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27th February 2020

Circular 007/20

Re: Appropriate Prescribing of Pregabalin

Dear Doctor,

Please find enclosed a letter from Prof Michael Barry, National Clinical Lead, Medicines Management Programme on the appropriate prescribing of Pregabalin. You will be aware that the Medical Council have raised patient safety concerns in relation to the prescribing of Pregabalin in September 2019.

To support your self-audit, Pregablin Prescribing Data Analysis will be made available to GPs in the coming months.

Your co-operation with this matter is appreciated.

Yours faithfully,

Shaun Flanagan
Primary Care Reimbursement and Eligibility

Re: Appropriate prescribing of Pregabalin

30 January 2020

Dear Colleagues,

I am writing to you to highlight the high level of prescribing of pregabalin and importantly, the risks associated with its use. You will be aware that the Medical Council have raised patient safety concerns in relation to the prescribing of pregabalin in September 2019.

Almost 39,000 patients were in receipt of pregabalin on the GMS Scheme in December 2018. Total expenditure on this medicine on the GMS Scheme in 2018 was approximately €24.4 million.

The need for vigilance when prescribing pregabalin due to the risk of addiction, and potential for illegal diversion and medicinal misuse has been previously highlighted.¹ A risk/benefit assessment should be undertaken prior to prescribing pregabalin to ensure appropriateness and to minimise the risks of misuse, abuse and dependence.

Pregabalin is licensed for use in adults in the following therapeutic indications:

- Treatment of peripheral and central neuropathic pain
- Treatment of generalised anxiety disorder
- Adjunctive therapy in patients with partial seizures with or without secondary generalisation.

Please find enclosed a summary guidance document ***Appropriate Prescribing of Pregabalin*** to support the safe use of this medicine. A prescribing analysis report of pregabalin for patients in your practice will issue in the coming months.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,



Professor Michael Barry,
National Clinical Lead, Medicines Management Programme.
www.hse.ie/yourmedicines

¹ The Early Warning and Emerging Trends Subcommittee of the National Advisory Committee on Drugs and Alcohol (June 2016). Clinical Advisory.

Vigilance is required when prescribing pregabalin due to the risk of dependence and the potential for illegal diversion and medicinal misuse.¹

➤ The relaxant and sedative effects of pregabalin make it desirable for use outside of its three licensed indications.² Patients misusing pregabalin describe improved sociability, euphoria, relaxation and a sense of calm.³ Pregabalin may be used to enhance the euphoric effects of other drugs such as opioids.²

➤ Drug-related death figures compiled by the Health Research Board have shown an increase in deaths where pregabalin was implicated, from 14 in 2013 to 45 in 2017.⁴

The Irish Medical Council advise all doctors prescribing pregabalin to follow best practice guidelines and to **only prescribe when absolutely required** (September 2019).

Licensed Indications

Pregabalin is licensed for three therapeutic indications in adults:

- Treatment of peripheral and central neuropathic pain
- Treatment of generalised anxiety disorder
- Adjunctive therapy in patients with partial seizures with or without secondary generalisation.

The dose range is **150 mg - 600 mg** per day (in either two or three divided doses).⁵

Appropriate Prescribing

- Undertake a risk/benefit assessment prior to prescribing
- Prescribe for a trial period to ascertain if effective
- Review on a regular basis for ongoing effectiveness.

In pain management, pregabalin is licensed for the treatment of **neuropathic pain only**.

Potential for Misuse, Abuse or Dependence

➤ Exercise caution if prescribing pregabalin for patients with a history of substance abuse. **Monitor patients for symptoms of misuse, abuse or dependence.**⁵

Diversion

➤ Consider the 'street value' of pregabalin and monitor for signs of diversion e.g. requests for increased doses and quantities, early prescriptions or replacement of 'lost' prescriptions.

Withdrawal Symptoms

- Can occur following discontinuation of short-term and long-term use
- Symptoms include anxiety, convulsions, depression, diarrhoea, dizziness, flu syndrome, headache, hyperhidrosis, insomnia, nausea, nervousness and pain.⁵

Tapering Dose

Public Health England (2014) suggest a gradual dose taper:

Reduce the dose weekly by a maximum of 50 – 100 mg.⁶

Specialist advice may be required to manage patients dependent on pregabalin.

➤ Refer to www.drugs.ie to access local services provided by the Addiction Services or Drugs and Alcohol Task Forces.

Counsel Patients Initiating Treatment on:

- The risk of harm with pregabalin including dependence⁶
- The risk of potentially fatal interactions between pregabalin and alcohol, and with other central nervous system (CNS) depressants, particularly **opioids**⁷
- The effect on ability to drive or operate machinery safely⁵
- The potential for withdrawal symptoms on discontinuation.⁵

Interactions with Central Nervous System Depressants

Pregabalin has adverse effects on the CNS.

- These effects may be additive if pregabalin is taken with other CNS depressants e.g. antidepressants, antipsychotics, anxiolytics, hypnotics and opioid analgesics.⁶
- Respiratory failure and coma have been reported in patients taking pregabalin and other CNS depressants.⁵

Side-effects

Very common side-effects are:

Dizziness	Somnolence	Headache
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Common side-effects include:⁵

Confusion	Memory impairment	Sedation	Blurred vision
Vertigo	Erectile dysfunction	Oedema	Muscle cramp
Fatigue	Weight increase	Vomiting	Dry mouth
Amnesia	Increased appetite	Constipation	Nasopharyngitis
Diplopia	Flatulence	Arthralgia	Insomnia



Renal Impairment

Dosage reduction is required in patients with impaired renal function.

Dosage reduction must be individualised based on creatinine clearance (see SmPC).⁵

References: 1. Early Warning and Emerging Trends Subcommittee of the National Advisory Committee on Drugs and Alcohol (June 2016). Clinical Advisory 2. Pregabalin Fact Sheet. Accessed at www.drugs.ie/pregabalin on 12/12/2019 3. Pregabalin information. Accessed at www.drugs.ie/pregabalin on 12/12/2019 4. Health Research Board (2019). National Drug-Related Deaths Index 2008 to 2017 Data. Accessed at www.hrb.ie/publications on 12/12/2019 5. SmPC Lyrica® hard capsules. May 2019. Accessed at www.medicines.ie on 12/12/2019 6. Public Health England (2014). Advice for prescribers on the risk of the misuse of pregabalin and gabapentin 7. British National Formulary, October 2019. 8. SmPC Summary of Product Characteristics