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MEDIA RELEASE

PBS RESTRICTIONS ON EPILEPTIC DRUGS “UNSAFE AND OUTDATED”

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THE Pharmaceutical Benefits Scheme's restrictions on anti-epileptic drug prescribing promote unsafe and outdated practice, according to the authors of a Perspective published online today by the *Medical Journal of Australia*.

Professor Christian Gericke from the School of Clinical Medicine at the University of Queensland in Brisbane, and Professor Terence O'Brien, the Van Cleef Roet Professor of Medicine (Neurology) at Monash University in Melbourne and President of the Epilepsy Society of Australia, wrote that the PBS “urgently needs to update anti-epileptic drug prescribing restrictions that put patients and prescribers at risk”.

In May 2018 the European Medicines Agency banned the use of valproate to women of childbearing age for the treatment of epilepsy unless not other effective treatment is available. This follows reports and longitudinal studies showing increased, dose-related risk of fetal malformations in babies born to mothers exposed to valproate during pregnancy. Most epileptologists have avoided prescribing valproate to pregnant women, largely because two new highly effective drugs – lamotrigine and levetiracetam – were made available.

In Australia only nine anti-epileptic drugs (AEDs) are available on the PBS without prescribing restrictions – phenobarbital, phenytoin, primidone, carbamazepine, sulthiame, ethosuximide, valproate, and two types of benzodiazepines (which are usually not used as monotherapy in epilepsy).

Since 1978 new AEDs with improved safety and efficacy are listed on the PBS, but with various prescribing restrictions, the most common being that “must have failed to be controlled satisfactorily by other anti-epileptic drugs”, rendering the newer drugs as “second-line” therapies.

“This includes levetiracetam and lamotrigine which are the recommended AEDs for first-line use in new-onset focal epilepsies in the 2018 American Academy of Neurology clinical guidelines, co-developed with the American Epilepsy Society, the 2018 United Kingdom National Institute for Health and Care Excellence guidance, and the 2017 German Society for Neurology guidelines, which are also endorsed by the Swiss and Austrian Neurological Societies,” Gericke and O'Brien wrote.

In addition to the PBS restriction as a second-line drug, the PBS listing of levetiracetam only allows its use in focal epilepsies.

“This is surprising as the Pharmaceutical Benefits Advisory Committee (PBAC), the official body that makes all recommendations concerning PBS listings to the Australian Minister of Health, decided in 2008 to extend the PBS listing of levetiracetam to generalised epilepsies,” Gericke and O'Brien wrote.

“It seems that the Department of Health administration never implemented this decision and the reasons for this have not been made public.”

The Therapeutic Goods Administration Advisory Committee on Medicines recommends that physicians avoid use of valproate in women of childbearing age for all non-seizure indications; for seizure indications, consider alternatives if they exist; and, always use the lowest effective dose.

“These TGA recommendations cannot be implemented into daily prescribing practice unless the PBS restrictions on the use of levetiracetam and lamotrigine as second line drugs are lifted and levetiracetam is also made available to patients with generalised or unknown onset epilepsies as already recommended by the PBAC,” wrote Gericke and O'Brien.

“In practice, most epileptologists ignore the PBS restrictions and follow the internationally recommended prescribing guidelines. This puts the practitioner at risk of legal and financial sanctions. Australian doctors treating patients with epilepsy are therefore stuck between the proverbial rock and hard place.”

The authors recommended that the Australian Department of Health review the current PBS restrictions on AED prescribing, prioritising lifting the prescribing restrictions on levetiracetam and lamotrigine; and reviewing the restrictions on other well tolerated and effective second and third line AEDs such as zonisamide, oxcarbazepine, lacosamide and perampanel.

“This long-awaited PBS update would finally allow Australian doctors to prescribe AEDs in line with international best practice without imposing a financial burden on patients or contravening PBS regulations,” they concluded.

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