10/2019

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Update on total number of reports
The number of lamotrigine reports as at 25/10/2019 was:

Total reports identifying lamotrigine	36 (+5)
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Number of cases of Brand Switch to Logem	25 (+4)

Of the 7 cases of lamotrigine which do not identify a Brand Switch, 3 are Logem brand and 4 do not state a Brand

Regards
Susan

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

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Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Wednesday, 7 August 2019 9:31 AM
To: Adam McRae
Cc: Adrienne Martin
Subject: RE: Lamotrigine reporting

Hi Adam
Friday is best for me
thanks
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health [redacted]

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My email address has changed to [redacted]

From: "Adam McRa[redacted]"
To: "Susan_Kenyon[redacted]",
Cc: "Adrienne Martin"[redacted]
Date: 07/08/2019 08:59 a.m.
Subject: RE: Lamotrigine reporting

Hi Susan
Are you free 1 2pm on Thursday or 1 1 45pm on Friday? We are also available 8 30 9 30am tomorrow morning
Lisa Williams let me know that CARM have received an adverse event report related to Logem Do you have any detail that you can share with us (alternatively we can discuss when we meet if that is more appropriate).
Kind regards
Adam

From: Susan Kenyon[redacted]>
Sent: Monday, 5 August 2019 4:17 PM
To: Adam McRae[redacted]
Subject: RE: Lamotrigine reporting

Generally my calendar is freer in the afternoons
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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My email address has changed to [redacted]

From: "Adam McRae" [redacted]
To: "Susan Kenyon [redacted]
Date: 05/08/2019 04:15 p.m.
Subject: RE: Lamotrigine reporting

Great I will confer with Adrienne when she is back in the office tomorrow any particular times that work better for you?
Cheers
Adam

From: Susan Kenyon [redacted]
Sent: Monday, 5 August 2019 2:27 PM
To: Adam McRae [redacted]
Cc: Adrienne Martin <[redacted]>; susan kenyon [redacted]
Subject: Re: Lamotrigine reporting

Hi Adam
Happy to discuss this just let me know a time
Regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [redacted]

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

My email address has changed to [redacted]

From: "Adam McRae" [redacted]
To: "susan.kenyon [redacted]
Cc: "Adrienne Martin" <[redacted]
Date: 05/08/2019 01:57 p.m.
Subject: Lamotrigine reporting

Dear Susan

I have recently joined the PHARMAC team as an Implementation Lead and will be working on the lamotrigine implementation We have suggested to Chris James that regular catch ups while we transition to sole supply of lamotrigine would be useful and he has suggested that I make contact directly with you Perhaps we could look to meet at some point over the next week or so and discuss an approach and content for regular updates (maybe a recurring teleconference).

It would be useful if I could involve Adrienne Martin (the Therapeutic Group Manager for Neurology) as she has been managing this transaction

Kind regards
Adam

Adam McRae | Senior Implementation Lead

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DDI [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | M: +64 21 960 622 | www.pharmac.govt.nz

Deirdre McCullough

From: Adrienne Martin
Sent: Tuesday, 29 October 2019 9:54 AM
To: 'Susan_Kenyon[redacted]
Cc: Lily.Chan[redacted]; Adam McRae
Subject: RE: Lamotrigine

HI Susan

Thanks for your email. It would be good to have a chat once you have further details from CARM. Let me know when is a good time to chat and I can give you a call.

