



## MAI Advocating for Better Access to Care and Medication in Ireland

One of The Migraine Association of Ireland's goals at the start of 2021 was to open the discussion for better 'Access to Care' in Ireland for those living with migraine in conjunction with the European Migraine and Headache Association (EMHA). Unfortunately, Ireland lags way behind in the medication approval process as well as the market availability compared to our neighbouring countries in the UK and Europe. We strongly believe migraine patients in Ireland should have the same medications available to them as other countries across the pond do, and that the standard wait time for medications to be approved should be reduced significantly.

MAI's Board Member, Jeff Smith M.D. delved into this in detail at the EMHA 2021 #TogetherTalks on the 16th of June where he showed the staggering difference compared to other countries and what we could do as a nation to

improve wait times. This event came off the back of the EMHA 'Access to Care' global survey which ran over a 6-week period asking participants to take part to tell them 'How they felt the access to care and cost of care was in their country'. Following on from this The Migraine Association of Ireland created a survey to ask migraine patients multiple questions on 'How they viewed the access to care and medication in Ireland'.

**A total of 83 participants** took part in the MAI survey. We asked **7 questions in total** around access to care, treatments and medications available in Ireland compared to other countries. Questions were targeted at those suffering from **episodic and chronic migraine**. We also **wanted to gain feedback** from migraine sufferers, therefore, we left some questions open to comment, while also having scored questions to gain a consensus to how those living with migraine feel about



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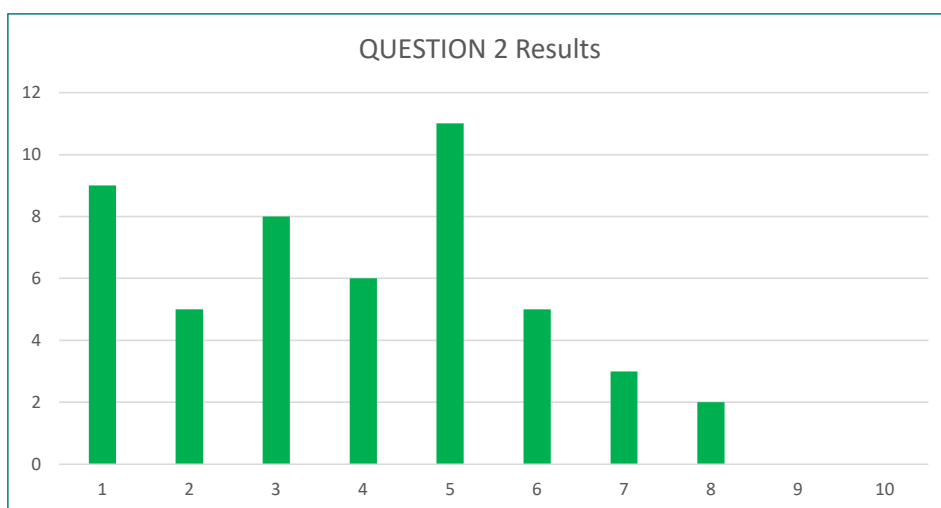
access to care in Ireland overall. The **results** are as follows...

- 44% stated they have episodic migraine, 56% suffer with chronic migraine.
- When asked how you would rate treatment options available in Ireland (1 being the lowest, 10 being the highest), most participants scored 5. The second highest score was 1, the remaining high scores all fell under 5 showing a lack of satisfaction overall.
- When asked how you would rate medication options available in Ireland, most participants scored 5. The second

highest scores were 3 and 4. Again, most of the high scores were on the lower side of the scale.

