PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

15 February 2023

Dr Fiona Imlach
Co-founder
Migraine Foundation Aotearoa New Zealand
69 Bay Road
Glendowie
Auckland

Via email: fiona@migrainefoundation.org.nz
CC: sarah@migrainefoundation.org.nz suzanne@migrainefoundation.org.nz

Dear Fiona

Thank you for your letter dated 20 January 2023 on behalf of the Migraine Foundation Aotearoa New Zealand, and specialists Dr Pyari Bose, Dr Calvin Chan, Dr Desiree Fernandez, and Dr Rosamund Hill.

We appreciate you taking the time to write to us to address your concerns regarding the process to date of the erenumab funding application, clinical advice process, and further consideration of galcanezumab.

Referral to Neurological Advisory Committee

We appreciate the concerns you have raised regarding the time that will have elapsed between the Pharmacology and Therapeutics Advisory Committee's (PTAC) review of the erenumab application and the next Neurological Advisory Committee meeting. We acknowledge that this delay is less than ideal and understand your concerns. As previously communicated, we do intend to hold a meeting for the Committee in 2023 and we will communicate with you the timing of this once it is scheduled. With the exception of the PTAC and the Cancer Treatments Advisory Committee meetings, the meetings of all of our Specialist Advisory Committees are generally organised one quarter in advance, as many factors, both internal and external, can influence both the scheduling and the number of papers that can be reviewed at any one meeting.

Over the last two years many Committee meetings have either been delayed or have been held virtually for reasons that have predominantly arisen as a direct and indirect result of the COVID-19 pandemic. Notably, we always need to work around the availability of our advisors and additionally, internal staff capacity has been a stretched resource over this time. Those meetings that were required to be held virtually also had to have shortened agendas to better accommodate those attending, which meant fewer applications could be reviewed over this time. Unfortunately, the October 2021 Neurological Subcommittee meeting was one of several meetings affected in this way.

We are now trying very hard to increase the frequency of our meetings across all 22 of our Committees to catch-up with the delays experienced regarding the assessment of applications affected and we are equally keen to improve the efficiency of this process in general.

The journey of any individual application through the assessment process can differ, depending on the nature of the application, the timing of meetings, and whether more than one Advisory Committee needs to review it. Sometimes, for example, the evidence supporting an application might be reviewed and appraised by PTAC before it is reviewed by a Specialist Advisory Committee in order to expedite the assessment process.

Erenumab for the treatment of episodic migraine

In PTAC's 2021 consideration of erenumab, it reviewed clinical evidence regarding the use of erenumab for episodic migraine, and it also made comments in its 2022 record regarding this indication. As you are aware, this second consideration included a request for advice from the Neurological Advisory Committee.

We ensure that up to date evidence is reviewed by our clinical advisors in a number of ways. Including, but not limited to:

- Pharmac staff, in preparation for clinical advice meetings, collate relevant documentation for the Committee regarding the application. This includes an updated literature search which is repeated if there is any delay from receipt of the application, or in the timing of review between Committees.

- We provide information from the original funding application and any further information reviewed to date.

- Committee members also do their own research in preparation for the meeting to ensure that relevant information is considered, this often includes discussing elements with relevant colleagues.

- Meetings between Pharmac staff and the applicant are offered to discuss the application in further detail.

As with all applications, these actions will be taken to ensure that the Neurological Advisory Committee has all relevant information when they review the application for erenumab for episodic migraine.

In addition, Pharmac is currently working to strengthen its collaboration with consumers and consumer groups to ensure that the consumer voice is better heard throughout our processes, and we are actively looking at ways of how to best incorporate this into the funding application assessment process. In the interim, until this is formalised, we would value meeting with you ahead of any Committee meetings to enhance our understanding of the lived experience for those with episodic and chronic migraine. Alternatively we would be happy to receive by email any further information pertaining to this application that you consider important that the Neurological Advisory Committee should consider, that has not been considered to date by PTAC [ie. noted in the records].

Process for seeking clinical advice

We appreciate your concerns regarding the lack of representation of members with a special interest in migraine or are migraine and headache specialists. To ensure that our Advisory Committees and Groups remain as versatile and responsive as possible to the wide range of applications they are asked to review, or clinical advice they are asked to provide, we try to

balance the membership so that it includes advisors who have both clinical expertise in the wider therapeutic area as well as the critical appraisal skills needed to review the supporting evidence. In addition, we try to ensure there is a breadth of representation and experience from health practitioners working across the sector and we are also looking to increase diversity within the wider Committee membership wherever possible.

We are always interested in hearing from senior healthcare professionals who might be interested in joining our Specialist Advisory Committees when vacancies arise.

Additionally, we are open to meeting with, or corresponding with health care professionals regarding the migraine treatment paradigm ahead of the Committee meeting.

Migraine language

Thank you for highlighting the issue with the terminology used in the August 2022 PTAC record regarding “acute” (sic) and episodic migraine. We always appreciate feedback on such matters and we will work to ensure appropriate and accurate language is used in the future.

Other Advisory Committee referral

As you have noted, in its 2021 review PTAC recommended that in addition to the Neurological Advisory Committee, Pharmac could seek further advice from the Analgesics Advisory Committee (previously Subcommittee) regarding the application for erenumab for migraine, the needs of patients with chronic headache, and the treatment paradigm for patients with chronic headache. We had previously received correspondence from the New Zealand Pain Society in support of this funding application, which likely influenced PTAC’s consideration to have the Analgesics Advisory Committee review the application at this time.

Pharmac’s current plans are to seek further advice on the erenumab application solely from the Neurological Advisory Committee as we believe that the advice received from this Committee will be sufficient to cover the points raised by PTAC and facilitate our assessment process so that erenumab can be ranked as an option for investment. Although the application may be referred to the Analgesic Advisory Committee at a future date, we anticipate this will be for noting by this Committee only, rather than for full review.

We do not anticipate this would result in further delays to the progression of the funding application.

Galcanezumab for treatment of episodic migraine and the process for its assessment

We are happy to consider galcanezumab for the treatment of episodic migraine as well as chronic migraine. Generally, when assessing an additional indication, we would require a new funding application. However, we are aware that in your funding application for galcanezumab for chronic migraine you also included clinical trials for its use in episodic migraine, so you will not need to submit a new full application.

We have accordingly updated the proposals on our public Application Tracker to reflect the additional indication. You will see that there are now two separate proposals for the two indications: https://connect.pharmac.govt.nz/apptracker/s/global-search/Galcanezumab

We would welcome a meeting with you to discuss the lived experience of people with episodic migraine. You are also welcome to submit any further information you would like to be considered in the assessment of galcanezumab for episodic migraine as ‘additional information’ to your original application. You can find more information on how to do this here: https://pharmac.govt.nz/assets/PharmConnect-Adding-Information-to-a-submitted-application.pdf.

We have also been in contact with the supplier (Eli Lily) around whether it has any further information which could be useful for the assessment of this application. Although we have not yet received this information from them, we will be sure to follow up with Eli-Lilly prior to seeking clinical advice on this application.

The application for galcanezumab will go through our usual process. We appreciate your concerns regarding the timeframe for this, however we will endeavor to keep you closely informed along the way.

Closing

We hope this letter is useful. If you have further questions regarding the funding process or these specific funding applications, please let me know. As highlighted above we would be happy to meet with you.

Alternatively, if you feel that this response has not fully addressed your concerns regarding our processes, you can make a formal complaint. More information about this is available on our website here: https://pharmac.govt.nz/about/contact/making-a-complaint/

Again, thank you for your letter and raising your concerns with us.

Yours sincerely

Dr David Hughes
Chief Medical Officer