Thanks
Adrienne

Adrienne Martin | Senior Therapeutic Group Manager/ Team Leader

PHARMAC | PO Box 10254 | Level 9, 40 Mercer Street, Wellington
DDI[redacted]4 | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Susan_Kenyon[redacted]>
Sent: Tuesday, 29 October 2019 9:17 AM
To: Adrienne Martin[redacted]; Adam McRae[redacted]
Cc: Lily.Chan[redacted]
Subject: Lamotrigine

Hi
Found an email this morning from CARM telling me they have received another fatal case for a young man taking lamotrigine
Cause of death unknown, brand unknown but appears to have switched. Case has been referred to the coroner.
Kind regards
Susan
Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health |[redacted]

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

My email address has changed to[redacted]

Deirdre McCullough

From: Adam McRae
Sent: Monday, 12 August 2019 8:33 AM
To: 'Susan_Kenyon[redacted]'; Adrienne Martin
Cc: Lily.Chan[redacted]
Subject: RE: meeting between PHARMAC and Medsafe re lamotrigine

Hi Susan and Lily
Thanks for taking the time to meet with us on Friday – just a few clarifying points in red. I will email Michael and copy you in with detail regarding the exceptional circumstances form:
https://www.pharmac.govt.nz/assets/lamotrigine-exceptional-circumstances-form.doc.
Also looking to lock some time in calendars for our next catch up How does **1.30pm Friday 13 September** work for you both?
Kind regards
Adam

From: Susan Kenyon[redacted]
Sent: Friday, 9 August 2019 2:55 PM
To: Adam McRae[redacted]>; Adrienne Martin[redacted]
Cc: Lily.Chan[redacted]
Subject: meeting between PHARMAC and Medsafe re lamotrigine

Hi
Thanks for coming to meet with us today
Please let me know if you agree that the following is a high-level summary of our discussion

Medsafe confirmed that there had been public and media interest in this brand switch.

Medsafe confirmed that there had been four reports to CARM that they had identified as 'brand switch' reports. It was noted that one report may not have involved a patient changing brands
It was noted that one report was of increased seizure frequency after changing brand.

PHARMAC confirmed that several applications had been made for exceptional circumstances funding, and will look into whether the number will be published on the website PHARMAC will provide more information on the exceptional circumstances process to Medsafe and CARM and a link to the website.
CARM will be able to inform reporters about the process if they get further reports

PHARMAC are tracking the use of the different brands There has been an increase in use of Logem Usage will continue to be tracked.

BPAC are close to publishing an article to help prescribers manage the change. The final version will be sent to Medsafe.

Prof Petrie is undertaking a study investigating patient experience through the switch and is providing advice to Green Cross Health

PHARMAC are also supporting community epilepsy support services and encouraging reporting to CARM

Re future actions
Medsafe will consider the need for a monitoring communication
The use of the term nocebo to be used with care
To meet again in about 1 month - subject to events

Kind regards
Susan

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

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

My email address has changed to [redacted]

Deirdre McCullough

From: Rachel Read
Sent: Friday, 1 November 2019 10:09 AM
To: 'Michael Roberts'
Cc: 'Keriana.Brooking[redacted]'; 'Peter.Jane[redacted]'; 'Chris James[redacted]'; 'Susan_Kenyon[redacted]'
Subject: Re: PHARMAC No Surprises death of two patients taking lamotrigine

Hi Michael

Please find below some supplementary information in relation to your inquiry about lamotrigine earlier in the week

Regards Rachel

PHARMAC is closely monitoring the lamotrigine brand change, and we have regular meetings scheduled with Medsafe staff This provides an opportunity to discuss any CARM reports for adverse events and other feedback related to the brand change. Some additional data on the monitoring we are undertaking, and share with Medsafe, is provided below for your information.

Data on brand changing

As at 7 October 2019, prescribing data indicated that 6725 patients had changed to the Logem brand of lamotrigine. We are aware that ~1000 patients were already taking the Logem brand prior to the transition period of change, so in total ~ 7725 patients are taking Logem (~60% of people taking lamotrigine were taking the Logem brand as at 7 October 2019).

Please note that, although we are aware that ~12500 patients take lamotrigine, this does not represent the number of people living with epilepsy in New Zealand The Ministry of Health website notes that there is no data on the number of people affected by epilepsy in New Zealand but it is thought to be from 45,000 to 50,000.