- When asked how you would rate treatment options for migraine in Ireland compared to other countries, most participants scored 5. Second to that high score was 2.
- When asked do you think Ireland is far behind other countries in relation to treatment/medication for migraine, 82% said yes.
- When asked what needs to happen to improve treatment options in Ireland, we had an array of responses suggesting better access to care, treatments, and medication options. Multiple participants stated they had to travel the UK for treatment, more access to Anti-CGRP drugs, more regular clinic times, more access to medications overall as it can be trial and error for those living with migraine to see what works for them and more access to devices to name a few.
- Lastly, we asked if there were any further comments our participants may like to add. Most said there needs to more awareness around how debilitating migraine is, GPs should be further educated in this area, chronic migraine should be put on the disability list and to quote one participant, "I honestly feel Ireland is way behind the rest of the western world in the acknowledgement and treatments available for migraine sufferers.

The conclusion from this survey is most participants view Ireland's access to care for migraine as lacking in much needed resources, medical professionals specialising in migraine, GPs with a full



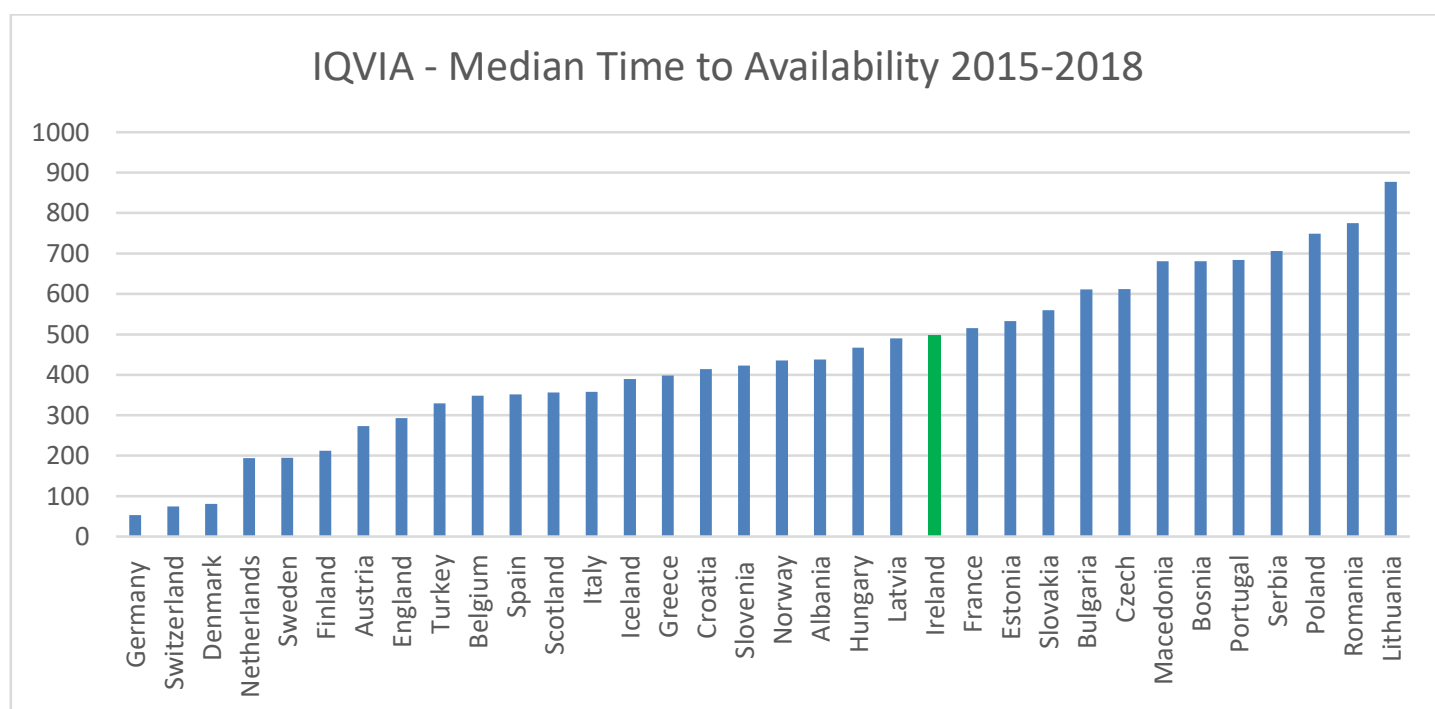
understanding of migraine, facilities nationwide and options for kids as well as adults. In addition, most feel waiting lists are too long, and this has a huge impact on their life overall. The word **'MORE'** was used in nearly every answer which further proves that migraineurs in Ireland feel they do not have enough options when it comes to care and medication to have the quality of life they deserve. The consensus is that Ireland is significantly behind other countries in relation to treatment options and access to medication for Migraine.

