20 May 2020

Adjunct Professor Paul Brent
Chairman of Australian Advisory Committee on Medicines Scheduling
Australian Government, Department of Health
medicines.scheduling@health.gov.au

Dear Adjunct Professor Paul Brent,

RE: Poisons Standard - ACMS and Joint ACMS/ACCS meetings, June 2020

The Society of Hospital Pharmacists of Australia is the national professional organisation for more than 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals.

Thank you for the opportunity to provide feedback on the proposed TGA medicines scheduling amendments. SHPA has consulted with our General Medicine Practice Group, Geriatric Medicine Practice Group, Mental Health Practice Group, Pain Management Practice Group and Medication Safety Practice Group, and our recommendations and views are summarised below.

Cannabidiol

SHPA does not support the down-scheduling and creation of a new Schedule 3 entry for cannabidiol where cannabidiol comprises of 98% or more of the total cannabinoid content, regardless of whether the cannabidiol is plant derived or synthetic. SHPA also does not support the suggested amendments to Schedule 8 and Schedule 4 excluding cannabidiol from schedule 8 when it is a whole plant cannabis product or distillate or isolate which contains at least 98% cannabidiol and less than or equal to 0.2% tetrahydrocannabinol (THC) and including it in Schedule 4 with amended conditions.

There is a lack of robust, high quality evidence around the safety and efficacy of cannabidiol for therapeutic use. Many of the studies purporting the benefits and safety of cannabidiol, particularly in low doses, lack sufficient sample size. Other systematic reviews have shown a substantial risk of bias in many studies [1]. The lack of medical consensus, particularly around the low dose use of cannabidiol, requires that its use be restricted to situations with appropriate medical review and supervision.

Given the poor evidence base, increased access to cannabidiol products through down-scheduling would not offer any benefits to Australian patients. On the converse, increasing the availability of these products may cause patients to be more susceptible to adverse effects and drug interactions which are difficult to clinically detect without appropriate medical and pharmacy oversight, and the required clinical resources to guide clinical use of cannabidiol.

The conditions mentioned in the TGA's safety review such as anxiety, insomnia, chronic and generalised pain require treatment by a medical practitioner and thus medicines to treat these conditions are not suitable to be in Schedule 3. Greater availability and reduced monitoring of cannabidiol could mean that patients do not receive appropriate care for these conditions and instead receive a sole treatment that remains unproven.

Ibuprofen

SHPA does not support increasing the preparation size of ibuprofen products from 200 milligrams to 400 milligrams in Schedule 2. Unrestricted access to larger doses of these medicines is not appropriate for the treatment of acute pain and fever. The provision of larger strength doses in schedule 3 will ensure patients better manage their pain by seeking advice from a pharmacist if continued supply of these medicines is required. This will ensure the safe and appropriate use of these medicines. A review of NSAIDs conducted by the TGA demonstrated prolonged use of NSAIDs is associated with cardiovascular risks and hepatotoxicity [2,3].

Sildenafil

SHPA does not support the down-scheduling and creation of a new Schedule 3 entry for sildenafil in oral preparations containing 50mg or less per dosage unit in packs containing four or less dosage units, or to include sildenafil in Appendix H to permit advertising of this medicine for erectile dysfunction.

Sildenafil is a phosphodiesterase type 5 inhibitor and can prolong QT intervals and increase the risk of arrhythmias, and its use is also cautioned in the setting of hepatic impairment. SHPA notes that the same proposed amendment to the scheduling of sildenafil was made in mid-2017 along with similar proposed amendment being made in mid-2018. This comes on top of another similar proposal for vardenafil, made in mid-2016 – each time these applications were subsequently rejected by the ACMS and we hope for the TGA to reach the same conclusion.

SHPA does not believe that pharmacies in the community setting have the adequate resources to screen for these risks, irrespective of any Appendix M entry that would mandate the pharmacist to undertake accredited Continuing Professional Development and confirm that a PDE5 inhibitor has previously been prescribed by a medical practitioner for the treatment of erectile disfunction.

If a Schedule 3 entry materialised, despite any Appendix M entry that would mandate the documentation of the supply of sildenafil in a clinical information system in accordance with professional practice guidance, community pharmacy does not have adequate resources to screen risks for a medicine such as sildenafil which also has known drug interactions – thus potentially leading to medication adverse events.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au

Yours sincerely,

Kristin Michaels

Chief Executive

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[1] Larsen C, Shahinas J. Dosage, Efficacy and Safety of Cannabidiol Administration in Adults: A Systematic Review of Human Trials. J Clin Med Res. 2020;12(3):129-41.

[2] Australian Government. (2016) Nonsteroidal anti-inflammatory drugs (NSAIDs) and spontaneous abortion. Therapeutic Goods Administration. Available at: https://www.tga.gov.au/sites/default/files/safety-reviewnonsteroidal-anti-inflammatory-drugs-nsaidsand-spontaneous-abortion-161018.pdf

[3] Australian Government. (2015). Submissions and TGA response: Non-steroidal anti-inflammatory drugs (diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen): proposed additional advisory statement for medicines. Therapeutic Goods Administration. Available at: https://www.tga.gov.au/submissionsand-tga-response-non-steroidal-anti-inflammatory-drugsdiclofenac-flurbiprofen-ibuprofen-ketoprofen-mefenamicacid-and-naproxen-proposed-additionaladvisory-statement-medicines