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Consultation: Proposed amendments to the Poisons Standard – referred to the Advisory Committee on Medicines Scheduling, November 2018 meeting

SEP 2018

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred for scheduling advice to the November 2018 meeting of the Advisory Committee on Medicines Scheduling. PSA's comments relate to proposed amendments to: nabiximols, racetams and nootropics.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 31,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Summary

***Nabiximols** – PSA supports the proposal to amend the Schedule 8 and Appendix D entries of nabiximols in the Poisons Standard on the basis of the overall safety profile and characteristics including low potential for dependence, misuse and abuse.*

***Racetams and nootropics** – PSA supports the proposed amendment to clarify entries relating to racetams through the creation of specific entries for each racetam substance in Schedule 4 as well as these substances being captured through a new Schedule 4 group entry for racetams.*

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 Apr 2018 – 30 Jun 2018. At: https://www.pharmacyboard.gov.au/About/Statistics.aspx

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Nabiximols

Proposed amendment

PSA understands the proposed amendment to nabiximols (and other cannabinoids cross referenced in the Poisons Standard) is to:

- down-schedule from Schedule 8 to Schedule 4, with wording of the current Schedule 8 entry revised to the effect that a buccal spray has:
    - a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of tetrahydrocannabinols per millilitre, and
    - is registered on the Australian Register of Therapeutic Goods
- delete the Item 1 entry in Appendix D
- retain current Appendix K entry.

Substance and product information

Currently, nabiximols is registered on the Australian Register of Therapeutic Goods as an oromucosal spray in a concentration of 80 mg/ml. Each millilitre corresponds to 27 mg of delta-9-tetrahydrocannabinol (THC) and 25 mg of cannbidiol (CBD) and lesser amounts of other cannabinoids (to an amount of 56 mg of total cannabinoids).[2]

Nabiximols oromucosal spray is indicated as treatment, for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.[3]

Patients are recommended to titrate their doses until an optimal dose is reached. The maximum recommended dose is 12 sprays per day.

Safety profile

The use of nabiximols oromucosal spray is not recommended in patients with serious cardiovascular disease.[4]

Adverse effects most commonly reported are mild or moderate dizziness, fatigue or fainting. These most frequently occur in the first few weeks of therapy and resolve without discontinuation

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[2] [redacted] Product Information. Version 2, p. 1. 7 Aug 2017. At: **https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2017-PI-01866-1&d=201809251016933**

[3] [redacted] oromucosal spray. ARTG ID 181978. Public summary. 10 Jul 2018. At: **http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=181978**

[4] [redacted] Product Information, op. cit., p. 7.

of treatment.[5]

Patient factors would be assessed by the relevant prescriber when considering initiation of treatment with nabiximols, and responses to treatment can be managed through monitoring of patients particularly with regards to the effects of initial doses.

Dependence, misuse or abuse

Possible intoxication effects following use of nabiximols are reported to be low and therefore dependence on nabiximols is suggested to be unlikely.[6]

It is stated[7] that nabiximols oromucosal spray used at the maximum recommended dose of up to 12 sprays per day has moderate potential for abuse. It is suggested that close monitoring is recommended if nabiximols is being considered for use by patients with a history of substance abuse. Other studies reported no evidence of addiction, abuse or misuse.[8,9]

PSA understands the classification of nabiximols in Schedule 8 in 2013 was seen to provide control over the potential for misuse and abuse.[10] However, PSA believes more recent evidence suggests the characteristics of nabiximols with regards to potential for misuse or abuse meet the scheduling factor for Schedule 4 (see table below).

Scheduling factors relating to abuse potential[11]	
Schedule 8	**Schedule 4**
The substance has as established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.	The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use.

5 ibid., p. 12.

6 ibid., p. 8.

7 ibid., p. 14.

8 Etges T, Karolia K, Grint T et al. An observational postmarketing safety registry of patients in the UK, Germany, and Switzerland who have been prescribed [redacted] (THC:CBD, nabiximols) oromucosal spray. Ther Clin Risk Manag 2016; 12:1667–75.

9 Patti F, Messina S, Solaro C et al. Efficacy and safety of cannabinoid oromucosal spray for multiple sclerosis spasticity. J Neurol Neurosurg Psychiatry 2016; 87(9):944–51.

10 Therapeutic Goods Administration. Australian Public Assessment Report for nabiximols ([redacted], Novartis Pharmaceuticals Australia Pty Limited). 27 Sep 2013. At: **https://www.tga.gov.au/sites/default/files/auspar-nabiximols-130927.pdf**

11 Australian Health Ministers' Advisory Council. Scheduling policy framework for medicines and chemicals. Version 1.0. Jan 2018. At: **https://www.tga.gov.au/sites/default/files/ahmac-scheduling-policy-framework-medicines-and-chemicals.pdf**

Product storage

Nabiximols oromucosal spray requires refrigeration during storage prior to opening for use. PSA is aware that this presents challenges at present for pharmacists in meeting storage requirements for Schedule 8 medicines.

Summary

Overall, PSA believes the proposed amendments to the Poisons Standard for nabiximols are appropriate.

Racetams and nootropics

PSA understands that currently brivaracetam, levetiracetam and piracetam are in Schedule 4 of the Poisons Standard but other racetams (nootropics), although captured as derivatives of the Schedule 4 entries of the three racetams above, are not specifically scheduled through individual entries.

PSA supports the proposed amendments as they will strengthen the way all of the racetam substances are captured in the Poisons Standard and improve clarity of entries.

PSA seeks clarification on the basis for inclusion of substances, for example, etiracetam (CAS number 33996-58-6) is not included on the list.

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