Exceptional circumstances process for lamotrigine

We have developed a specific process for considering funding for a specific brand of lamotrigine for patients who, due to exceptional clinical difficulties, are unable to manage a change of brand or have not tolerated the change. As of 30 October 2019 we have received 70 applications with 28 being approved, 10 not progressed (due to lack of information) and 9 declined (considered appropriate to trial Logem). The remaining 23 are under assessment. The majority of these relate to the epilepsy indication

Co-payment waiver for additional GP visits

Some people may return to their GP with concerns following the change to the Logem brand and need additional support to make a successful change We have developed a mechanism to reimburse General Practice clinics that waive patient co payments for return visits. The intention is to provide additional support to make a successful brand change. To date we have received 8 claims for reimbursement. As the uptake seems to be relatively low are looking to proactively communicate the mechanism again through appropriate channels.

Rachel Read| Policy Manager, Engagement and Implementation

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DDI: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | M: [redacted]
www pharmac govt nz

From: Susan Kenyon [redacted]
Sent: Wednesday, 30 October 2019 12:11 PM
To: Michael Roberts <[redacted]>
Cc: Keriana.Brooking [redacted] Peter.Jane [redacted]; Rachel Read <[redacted]>; Chris.James [redacted]
Subject: RE: PHARMAC No Surprises death of two patients taking lamotrigine

Hi Michael
I'll try to answer your questions, although there are a lot of unknowns.

The Centre for Adverse Reactions Monitoring (CARM) has been in operation since 1965 They collect reports of any *suspicions* that someone has had an adverse reaction to a medicine. Any one can report and they can report on anything that is a medicine or they think is a medicine, the Centre never refuses to accept a report CARM get between 4,000 and 5,000 reports per year. Each report is reviewed by a medical assessor against the WHO causality method to determine the probability that the medicine caused the reaction
Reports with a high probability are prioritised for further investigation and review by Medsafe.
Medsafe can refer issues to the Medicines Adverse Reactions Committee if we feel that we need additional advice
The minutes and papers for this Committee are published on our website.
We also have regular information sharing meetings with other international medicines regulators and we get advice from them.
We contact the pharmaceutical company to review their data as well when necessary
In terms of actions we can ask the company to update their product information (data sheet) published on our website This could include changing indications, contraindications and adding warnings
We can ask the sector for additional information by making an issue a medicine monitoring issue - also on our website
If the issue is known about we can remind healthcare professionals through our quarterly publication *Prescriber Update* also published on our website
For more urgent safety issues we can issue a monitoring communication or alert communication.
In cases where the benefits of a medicine no longer outweigh the risks of harm we can undertake a statutory risk benefit review under s36 of the Medicines Act 1981. This can result in revocation of the consent to distribute the medicine

In the case of a brand switch the actions we can take are very limited as the generic is essentially the same as the innovator or it would not have been approved. However even when different brands meet the bioequivalence criteria that does not mean that every single person will experience the same effects For most medicines this is not an issue but for medicines with a narrow therapeutic window or some antiepileptics this can be a problem which is why we reminded PHARMAC of this during their consultation on lamotrigine

The rate of sudden unexpected death in epilepsy in NZ 2007 2016 was published
as a poster (attached)

The authors estimated that 40 people with epilepsy in New Zealand die from SUDEP - the risk is higher in young people
The number of deaths where the person was taking lamotrigine was not stated but from the pie chart it looks like around 20% of those who died were taking lamotrigine (but note that not all cases were included in this analysis) In which case *a very rough estimate* based on these figures might be 8 deaths per year in people with epilepsy taking lamotrigine

According to the pharmaceutical web tool there are around 12,000 patients talking lamotrigine, but not all of these are patients with epilepsy as it is also used as a mood stabiliser in bipolar disorder.

CARM data

The first report for lamotrigine was received in 1992. Up until end June this year CARM have received 162 reports where lamotrigine was suspected of causing an adverse reaction Six people were reported to have died during this time period.
The reported reactions in the fatal reports were sudden death x2, seizure x2 , pancreatitis and suicide The last death report received before the brand switch was in 2015.
The most commonly reported reaction has been skin rash

In terms of the current reports all have been referred to the coroner so we would normally await their decision The coroner will contact us if they determine that there are actions that Medsafe should take - as they have done for deaths related to other medicine use We have also contacted the coroners office to ask that they provide us with the reports in any case. However this normally takes some time.

