



## **Epilepsy Ireland Valproate Survey Dec 2016**

Epilepsy Ireland conducted an online survey on valproate awareness between November and December 2016.

The aim of the survey was to determine the levels of awareness around the restrictions on valproate use; the risks involved for women of child-bearing potential and the level of communication taking place between patients and their medical teams on the issue.

Epilepsy Ireland believes that all patients who could potentially be affected by the serious side-effects of valproate should be informed of the risks by their medical team and that informed decisions should be taken on their future epilepsy treatment.

Similar surveys had been previously conducted in both April and November 2015. People who had taken the earlier survey in November 2015 could still take this survey if they so wished.

The survey was restricted to women with epilepsy taking valproate and parents of children taking valproate. There were 28 valid respondents, a lower number than previous surveys which were completed by 131 respondents (April 2015) and 62 respondents (November 2015).

## Results

29 responses were received. One was disqualified for not meeting the criteria for taking part (not female/ not parent of female child), leaving 28 valid responses. The tables below show the data from the December 2016 survey along with comparative data from the previous surveys where possible.

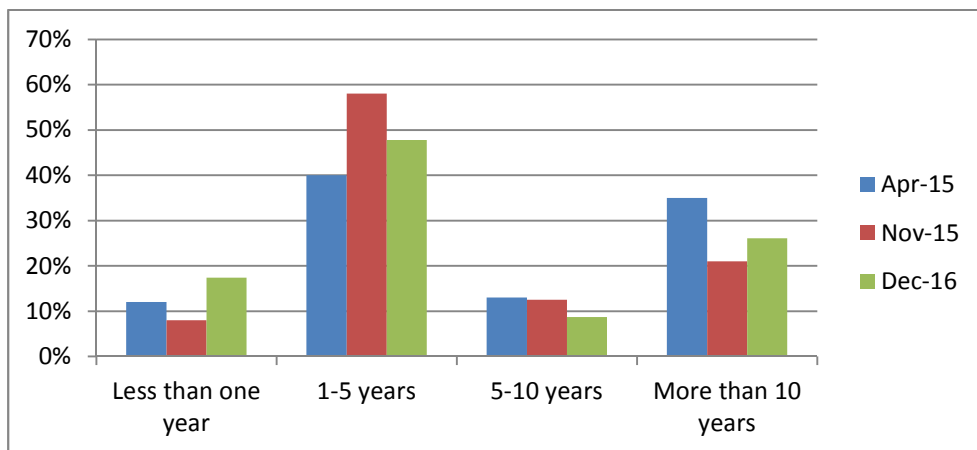
### Age Profile

Age profile	April 2015	Nov. 2015	Dec. 2016
0-12	38.9%	41.7%	<b>17.4%</b>
13-45	50.4%	47.9%	<b>73.9%</b>
46-65	9.9%	10.4%	<b>8.7%</b>
65+	0.8%	0.0%	<b>0.0%</b>

### For how long have you/ your child been taking the drug Valproate?

The majority of respondents were either on the drug for between 1-5 years or for more than 10 years. This was consistent with previous surveys

	April 2015	Nov. 2015	Dec. 2016
Less than one year	12%	8%	<b>17.4%</b>
1-5 years	40%	58%	<b>47.8%</b>
5-10 years	13%	12.50%	<b>8.7%</b>
More than 10 years	35%	21%	<b>26.1%</b>