*It is vital to note that we had a lot of positive feedback from participants about migraine clinics, specialists, GPs, and pharmacists in Ireland stating that they felt supported and have learned so much from them on how to try to manage their migraine.*

After the results were in for both surveys the EMHA in conjunction with MAI held

the #TogetherTalks online webinar on 'Better Access to Care'. As mentioned previously, Jeff Smith M.D. spoke at this event after his in-depth research into Ireland's access to medications process. Jeff is a physician by training and has worked for pharmaceutical companies for the last thirty years, most recently with Alder Biopharmaceuticals who have developed one of the anti-CGRP medications. The company was recently taken over by Lundbeck which led to Jeff's retirement from the company, and he is now a Board member of MAI. The talk was moderated by Sadhbh Armstrong, MAI Regional Development Officer.

Jeff wasted no time in stating the facts and gave a highly engaging presentation covering all areas taking Ireland v-s Belgium for example. In Ireland, the actual medication approval process takes just under 550 days, whereas Belgium's actual medication approval process takes just over 200 days from start to finish.





## **Ireland's medication approval process timeframe is broken down as follows:**

NCPE Rapid Review and NCPE HTA takes 242 days

HSE price discussions and drugs review and approval takes 307 days

Totalling 549 days

## **Belgium's medication approval process timeframe is broken down as follows:**

INAMI-RIZIV Assessment, CRM/CTG Assessment, Minister Recommendation and Post-minister Recommendation takes 210 days in total.

Granted, this is an example of a highly efficient approval process in Belgium's case, but Ireland falls way behind most EU countries in the approval process. In an IQVIA study on the 'Median time to availability 2015-2018' which included the UK at the time, Ireland is as low as 13 on the list of the number of days for medication approval. See the graph on previous page.

## **The current drugs available for migraine in Ireland are:**

**Acute Treatment** – Triptans, Analgesics (e.g., Aspirin, Paracetamol, Non-steroid anti-inflammatory drugs (e.g., ibuprofen)

**Prevention of migraine** – Beta blockers (e.g., Propranolol), Anti-depressants (e.g., Amitriptyline), Anti-epileptics (e.g., topiramate), Calcium channel blockers (e.g., nifedipine), Serotonin reuptake inhibitors (e.g., fluoxetine), Botulinum toxin.

## **Anti-CGRPs and other drugs waiting for approval and to be made available in Ireland are:**

Erenumab – By Novartis

Fremanezumab (Ajovy) – By Teva

Galcanezumab – By Eli Lilly

Eptinezumab – By Lundbeck

Gepants and Ditans

## **What is CGRP and what does it do?**

- It is a substance that is released in the trigeminal nerve.
- It spikes during migraine.
- CGRP dilates blood vessels.
- Degrades mast cells (cells which control inflammation during allergic reactions)
- Creates an inflammatory fluid in the blood vessels.

There are 2 main approaches for targeting CGRP in migraine: large molecule monoclonal antibodies given by injection to prevent attacks and small molecule absorbable tablets for acute and possibly preventative treatment. Medications act by either blocking a receptor called the calcitonin gene-related peptide receptor

(CGRP-R), or binding to the substance (CGRP) and not allowing it to reach the nerve. For more information see Prof. Peter Goadsby's Interview from the European Academy of Neurology Congress 2016 on our website [www.migraine.ie](http://www.migraine.ie)

Several pharmaceutical companies are involved in the manufacture of anti-CGRP and other drugs. The main ones are Amgen/Novartis Inc, Teva, Eli Lilly, Lundbeck, Allergan and Biohaven Pharmaceuticals.