From the other reports received by CARM at least some of the patients appear to have difficult to treat epilepsy/bipolar disorder so it may be helpful to remind their doctors that they can apply for exceptional circumstances funding without trying to switch first.
Please feel free to call me if you need any further information.

Kind regards
Susan

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

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My email address has changed to [redacted]

From: "Michael Rob [redacted]
To: "Susan Kenyon [redacted]z>;
Cc: "Rachel Read" [redacted] "Peter Jane [redacted]>, "Keriana.Brooking [redacted]"
Date: 30/10/2019 09:49 a.m
Subject: RE: PHARMAC No Surprises - death of two patients taking lamotrigine

---

Kia ora Susan, thank you for your advice yesterday. Please indicate if I should be seeking advice on this subject via another part of the Ministry, or indeed whether it is something more on the PHARMAC side

We are closely following the impact of the brand change here in the office, and are keen for some more information regarding how it is being monitored. There is the CARM process I understand, but I wanted to check whether there are other systems in place too.

Secondly, are you or PHARMAC able to provide some historical mortality information regarding epilepsy treated by lamotrigine? Acknowledging that epilepsy is a condition that can cause sudden events such as these, we are keen to know how this compares to the long run trend.

Finally, are you able to provide advice regarding what stages would trigger further policy responses? We're eager to know what the potential next steps are if sadly this occurs again

Apologies again if you're not the right point of contact for this request.

Thanks
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]

From: Michael Roberts
Sent: Tuesday, 29 October 2019 4:00 PM
To: 'Susan Kenyon [redacted]>
Cc: Rachel Read [redacted]>; 'Peter.Jane [redacted]>
Subject: FW: PHARMAC No Surprises - death of two patients taking lamotrigine

Kia ora Susan,

PHARMAC have notified the office of a second fatality with a possible link to lamotrigine. Has this second fatality (three in total including the one reported on last week) come through the CARM system?

The office is very keen to have more information about how this process works Are you able to provide a rough precis of how CARM functions, what the timeframes for concluding whether there is a trend and further decisions are needed.

Secondly, I understand, sadly, that individuals with epilepsy can suffer a sudden fatal incident, and that these incidents must occur a number of times a year due to there being 11,000 people living with the condition Are we at a stage where these three deaths indicates something is out of the norm, or is this number, sadly, a consequence of 11,000 people living with epilepsy?

Thanks, please give me a call if I can clarify further

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]

From: Rachel Read [redacted]
Sent: Tuesday, 29 October 2019 3:40 PM
To: Michael Roberts [redacted]>; Lizzy Cohen [redacted]>
Subject: RE: PHARMAC No Surprises death of two patients taking lamotrigine

Hi Michael

Sorry this is all the information we have at this time

Cheers Rachel

Rachel Read| Policy Manager, Engagement and Implementation

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

From: Michael Roberts [redacted]>
Sent: Tuesday, 29 October 2019 3:38 PM
To: Lizzy Cohen [redacted]>
Cc: Rachel Read [redacted]>
Subject: RE: PHARMAC No Surprises death of two patients taking lamotrigine

Kia ora Lizzy,

Do we have information regarding when they occurred?

