Lamotrigine Implementation Project Team

Meeting held 13 January 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin, Senior Therapeutic Group Manager/Team Leader
Andrew Oliver, Therapeutic Group Manager
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Peter Murray, Deputy Medical Director
Rochelle West, Senior Funding Co-ordinator/Team Leader

MINUTE

	Subject	**Reference**

1. **Review of minutes from 16 December 2019:**

   Noted HDC response had been sent.

2. **Serious adverse event checklist:**

   Noted that no adverse events had been reported directly to PHARMAC to date.

   Noted that this item will be removed as unlikely to receive reports directly.

3. **Update on EC applications:**

   Noted that as at 2 December 2019 there are:

   - 1741 applications in total
   - 1643 approved
   - 57 to be entered
   - 24 under assessment
   - 17 declines and withdrawn

   Noted that applications are on a same day approval.

   Noted that daily application numbers were stable (around 40).

   Adrienne has submitted an analysis request to ascertain level of patient churn by indication (to ascertain numbers of EC applications that may discontinue).

   Adrienne and Adam to develop an internal data request (for MoH) for decrypted NHI of lamotrigine patients by indication in the 12 months proceeding 1 October 2019 to identify patients that were not previously treated on another brand of lamotrigine (i.e. to identify potential new initiations on Lamictal or Arrow-Lamotrigine).

   Rochelle to ascertain the numbers off EC applications with 6-month approvals.

   Rochelle to provide updated numbers of EC applications (dose and strength by brand) for suppliers.

Noted that ongoing management of the approved EC applications needed to be considered. Additional data will inform this, at this stage will continue to administer through EC, however, could potentially consider adding additional doses current approvals to allow flexibility. Will revisit ongoing management when new applications numbers have declined.

Adam to add an additional check box to the application form to indicate that the patient was on lamotrigine prior to 1 October 2019 (to reduce potential applications for any new initiations).

4. **Communications update:**

Noted no media activity.

Noted 30 enquiries to date this month, mainly around GP co-payments and individual EC applications.

Noted 3 OIA's with draft responses.

Noted draft response to Maria Lowe of Epilepsy Waikato. Noted that her letter highlights bpac article. Bpac have shared a response with PHARMAC – no further action required.

5. **Update adverse event reports:**

Noted a clash with the upcoming Medsafe meeting. Adam will contact to reschedule the 23 January meeting.

6. **Lamotrigine data update:**

Noted approximately 10,700 patients have switched to Logem as at mid-December. This brings total patient numbers on Logem to around ~10,000 assuming 1,700 EC applications are switch backs and 1,000 existing Logem patients.

7. **Action items**

1. Adrienne and Adam to develop data request for NHI decrypted scripts.
2. Rochelle to investigate numbers of 6-month renewals approved.
3. Rochelle to provided updated numbers for suppliers.
4. Adam to update EC form.
5. Adam to rearrange Medsafe meeting.

Lamotrigine Implementation Project Team

Meeting held 27 January 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin, Senior Therapeutic Group Manager/Team Leader
Andrew Oliver, Therapeutic Group Manager
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Lisa Williams, Director of Operations
Peter Murray, Deputy Medical Director
Rochelle West, Senior Funding Co-ordinator/Team Leader

MINUTE

	Subject	**Reference**

1. **Review of minutes from 13 January 2020:**

Noted NHI decryption could only be requested on a case by case basis

Number of 6-month applications approved still to be determined.

Updated EC numbers have been provided to suppliers.

EC form updated to with check box confirming patient was on lamotrigine prior to 1 October 2019.

Medsafe meeting re-arranged to 28 January 2020.

2. **Update on EC applications:**

Noted that 1900 applications had been received.

Rochelle to provide updated numbers (in the format on the website) to Liz cc Adam.

