Pharmac Consumer Workshop 1: Migraine Foundation Aotearoa New Zealand

7 November 2024

This summary was prepared by Migraine Foundation Aotearoa New Zealand for the first of two Pharmac Consumer Workshops, where we were invited to prepare a 7-minute kōrero (along with 28 other consumer groups) on the key areas that affect our organisation and its relationship with Pharmac, for example (but not limited to) engagement, the funding journey, prioritisation, transparency and decision-making processes.

Background

Migraine Foundation Aotearoa New Zealand (MFANZ)

Founded in 2022, we are a registered charity run solely by volunteers. MFANZ is the only migraine charity in New Zealand. Our mission is to raise awareness of the impact of migraine disease and support people living with migraine in Aotearoa New Zealand (NZ).

What is migraine?

Migraine is a disabling, neurological condition with a genetic basis. It usually presents as a moderate to severe headache affecting one side of the head, associated with sensitivity to light, sound, smell and touch, and/or nausea and vomiting. Other symptoms, occurring before, during and after attacks, include fatigue, brain fog, neck stiffness and mood changes.

Migraine disease affects 1 in 7 New Zealanders, an estimated 753,000 individuals in 2021. Around 10% of people with migraine (or 1-2% of the population) are estimated to have chronic migraine, where headache occurs on 15 days or more per month. If headache is less frequent, this is known as episodic migraine.

Migraine is the top cause of disability amongst all neurological conditions. Migraine can affect people's ability to work, study, progress in their careers and engage in social activities and family life.

Treatment for migraine

Acute treatment is used to manage migraine attacks when they occur. Simple analgesia (paracetamol and non-steroidal anti-inflammatory drugs) and triptans (migraine-specific acute medication) are mainstays of treatment. Opioids are not recommended and these, as well as

excessive use of other acute treatments, can cause a medication overuse headache, which is a chronic disabling headache.

When migraine attacks are frequent and severe, **preventive medications** are used. Up until 2018, the only preventive medications available were drugs developed for other conditions (such as depression, epilepsy and hypertension) which commonly cause side effects and are only effective in 50% of people. Since 2019, a range of new, migraine-specific medications have come to market, targeting a neuropeptide (calcitonin gene-related peptide, CGRP) that causes migraine attacks. These are safer, more effective and have fewer side effects than the older medications.

Three of these are now available in NZ. Erenumab (Aimovig) and galcanezumab (Emgality) are monoclonal antibodies administered subcutaneously by an auto-injector pen once a month. Atogepant (Aquipta) is an oral tablet taken daily, of a class known as the gepants. All are migraine preventive medications.

Key areas affecting our organisation and its relationship with Pharmac

Positive aspects of Pharmac's processes

Consumer applications to Pharmac

The pharmaceutical company Eli Lilly brought Emgality to NZ in 2022 but did not make an application to Pharmac or make any commitment to doing this. This shows how even well-resourced pharmaceutical companies do not want to engage with the Pharmac process. However, MFANZ was able to put in a consumer application.

Consumer involvement in Committee meetings

MFANZ was invited to present to the Neurological Advisory Committee after we made the application for Emgality. MFANZ provided patient stories, evidence from a survey we ran in NZ and facilitated expert input from a headache specialist.

Parallel Medsafe and Pharmac applications

The ability for pharmaceutical companies to apply to Medsafe and Pharmac simultaneously, was implemented in 2023. This meant that Aquipta was assessed along with the two other migraine medications by the Neurological Advisory Committee even before Medsafe approval (which was granted several months later). Without this, there would have been a long delay in accessibility in NZ, given the infrequency of these meetings.

Areas for improvement

All of the issues around Pharmac's processes contribute to the problem we have in NZ of pharmaceutical companies not even bringing their drugs to our market. It is not only that we are a small market, it is because of the perception and/or reality that this is a difficult, time consuming and prolonged process without any guarantee of a positive outcome.

The Options for Investment (OFI) list

The OFI is a major root of the issues that Pharmac has around prioritisation, transparency and consumer engagement. This cannot be ignored as out of scope of any review of Pharmac. The issue is not primarily with Pharmac but with the Government's long-standing under-funding and

under-valuing the importance of investing in treatments, to save lives, reduce disability, improve quality of life and productivity and prevent disease and disease progression.

If Pharmac has assessed a medication as being cost-effective and beneficial, the drug should be funded and made available to consumers. The OFI is fundamental to the reason why new medications are not available or funded in NZ and thousands of Kiwis are missing out on beneficial treatments that are standard of care in other countries we like to compare ourselves with.