Thanks

Michael Roberts | **Private Secretary Health**
Office of Hon Dr David Clark
Minister of Health | Associate Minister of Finance
Mobile [redacted]

From: Lizzy Cohen [redacted]]
Sent: Tuesday, 29 October 2019 3:32 PM
To: Michael Roberts [redacted]>
Cc: Rachel Read [redacted]>
Subject: PHARMAC No Surprises death of two patients taking lamotrigine

Good afternoon,

No surprises to the Minister - death of two patients taking lamotrigine

Following the no surprises briefing on lamotrigine we sent you last week, Medsafe has today advised PHARMAC that the Centre of Adverse Reactions Monitoring (CARM) has received notice of two more fatalities of patients taking lamotrigine. The details provided are that one patient was a young man taking lamotrigine, brand unknown, and that he appears to have changed brands. The cause of death is unknown and the case has been referred to the coroner. No information has yet been provided on the second fatality

Kind regards,
Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

PHAR[redacted]10 2[redacted]ercer Street, Wellington
DDI: [redacted] | M: [redacted] | P: +64 4 460 4990 | F: +64 4 460 4995 | www.pharmac.govt.nz
[redacted]

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immediately and delete this message.
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Deirdre McCullough

From: Rachel Read
Sent: Tuesday, 29 October 2019 3:40 PM
To: Michael Roberts; Lizzy Cohen
Subject: RE: PHARMAC No Surprises - death of two patients taking lamotrigine

Hi Michael

Sorry this is all the information we have at this time

Cheers Rachel

Rachel Read| Policy Manager, Engagement and Implementation

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

From: Michael Roberts [redacted]>
Sent: Tuesday, 29 October 2019 3:38 PM
To: Lizzy Cohen [redacted]>
Cc: Rachel Read [redacted]>
Subject: RE: PHARMAC No Surprises death of two patients taking lamotrigine

Kia ora Lizzy,

Do we have information regarding when they occurred?

Thanks

Michael Roberts | Private Secretary Health
Office of Hon Dr David Clark
Minister of Health | Associate Minister of Finance
Mobile [redacted]

From: Lizzy Cohen [redacted]
Sent: Tuesday, 29 October 2019 3:32 PM
To: Michael Roberts [redacted]>
Cc: Rachel Read [redacted]
Subject: PHARMAC No Surprises death of two patients taking lamotrigine

Good afternoon,

No surprises to the Minister death of two patients taking lamotrigine

Following the no surprises briefing on lamotrigine we sent you last week, Medsafe has today advised PHARMAC that the Centre of Adverse Reactions Monitoring (CARM) has received notice of two more fatalities of patients taking lamotrigine The details provided are that one patient was a young man taking lamotrigine, brand unknown, and that he appears to have changed brands. The cause of death is unknown and the case has been referred to the coroner. No information has yet been provided on the second fatality.

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Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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[redacted]

Deirdre McCullough

From: Adam McRae
Sent: Wednesday, 4 September 2019 4:26 PM
To: 'Susan_Kenyon[redacted]'; Lily.Chan[redacted]
Cc: Adrienne Martin
Subject: Scheduled catch up

Hi Susan and Lily
Just looking though my diary I noticed we have a catch up scheduled for next Friday 13 September from 1.30 to 2.30pm. Does that still suit you both.
Kind regards
Adam

Adam McRae | Senior Implementation Lead

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Deirdre McCullough

From: Lily_Chan[redacted]
Sent: Friday, 18 October 2019 3:30 PM
To: Adrienne Martin
Subject: Susan's phone number

Hi Adrienne

Susan's number is [redacted]. She is back at her desk now.

Thank you,
Lily

Lily Chan | Principal Technical Specialist (Pharmacovigilance) | Clinical Risk Management | Medsafe | Ministry of Health
[redacted]

Deirdre McCullough

From: Susan_Kenyon[redacted]
Sent: Friday, 1 November 2019 8:42 AM
To: Adrienne Martin; Adam McRae
Cc: Lily.Chan[redacted]
Subject: Update on lamotrigine report numbers

Numbers provided at 31/10/2019

Total reports identifying lamotrigine	43
Number of cases describing Brand Switch	35
Number of cases of Brand Switch to Logem	31

Of the 8 cases of lamotrigine which do not identify a Brand Switch, 4 are Logem brand and 4 do not state a Brand

Susan Kenyon | Manager | Clinical Risk Management | Medsafe | Ministry of Health | [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]