Noted that the MoH is checking individual applications on a case by case basis. This process is timing consuming and labour intensive and is slowing applications down (taking three days to confirm). Rochelle will identify an appropriate contact at MoH so the issue can be escalated if required. Noted that 3 applications have been received that do not appear to have a previous dispensing for lamotrigine. The quality of the data may be an issue, however, in these instances we will return to the applicant noting this and that applications are pending awaiting clarification. Applications where there is a mismatch between the stated brands and those dispensed will continue to be approved at this stage (e.g. states an issue with the brand change where an individual does not appear to have a dispensing for Logem).

3. **Communications update:**

Noted a recent media article on Logem in relation to bipolar disorder. This media coverage included the safety messages specified.

Still receiving a number of phone and email enquiries regarding lamotrigine. The majority were enquires on how funding for a specific brand or following up on an EC application.

4. **Update from Medsafe re adverse event reports:**

Noted next meeting scheduled for 28 January 2020.

5. **Lamotrigine data update:**

Noted approximately 11,187 patients have switched to Logem.

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Lamotrigine-Tracker

6. **PTAC and TMESC**

Noted that PTAC and the Tender Medical Evaluation Subcommittees were meeting in February.

Pete to write a paper providing an update to PTAC and will send to Adam and Adrienne for review.

Adam to write a paper for TEMSC, updating them on lamotrigine and noting that the TMESC can refer tender items for clinical advice if they see a need, however, TEMSC role relates to suitability in assessing tender items (rather than specific clinical advice). Adam and Adrienne to attend meeting to field questions related to this item.

7. **Review:**

Noted that the external reviewer is likely to be confirmed this week (General Counsel will meet). Noted communications are preparing reactive messages for this, and this will be raised at the upcoming Health Select Committee.

8. **Action items**

1. Rochelle to provide numbers of patients with 6 month approvals
2. Rochelle to provide updated EC numbers to Liz for web publication
3. Rochelle to identify a point of contact at MoH to discuss decrypted NHI data
4. Pete to prepare update paper for PTAC (Adrienne and Adam to review)
5. Adam to prepare paper for TMESC (Adrienne to review)

Lamotrigine Implementation Project Team

Meeting held 17 February 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin, Senior Therapeutic Group Manager/Team Leader
Geraldine MacGibbon, Manager Pharmaceutical Funding
Graham Beever, General Counsel
Hannah Tibble-Gotz, Pharmaceutical Enquiries Management
Jane Wright, Senior Communications Adviser
Jayne Watkins, Senior Adviser/Team Leader
Lisa Williams, Director of Operations
Peter Murray, Deputy Medical Director
Rochelle West, Senior Funding Co-ordinator/Team Leader

MINUTE

	Subject	**Reference**

1. **Review of minutes from 27 January 2020:**

   Noted NHI decryption had been escalated within the Ministry

   Papers for PTAC and TMESC prepared

   EC numbers updated on web page

2. **Update on EC applications:**

   Noted that Jayne and Rochelle were to receive Ministry training and access to NHI look up. This will allow access to dispensing history by NHI.

   Noted that current EC numbers were:

   - 2130 applications
   - 2046 approved
   - 53 under assessment
   - 24 declined
   - 7 withdrawn

   Noted that there has been an increase in the number of applications being declined. This mainly relates to applications for patients who have not previously been on a brand of lamotrigine (ie. new patients).

   Adam to update Sarah F in advance of this week's select committee.

   Noted applications had dropped to 10-15 per day for approximately a week.

   Noted that when updating the numbers on the web page to include rationale for increase in decline numbers "the number of applications being declined has increased as dispensing data indicates that these applications are for individuals that were not previously on another brand of lamotrigine and for who Logem is an appropriate treatment option".

   Noted that Jayne would be taking over responsibility for management of the EC process moving forward.

Noted web site had been updated with information relating to changing nominated pharmacy.

Adrienne currently awaiting data on patient churn by indication to inform thinking as the majority of EC applications relate to epilepsy.