### Did you take part in our previous surveys on the use of valproate?

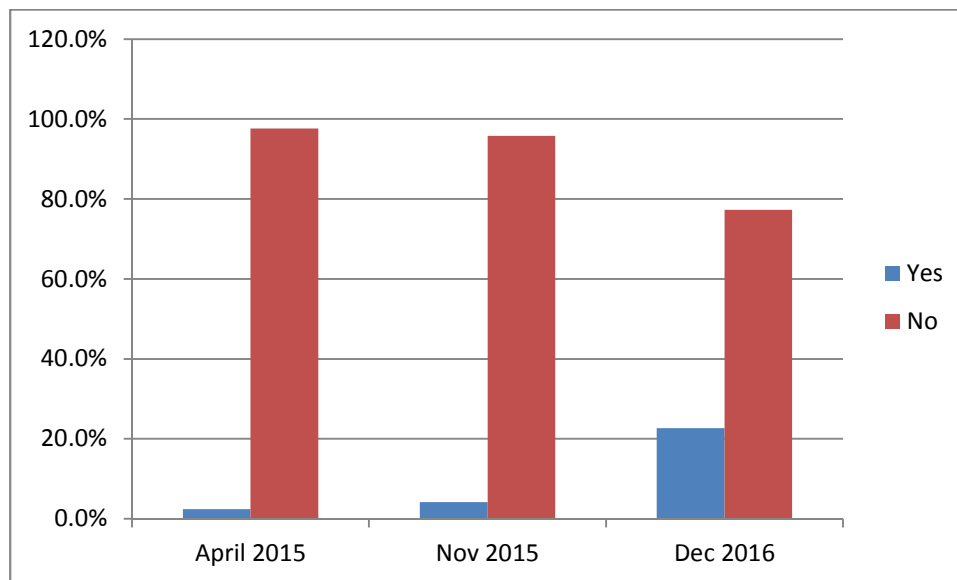
Only 4% of the respondents had taken the survey before.

Answer Options	Response Percent	Response Count
Yes	4.3%	1
No	78.3%	18
Not sure	17.4%	4

**Have you received a letter or phone call from your medical professional/ team in the past year about the new restrictions on the use of Valproate in women and girls?**

The most recent survey has found a significant increase in the number of proactive communications from medical professionals on the subject with almost 1 in 4 stating they had received a letter or phone call. This is up from just 2.4% in April 2015 and 4.2% in November 2015. 50% of respondents said that the letter was received before June 2016 and 50% said afterwards. In May/ June 2016, Sanofi wrote to all HCPs informing them of the issues and including information for professionals and patients.

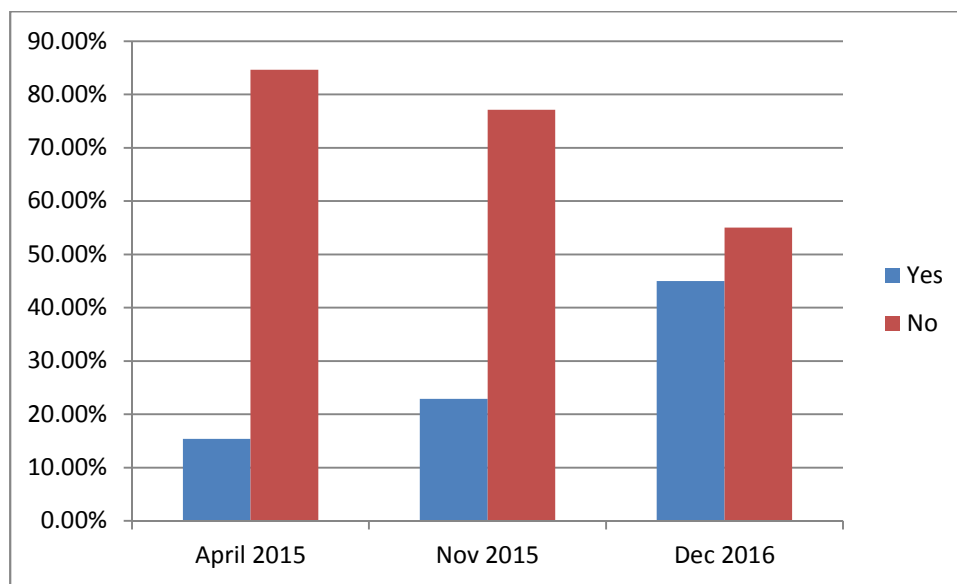
	April 2015	Nov. 2015	Dec. 2016
Yes	2.4%	4.2%	<b>22.7%</b>
No	97.6%	95.8%	<b>77.3%</b>



**Has your medical professional/ team scheduled an appointment to review your use of Valproate since December 2014?**

Again there is a significant increase in the number of appointments scheduled, from 15% and 23% of respondents in previous surveys to 45% in December 2016. 37.5% of appointments had been scheduled since June 2016.