## **Erenumab – By Novartis**

The Marketing Authorisation was granted in Ireland in the Summer 2018 and Novartis is currently awaiting the results of the Health Technology Assessment for the Irish licensing application. The Migraine Association wrote the supporting patient organisation document as part of this process.

### *Current Access:*

Erenumab was available on a managed access programme, but this was closed to new patients in June 2019.

### *NCPE Verdict:*

The National Centre for Pharmacoeconomics (NCPE) has recommended Erenumab for chronic migraine only – we are still awaiting the HSE verdict.

## **Fremanezumab (Ajovy) – By Teva**

Teva's version of anti-CGRP medication, Fremanezumab (Ajovy) became available on a 'Free of Charge' or 'Compassionate Grounds' programme, which is like the managed access programme, from July 2019. New patients can only access Fremanezumab through their Neurologists.

Teva is also awaiting the results of the Health Technology Assessment for the Irish licensing application. The Migraine Association wrote the supporting patient organisation document as part of this process also.

### *Current Access:*

Patients can only access Fremanezumab through their Neurologist as explained above, after having failed three or more preventative medications. Other criteria may also apply.

### *NCPE Verdict:*

The NCPE has recommended Fremanezumab for both Episodic and Chronic Migraine – we are still awaiting the HSE verdict.

## **Galcanezumab – By Eli Lilly**

Eli Lilly's Galcanezumab is next, but we have no news as to its availability yet. Galcanezumab has been granted FDA approval in the US to treat episodic Cluster Headache in adults. So far it is the only one of the new treatments to be approved for Cluster Headache.

## *NCPE Verdict:*

They are currently awaiting submissions of HTAs which will be looking at the efficacy of the medication and cost effectiveness against current treatments.

## **Eptinezumab – By Lundbeck**

Eptinezumab (Yvepti) by Lundbeck has yet to be submitted to the NCPE for evaluation and authorisation.

## **Gepants and Ditans**

Gepants are 'cousins' of Erenumab, Fremanezumab, etc., they are small molecule drugs which block the CGRP receptor and are effective at relieving migraine. They are currently only available in the US and as acute treatments. Gepants rapidly penetrate the brain so work quickly. Studies on the preventative properties of Gepants are ongoing.

The FDA in the US has authorised two Gepants, but they have not arrived in Ireland yet. These are:

- Utopgepant (Ubrelvy)
- Rimegepant (Nurtec ODT)

Lasmiditan (Reyvow) by Eli Lilly, is not an anti-CGRP medication but the first of a new group of headache medicines that are called a "Ditan". It is an Antagonist at the 5-HT 1F serotonin receptor, whereas Triptans work on the 5-HT 1B and 5-HT 1D receptors. Like a Triptan, Lasmiditan can stop a migraine when taken at the appropriate time, but unlike a Triptan, it is thought to decrease stimulation of the trigeminal system and treat migraine pain **without causing vasoconstriction** so may be helpful for people for whom Triptans are contraindicated due to cardiovascular problems. Lasmiditan is not available in Ireland yet.

For further information and updates on the latest information on the availability of the new Anti-CGRP medications in Ireland keep an eye on our website. For general updates you can go to <https://www.cgrpforum.org/>.

While we understand that many other factors come into play when it comes to medication approvals and better access to care, it is simply not acceptable for Ireland to be so far behind neighbouring countries and to not have the same options available to those suffering with migraine. Currently there is no law for medication approval in Ireland, whereas in the UK if a medication is not approved by the said deadline, the parties are held accountable and fined. This type of process helps push approval along faster for obvious reasons.

The Migraine Association of Ireland would like to see a positive change in the process overall that will reduce the timeframe for medication approval and availability in Ireland significantly and in turn help those living with migraine have a better quality of life.

For more information, visit [migraine.ie](http://migraine.ie)