3. **Closure of exceptional circumstances:**

Noted that by the end of March 2020 it will be six months since sole supply. With the easing of application numbers and the elapsed time it is likely that individuals requiring access to their previous brand of lamotrigine have been identified or have successfully been switched to Logem.

Adrienne is to seek advice on the clinical appropriateness form EC panel members on closing off the lamotrigine exceptional circumstances process (Pete, Rochelle, Jayne and Adam to review).

Pending clinical advice, a three week notification would be issued to the sector. Jane to develop communications for this. Noted that it would be important to communicate this with paediatric neurologists in particular (through the League Against Epilepsy).

In alignment with this an amendment to the agreement with Mylan is to be drafted.

Noted that a plan for ongoing management of approved applications would be most appropriately developed post closure of the exceptions process.

4. **GP co-payment waivers:**

Noted that numbers of claims were reducing with only a handful being received. Originally communications specified that claims needed to be submitted to PHARMAC by 31 January 2020.

Adam to manage removal of this process from the web site, however, will continue to process claims that are received.

5. **Communications update:**

Noted a recent study be Keith Petrie in relation to CARM reporting and television media coverage had been published.

Noted a number of OIAs were in progress.

6. **Update from Medsafe re adverse event reports:**

Adam to arrange next meeting for early March.

7. **Lamotrigine data update:**

Adam to reiterate data request for regular updates of tracker. Additional data may be required in the future to inform decision making.

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Lamotrigine-Tracker

8. **TMESC**

Noted that Adrienne and Adam presented to TMESC regarding the lamotrigine brand change. The Subcommittee were supportive of the time taken and clinical advice received in relation to the brand change. Members of the

Subcommittee noted that it was extremely difficult to counsel and reassure patients regarding the brand change during intensive media coverage of deaths being attributed to the change in brand.

9. **Review:**

Noted that the external reviewer is underway. Jonathan Coates has received information and documentation for the pre-decision components. Currently documentation in relation to implementation was being collated. Key staff will be meeting with the external reviewer in the coming week.

10. **Response to coroner**

Noted that the response to the coroner was in final draft for sign out this week.

11. **Peter Bergin data request:**

Noted that Peter Bergin had requested information in relation to his ongoing research into SUDEP (in conjunction with the Chief Coroner). This data request would be managed through the OIA process, and a request for identifiable patient data referred to the Ministry.

8. **Action items**

1. Jayne primary contact for lamotrigine exceptional circumstances moving forward
2. Adam to update Sarah F with EC numbers
3. Adrienne to seek clinical advice on closing off exceptional circumstances process
4. Jane to develop communications messages regarding closing off exceptional circumstances process
5. Adam/Adrienne to develop stakeholder notification regarding closing off exceptional circumstances process
6. Adrienne/Graham to develop amendment to Mylan agreement post March 2020 reflecting EC approval numbers
7. Adam to remove information on GP co payment waivers from web site
8. Adam to arrange a meeting with Medsafe for an update in early March
9. Adam to place request for regular lamotrigine tracker updates
10. Key staff to be available to meet with external reviewer

Lamotrigine Implementation Project Team

Meeting held 24 February 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin, Senior Therapeutic Group Manager/Team Leader
Andrew Oliver, Therapeutic Group Manager (2nd Nuerology)
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Jayne Watkins, Senior Adviser/Team Leader
Lisa Williams, Director of Operations
Peter Murray, Deputy Medical Director

MINUTE

Subject **Reference**

Review of minutes from 17 February 2020:

- EC numbers provided to Sarah F in advance of Health Select Committee
- Clinical advice received on returning exceptional circumstances process to standard NPPA approach
- Adrienne/Graham to develop amendment to Mylan agreement post March 2020 reflecting EC approval numbers
- Information on GP co-payment waivers removed from web site
- Medsafe meeting scheduled for 13 March 2020
- Ashton providing weekly lamotrigine data updates
- Meetings scheduled with external reviewer

Closure of exceptional circumstances:

Noted that Withheld under section 9(2) had provided clinical feedback in support of ending EC application process from the end of March.