	April 2015	Nov. 2015	Dec. 2016
Yes	15.4%	22.9%	<b>45.0%</b>
No	84.6%	77.1%	<b>55.0%</b>



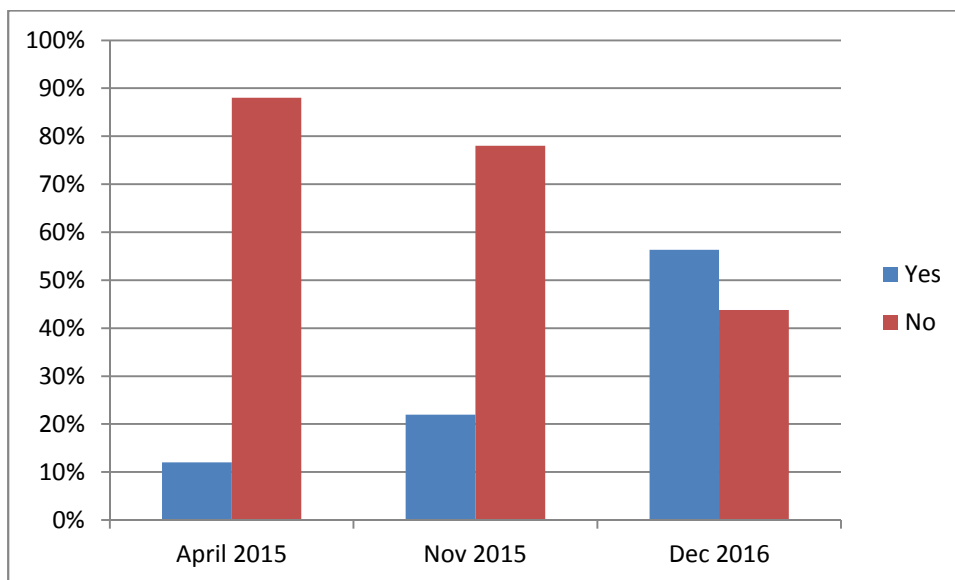
**Have you had an appointment about epilepsy with your medical professional/ team since December 2014?**

84.2% of respondents have had an appointment with their medical team since December 2014, when the European Medicines Agency issued the new restrictions on the use of valproate. This compares with 77% of in November 2015, and 43% in April 2015 and is to be expected given the longer time period. 56% of these appointments took place since June 2016.

## Did your medical professional/ team discuss the new restrictions with you at this appointment?

This is one of the key questions of the survey. The findings show that half of the respondents said Yes in November 2016 compared to just 22% in November 2015 and 11% in April 2015. While this is an encouraging finding and the first time that a majority answered in the affirmative, the fact remains that despite the distribution of HCP information and patient information materials to medical teams on two occasions, almost half of women/ parents of girls taking epilim have not had conversations with their medical team about the dangers associated with the drug.

	April 2015	Nov. 2015	Dec. 2016
Yes	11.5%	22.2%	<b>56.3%</b>
No	88.5%	77.8%	<b>43.8%</b>

