[redacted]

10 May 2018

medicines.scheduling@tga.gov.au

RE: Proposed amendments to the Poisons Standard - ACMS meeting, June 2018

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 5,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practicing in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA believes that any changes to the scheduling of medicines should be driven and underpinned by the principles of consumer safety, evidence-based medicine and quality use of medicines. SHPA has the following comments to make with respect to proposed amendments to the Poisons Standard.

Codeine

SHPA supports the up-scheduling of medicines containing more than 12mg of codeine to Schedule 8, given the evidence of codeine medicines being associated with adverse health risks[1,2]. SHPA notes that further restricting access to subtherapeutic doses of codeine is consistent with our Choosing Wisely Australia recommendation advising against the use of low-dose codeine.

As federal and jurisdictional governments continually invest in real-time prescription monitoring systems which focus strongly on Schedule 8 medicines, this up-scheduling would empower clinicians to appropriately monitor codeine prescribing and supply to ensure optimal and safe patient care.

Ibuprofen combined with paracetamol

SHPA does not support increasing the pack size of ibuprofen and paracetamol combination products from 30 tablets to 50 dose units in Schedule 3. Access to larger quantities of these medicines is not appropriate for the treatment of acute pain. The provision of a smaller pack size will prompt patients to better manage their pain by seeking advice from a pharmacist if continued supply of these medicines is required. A review of NSAIDs conducted by the TGA demonstrated prolonged use of NSAIDs is associated with cardiovascular risks and hepatotoxicity[3,4].

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 eight 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 and a similar proposal for vardenafil was made in the mid-2016 – both 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 use a patient assessment tool to facilitate patient screening and assessment. The contents of any patient assessment and screening tool must be consulted on and validated by expert clinicians.

If a Schedule 3 entry materialised, the disparate nature of supply recording and documentation of Schedule 3 medicines in community pharmacies would lead to doctors being unaware of their patients using sildenafil – which has known risks and 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 or (03) 9486 0177.

Yours sincerely,

Kristin Michaels
Chief Executive

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[1] TGA. (2018). Codeine information hub: Codeine use can be harmful. Retrieved from https://www.tga.gov.au/codeine-information-hub-codeine-use-can-be-harmful

[2] Shaheed, C. A., Maher, C. G., & McLachlan, A. (2016). *Investigating the efficacy and safety of over-the-counter codeine containing combination analgesics for pain and codeine based antitussives*.

[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/submissions-and-tga-response-non-steroidal-anti-inflammatory-drugsdiclofenac-flurbiprofen-ibuprofen-ketoprofen-mefenamic-acid-and-naproxen-proposed-additionaladvisory-statement-medicines

[4] 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-review-nonsteroidal-anti-inflammatory-drugs-nsaidsand-spontaneous-abortion-161018.pdf