The OFI is increasing inequities in access. For example, there are now three anti-CGRP migraine preventive medications available in NZ. All of them are on the OFI but have not been progressed to funding. These cost between $300-700 per month. People who can afford to pay for these out of pocket are now using these medications. Many more are unable to afford these and many of these are those who may benefit the most, such as people who are unable to work because of migraine.

Pharmac needs to actively solicit and provide evidence to the Minister of Health that more funding is needed for it to fulfill its purpose of delivering the best health outcomes for New Zealanders.

Appropriate expertise in Committee meetings

Pharmac needs to ensure that specialists with expertise in particular areas are included in the consideration of applications, even within specialist committees but particularly for Pharmacology and Therapeutics Advisory Committee (PTAC) meetings.

For example, the PTAC meeting minutes from 19-20 August 2021, which considered the application of erenumab for migraine prevention, contained significant errors about migraine due to lack of expertise on the Committee.[1] They made incorrect statements about migraine prevalence and lack of data on migraine in Māori and Pacific in NZ. They failed to consider the gender inequity of migraine disease and the unequal impact on working-age people. They recommended restricting erenumab to only those with chronic migraine, without providing a justification or considering the evidence for this. They also made other unjustified and unsubstantiated comments around the capability of GPs to manage monoclonal antibody treatments and disposal of injector devices which may have contributed to their recommendation to fund erenumab at a **low priority** for chronic migraine only. Note that subsequently, the Neurological Advisory Committee recommended funding erenumab at **high priority,** for both episodic and chronic migraine.

Additional expertise can be needed even within the specialist committees. When the Neurological Advisory Committee considered three migraine preventive medication applications in September 2023, they benefited from being able to ask questions from a headache specialist who had experience in using these medications. Not all neurologists have an interest or particular expertise in headache and migraine, which can lead to poor decision making. Please also see our feedback to PTAC for discussion on this.[2]

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[1] https://migrainefoundation.org.nz/wp-content/uploads/2024/02/Feedback-from-MFANZ-on-ereunumab-decision_April-2022.docx-1.pdf

[2] https://migrainefoundation.org.nz/wp-content/uploads/2024/02/MFANZ-Feedback-to-PTAC-Dec-2022.docx.pdf

Timeliness of Committee meetings

Delays in Advisory Committee meetings has led to substantial and unacceptable delays in the consideration of applications. An example:

Feb 2021 – An application for erenumab was submitted.

August 2021 – PTAC recommended funding erenumab at low priority for chronic migraine. They also considered that Pharmac could seek advice from the Neurology Subcommittee and the Analgesics Subcommittee [sic]

April 2022 – MFANZ was founded and provided feedback on the PTAC decision on erenumab, including a critique of their evidence and decision making.[1]

August 2022 – PTAC considered MFANZ's feedback and recommended that Pharmac seek advice from the Neurological Advisory Committee on erenumab.

November 2022 – MFANZ submitted an application to Pharmac for galcanezumab.

December 2022 – MFANZ provided further feedback,[2] raising concerns that the Neurological Advisory Committee did not have any future meetings scheduled and had not met since October 2021.

August 2023 – AbbVie submitted an application for atogepant.

September 2023 – Neurological Advisory Committee met to discuss all three applications (atogepant, galcanezumab and erenumab).

December 2023 – Neurological Advisory Committee published recommendation that all three of the new medications be approved for funding, at high priority, for both episodic and chronic migraine.

June 2024 – All three medications added to Pharmac's OFI.

This timeline demonstrates both the worst of Pharmac's process and the potential for it to work better. It took over 3 years for erenumab to get to the OFI, due to delayed organisation of advisory committee meetings. But it took less than a year for atogepant to reach this milestone. **MFANZ had advocated for these medications to be considered at a single meeting, for the sake of efficiency and timeliness.**

Pharmac needs to commit to regular scheduled Committee meetings and progressing applications in a more timely manner. **It should not be the responsibility of advocacy groups to monitor and request for this to happen.**

Management of 'inactive' applications

Again, this would not be an issue if we did not have the abominable OFI. Applications on the OFI can be left languishing for years with no communication about what is happening with them. On occasion Pharmac will propose to decline these applications and the process around this is obscure and protracted.

An example. As noted above, triptans are migraine-specific treatments that are the best option we have for treating migraine attacks (newer migraine-specific treatments exist but none are available

in NZ). Two triptans are available and funded in NZ (sumatriptan, as an oral tablet and an injection) and rizatriptan (a dissolvable tablet). There are seven triptans available worldwide. All triptans have slightly different actions and formulations. Longer-acting triptans (naratriptan and frovatriptan) can be used for treatment of menstrual migraine, which tends to be more severe and prolonged than other migraine attacks. Menstrual migraine only affects women. No long-acting triptans are available in NZ.