Adam, Adrienne and Jane to develop a communications plan to sector partners, health professional organisations and other interested parties. The intention is to give three weeks' notice of end of the 'widened access' process & to communicate that future applications would be dealt with via our standard NPPA application mechanisms. We will still use our discretion to consider apps where appropriate, i.e. will still look at exceptional cases

Ongoing management of approved EC applications to be investigated. Awaiting data of churn by indication, Adrienne to follow up.

Communications update:

Noted a Kim Hill RNZ piece on fraud in the generics industry aired over the weekend. Nicole Bremmer from TVNZ has placed a media query in relation to this. To be referred to Medsafe as all Qs are regulatory matters.

Update from Medsafe re adverse event reports:

Meeting scheduled for 13 March 2020.

Lamotrigine data update:

Ashton providing a weekly update of the tracker.

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Lamotrigine-Tracker

Review:

Noted meetings have been arranged with key staff and the independent reviewer. Information regarding the review has been placed on the web site. A clinical advisor has also been appointed (Matthew Doogue, Clinical Pharmacologist CDHB).

Response to coroner

Noted that the response to the coroner has been signed off.

8. **Action items**

1. Adam, Adrienne and Jane to develop communications to support the end of the widened EC application process
2. Adrienne to follow up churn data
3. Agenda further discussions on ongoing management of approved EC applications

Lamotrigine Implementation Project Team

Meeting held 9 March 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Andrew Oliver, Senior Therapeutic Group Manager
Geraldine MacGibbon, Manager Pharmaceutical Funding
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Jayne Watkins, Senior Adviser/Team Leader
Lisa Williams, Director of Operations
Peter Murray, Deputy Medical Director

MINUTE

	Subject	**Reference**

1. **Review of minutes from 24 February 2020:**
   - Communications plan for ending of widened access had been developed
   - Additional request placed for patient churn data

2. **EC Update:**
   - Received 2270
   - Approved 2124
   - Declined 43
   - Withdrawn 7
   - Under assessment 94

   Noted that 35 were currently being processed i.e. technically approved, would reflect this in the approved numbers on the web site.

   Communications and engagement plan for the ending of widened access currently with Sarah F and Lisa for approval. This will be revisited in a two weeks' time. At current volumes approvals can be managed utilising internal resources. Any amendment to the Mylan agreement to be examined when a firm date for ending widened access is decided.

   In relation to ongoing management, switching current exp numbers to chem numbers is not possible. However, exp numbers do not carry validation on the dose or pharmacy. Jane and Adam to develop a communication to pharmacy noting that these requirements will be relaxed for lamotrigine and claims for different dosages or dispensing at different pharmacies will be permitted.

   Noted that there is potential to include a pop up in Toniq pharmacy software alerting pharmacists of this, less likely to be able to include in Rx. One.

3. **Media and communications:**

Noted media queries in relation to reporting of a sixth fatality. Have worked to get safety messages included in coverage.

Volume of enquires is declining.

4. **Medsafe and CARM reporting**

Received notification of sixth fatality from Medsafe post media coverage. Noted that there are 191 reports to Medsafe relating to lamotrigine 171 identifying Logem. Meeting scheduled for 13 March.

5. **Independent review**

Staff had meet with external reviewer last week. Process went well. Noted a number of follow up questions to be completed and complied by legal.

6. **Data update**

Noted the latest data indicates 11,872 unique patients since May 2019, however, this total would include new initiations since October 2019 not just those that have changed brands.