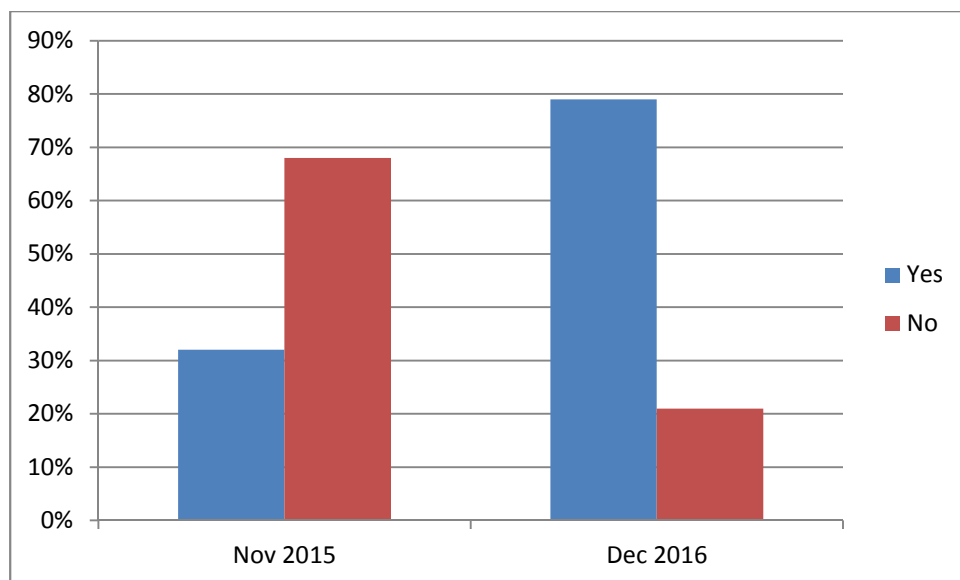


In addition, we asked what the outcome of the discussions was and received eight responses:

- Decided to remain on the drug, dosage unchanged, prescribed folic acid.
- Remain on the drug
- Drug not changed as had previously been on lamotrigine and had seizures so switched to valproate and seizure free since then. Had previously been on valproate but when having children moved to lamotrigine, had jerks and seizures so when decision to have no more children made after last seizure went back on valporate.
- Had it changed for 1.5 years to Keppra but Keppra didn't work and I asked to be put back onto epilim as nothing else has ever worked to control my epilepsy
- Kept on the same level
- We made decision to stay on epilim for now.
- I remained on the drug and the dosage
- Changed and another drug added

## Before taking this survey, were you aware of the new restrictions on the use of valproate in women and girls?

In December 2016 most respondents said they were aware of the restrictions on use of valproate, up to 79% saying 'yes' against 21% 'no'. This is a significant improvement over the previous survey (33% Yes; 67% No) especially considering that only 4% of the respondents had taken part in our previous surveys.



## Where did you hear about the restrictions?

Of the 26 respondents who qualified to answer this question, 10 had heard about it from their medical professional, 9 from Epilepsy Ireland, and 6 from media or online sources.

Answer Choices	Responses
My healthcare team (neurologist, epilepsy nurse, GP etc)	66.67% 10
Epilepsy Ireland (website, newsletter, social media, staff member, information meeting etc)	60.00% 9
From taking this survey previously	6.67% 1
From the media (Newspaper/ Radio/ Online)	40.00% 6
From somebody else in a similar situation	13.33% 2
Not sure	0.00% 0

## Key Points

- Almost 1 in 4 have received a letter or phone call from their medical team in the past year about valproate, up from just 4% and 2%.
- Almost half of respondents have had an appointment to review their use of valproate, double the rate from the previous study.
- Over half have had face to face discussions on the issue in the past two years which is a significant increase but still means that in over 40% of relevant cases, no discussions have taken place.
- Almost 8 in 10 people are now aware of the risks associated with valproate, a major improvement from 2015.
- The majority of people state that they became aware either through their HCP team or through Epilepsy Ireland, a finding consistent with previous surveys.

## Conclusions

The December 2016 survey relies on a smaller sample size than both the November 2015 and April 2015 surveys. However, the available information clearly shows that there are improvements in both awareness of the risks of valproate and in communication between patients and professionals on the issue.

There is an upward positive trend on all the key measurements we employed and this is to be welcomed.

However, given the serious potential consequences, we believe that more should and can be done to improve awareness and communication further. We want to see further improvement from 56% who state that their HCP discussed valproate risks with them at medical appointments. We believe that every woman or parent of a girl on valproate should have had discussions with their team since the EMA rulings on valproate over 2 years ago.

We also believe that every woman or parent of a girl on valproate should know the risks. Epilepsy Ireland continues to highlight the issue, as evidenced by the fact that 60% of respondents both in 2015 and 2016 said they had become aware via Epilepsy Ireland. However more needs to be done to move the 79% awareness are closer to 100%. In 2016, HSE developed excellent new information resources on valproate, which to date have only been posted online. We want to see these resources printed and distributed widely to HCPs and we want to see greater steps taken to proactively increase public awareness through the media and other available channels.