

medicines.scheduling@tga.gov.au

RE: Proposed amendments to the Poisons Standard - ACMS meeting, July 2017

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 4,400 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.

Esomeprazole

SHPA does not support the down-scheduling of esomeprazole to Schedule 2. We believe that these medicines should be scheduled (at a minimum) in Schedule 3 to ensure appropriate consultation and review by a pharmacist to minimise the number of people who move to long term use of these medicines.

As part of Choosing Wisely Australia the Royal Australian College of General Practitioners (RACGP) have flagged the [long term use of proton pump inhibitors](#) (PPIs) as one of the top five tests, treatments or procedures which should be questioned by GPs and their patients. That statement is based on the evidence that a high proportion of patients are kept on maximal doses long term, and adverse effects of long term use include increased risk of gastrointestinal infection (incl. *Clostridium difficile*), community acquired pneumonia, osteoporotic fractures, interstitial nephritis, and nutritional deficiencies, particularly in the elderly or immunocompromised

SHPA notes that a similar down-scheduling amendment proposal was made to the Advisory Committee on Medicines Scheduling (ACMS) in late 2015, which was ultimately refused by the ACMS. This decision was supported by SHPA at the time, and we expect the ACMS to come to a similar conclusion in this instance.

Stiripentol

Due to stiripentol's sedative effects, SHPA supports a new Appendix K entry for this medicine.

Vardenafil, sildenafil

SHPA does not support the down-scheduling and creation of new Schedule 3 entries for vardenafil in oral preparations containing 10mg or less per dosage unit in packs containing

not more than 8 dosage units, or for sildenafil in oral preparations containing 50mg or less per dosage unit in packs containing not more than 8 dosage units.

Vardenafil and sildenafil are both phosphodiesterase type 5 inhibitors and can prolong QT intervals and increase the risk of arrhythmias, and its use is also cautioned in the setting of hepatic impairment. SHPA does not believe that pharmacies in the community setting have the adequate resources to screen for these risks.

SHPA notes that the same proposed amendment to the scheduling of vardenafil was made in the middle of 2016, and was subsequently refused by the ACMS. This decision was supported by SHPA at the time, and we expect the ACMS to come to a similar conclusion in this instance.

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 jdeweever@shpa.org.au or (03) 9486 0177.

Yours sincerely,



Kristin Michaels
Chief Executive Officer