7. **Action items**

1. Jane/Adam to write communication to pharmacy regarding relaxing dose and nominated pharmacy requirements
2. Jayne to further investigate possibility of software pop ups for [pharmacy
3. Withheld under section 9(2)(h)

Lamotrigine Implementation Project Team

Meeting held 31 March 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Geraldine MacGibbon, Manager Pharmaceutical Funding
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Jayne Watkins, Senior Adviser/Team Leader
Peter Murray, Deputy Medical Director

MINUTE

Subject **Reference**

1. **Review of minutes from 9 March 2020:**
   - Noted relaxation of nominated pharmacy and dose communicated

2. **EC Update:**
   - Received 2365
   - Approved 2266
   - Declined 50
     Withdrawn 7
   - Under assessment 40

   Noted that volumes decreasing and manageable.

   Jayne to update EC form and website to note that previous dispensing data would be verified.

   Agreed to delay ending widened access.

3. **Media and communications:**
   No coverage.

4. **Medsafe and CARM reporting**
   Adam to email Medsafe to see if there is an update.

5. **Independent review**
   Draft due to PHARMAC today, with feedback mid April, finalisation end of April. May be some slippage.

6. **Mylan contract**
   Jayne to update Mylan on EC numbers.

   Adrienne and Graham to work on an amendment letter to Mylan reflect principles of alternative brand arrangement in light of the widened EC process.

7. **OIAs**

Data had been released to Peter Bergin for SUDEP study and he was happy with this

Withheld under section 9(2)(a) OIA regarding correspondence with Southland DHB in peer review by 3 April.

Lamotrigine Implementation Project Team

Meeting held 20 April 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin Senior TGM/Team Leader
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Jayne Watkins, Senior Adviser/Team Leader
Lisa Williams, Director of Operations
Peter Murray, Deputy Medical Director

MINUTE

Subject **Reference**

1 **Review of minutes from 31 March 2020:**

- Noted relaxation of nominated pharmacy and dose communicated

2. **EC Update:**

Received 2,411
Approved 2,324
Declined 64
Withdrawn 6
Under assessment 12

No further work on ceasing widened access at this stage

Update web site and form to note that letter to Dr Sharpe is with Ken for approval Medsafe to review

Web site and form to be updated noting that dispensing history would be checked.

3 **Media and communications:**

No coverage.

4 **Medsafe and CARM reporting**

Adrienne and Adam met with Medsafe they do not have access to CARM databases and could not update. Happy to talk to Dr Sharpe re regulatory approvals and safety

5. **Independent review**

Access to Dr Matt Doogue meant that report was likely to finalised shortly and to PHARMAC for a review

6. **Mylan contract**

Jayne to update on EC numbers to suppliers

Graham and Adrienne to work on amendment offline

Lamotrigine Implementation Project Team

Meeting held 4 May 2020

Attendees: Adam McRae, Implementation Lead (Project Manager)
Adrienne Martin Senior TGM/Team Leader
Andrew Oliver, Senior TGM
Graham Beever, General Counsel
Jane Wright, Senior Communications Adviser
Janet Mackay, Manager, Implementation Programmes
Jayne Watkins, Senior Adviser/Team Leader
Lisa Williams, Director of Operations

MINUTE

Subject **Reference**

1. **Review of minutes from 20 April 2020:**
   - Noted relaxation of nominated pharmacy and dose communicated
2. **EC Update:**
   - Received 2,444
   - Approved 2,346
   - Declined 68
   - Withdrawn 7
   - Under assessment 17
   - More information 6
3. **Media and communications:**

   Nil.
4. **Medsafe and CARM reporting**

   Nil.
5. **Independent review**

   To be examined by the board, process to respond to concerns raised but not specific recommendations.

   Need to receive final paper this week or next.

   CAC/PTAC involvement at which time.

   To be provided to the Chief Coroner.

   Release to be sequenced with the select committee (potentially a week or two within the board meeting, coms plan being drafted).
6. **Mylan contract**

   Legal has drafted a side letter alongside the Mylan agreement. LW to be a signatory. AM to discuss with Mylan.