Individual triptans don't work for around 20-25% of people. Migraine treatment guidelines recommend trying several different triptans if one does not initially work. In the research literature, people with migraine are defined as 'refractory' to triptan treatment if they have not had success with three or more triptans. No one in NZ is refractory because we currently only have two triptans.

The pharmaceutical company GSK put in an application for naratriptan in **1997**.[3] Twenty-four years later, in **March 2021**, Pharmac declined this application. Naratriptan was previously available in NZ but has not been available since September 2021.

In **March 2022**, after being on Pharmac's prioritisation list **since 2013**, an application to consider additional triptans was declined by Pharmac. MFANZ was not yet in existence and did not have the opportunity to provide input into this decision. If MFANZ had been in existence, we would have raised serious concerns about the lack of transparency and poor process taken in the review of this application.

In **2007**, AstraZeneca made an application to Pharmac for zolmitriptan, which has a nasal spray formulation useful for those with migraine accompanied by severe nausea and vomiting. The application was initially declined, primarily because of cost, but also because PTAC members considered 'listing zolmitriptan nasal spray could further grow the market for antimigraine drugs.' This appeared to imply that PTAC did not consider migraine worth treating and provides yet another example of how PTAC needs to include consumer and other expert advice into its process. However, PTAC reconsidered the zolmitriptan application in **2008** after additional information was supplied, and recommended zolmitriptan to be listed if cost-neutral compared to sumatriptan. In **2013**, zolmitriptan was added to the cost-neutral or cost-saving priority list.

In **December 2023**, Pharmac proposed to decline the zolmitriptan application, justifying this because the additional triptans application had been declined in 2022. There did not appear to be any consideration of additional evidence published in the very long interim period since either application had been reviewed by a Committee. In **February 2024**, we strongly opposed the declining of this application[4] along with all four of NZ's headache specialists, but we have yet to hear the result of this.

This drawn-out and unsatisfactory process is another barrier towards being able to access beneficial medicines. In the absence of the newer acute migraine treatments that are available in other countries (gepants and ditans), we would at least like to have access to a broader range of triptans,

[3] https://connect.pharmac.govt.nz/apptracker/s/application-public/a0R2P000000OciNUAS/naratriptan

[4] https://migrainefoundation.org.nz/wp-content/uploads/2024/02/MFANZ-response-to-proposed-declining-of-inactive-application-for-zolmitriptan.docx.pdf

given that not everyone with migraine will find sumatriptan and rizatriptan effective. But that's all we have in NZ.

Lack of horizon scanning

We would also like to have access to the newer acute migraine medications in NZ and the other preventive medications that are not available here. Pharmac's passive system of waiting for applications means that it is not fulfilling its function of providing treatments that will benefit patients in NZ.

Consideration of societal costs

We support the inclusion of societal costs in Pharmac's cost-benefit considerations when assessing medications. For migraine disease, a significant cost is from lost productivity. Migraine is most common in people of working age and the impacts of migraine on employment, through being unable to work, absenteeism and presenteeism, are well known. There would be a substantial societal, as well as individual, benefit to having access to more effective migraine treatments.

Support for engagement of NGOs

We are a volunteer run group which means that when we provide feedback, or are asked to present or contribute to a day-long workshop, this means one or more of us has to take unpaid time out to prepare, consult with our community and stakeholders and turn up. All of this work, making submissions and applications, doing research to support these, reviewing and critiquing Pharmac's processes, is pro bono. Pharmac can show respect and that they value our time and expertise by listening to our feedback and acting on it. Pharmac has demonstrated they can do this by responding promptly and positively to the feedback we provided regarding the erenumab application. However, we are still waiting for a response regarding the zolmitriptan submission.

It is of serious concern that before our organisation existed, decisions were being made about migraine treatments that had no consumer input, did not appear to be based on current or relevant evidence and relied on ill-informed 'experts' who did not have expertise in migraine or headache medicine. If there is no peak body on a condition, Pharmac still has a responsibility to engage with and consider feedback from consumers, who will otherwise be seriously disadvantaged. Processes to do this in cases where there is no formal advocacy group need to be developed.

Respectful engagement also means finding out from consumer groups what is the most appropriate and suitable method for engagement, depending on factors such as volunteer time, levels of disability and capacity. This may be different for different groups and consumers but the onus is on Pharmac to accommodate these preferences.