



Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

15 May 2018

Therapeutic Goods Administration

RE: ASCEPT Feedback to TGA Consultation: Proposed amendments to the Poisons Standard being referred to the June 2018 meetings of the ACCS, ACMS and Joint ACCS/ACMS

The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) thank you for the opportunity to provide comment on the Proposed amendments to the Poisons Standard being referred to the June 2018 meetings of the ACCS, ACMS and Joint ACCS/ACMS.

ASCEPT is the leading professional body in Australasia for clinical pharmacology policy and practice and its members' expertise encompasses experimental and clinical pharmacology and toxicology (including: clinical trial and regulatory issues, pharmacovigilance and quality use of medicines). ASCEPT members serve on most Commonwealth and State committees concerned with medicines regulation or quality use of medicines.

ASCEPT Feedback to TGA Consultation: Proposed amendments to the Poisons Standard being referred to the June 2018 meetings of the ACCS, ACMS and Joint ACCS/ACMS

Proposed amendments referred for scheduling advice to ACMS #24

Substance	Comments from ASCEPT
Budesonide	No objection
Ibuprofen and Paracetamol	No objection
Codeine	ASCEPT agrees with the suggested changes codeine scheduling and accepts the proposed rationale
Sildenafil	ASCEPT does not support the proposed rescheduling and advocates sildenafil remains Schedule 4, primarily on the grounds of patient safety. Sildenafil has several important precautions and contraindications of use, including (Australian Medicines Handbook [AMH], January 2018): <ul style="list-style-type: none">• Renal impairment (CrCl < 30mL/min)

ASCEPT is the professional and independent society in Australia and New Zealand with expertise in the use and toxicity of medicines and chemicals

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- Mild-to-moderate hepatic impairment
- Anatomical deformation of the penis
- Bleeding diathesis
- Men for whom sexual intercourse is inadvisable (e.g. unstable angina) – AMH suggests an exercise stress test may be helpful prior to considering sildenafil in these patients
- Hypotension

Identification and management of these potential precautions and contraindications is most appropriately assessed by a medical practitioner for the first prescription. Additionally, AMH recommends consideration be given to undiagnosed cardiovascular disorders before prescribing sildenafil, due to the potential for precipitation of myocardial infarction with sildenafil use. The availability of 'My Health Record' to community pharmacists may be helpful in a pharmacist being made aware of some of these potential precautions and contraindications, however ASCEPT believes this is unlikely to be sufficient in all cases. If a patient has undiagnosed cardiovascular (or for that matter, liver or renal) disease, this will clearly not be in the 'My Health Record'.

Secondly, ASCEPT does not see how re-scheduling will help destigmatise erectile dysfunction or lead to improvements in treatment seeking behaviour for chronic medical conditions. Thirdly, ASCEPT does not accept that men who have not attempted to obtain prescription sildenafil from a medical practitioner will be more comfortable obtaining non-prescription sildenafil from a pharmacy.

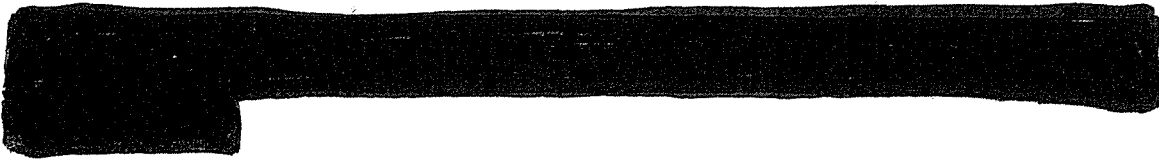
Therefore, ASCEPT believes that the potential benefits of re-scheduling sildenafil do not outweigh the potential risks to patient safety.

ASCEPT notes that sildenafil is available over-the-counter in pharmacies in other jurisdictions (e.g. New Zealand) but note that in these circumstances, pharmacists requires specific credentialing. If rescheduling of sildenafil were to occur, ASCEPT would advocate this process, rather than merely making educational material available to pharmacists, as is currently proposed.

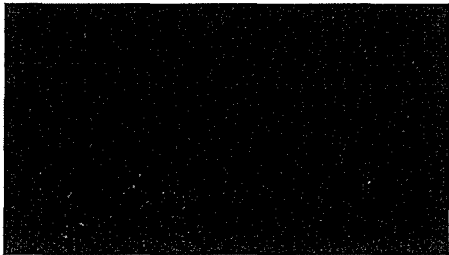
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Cannabidiol and tetrahydrocannabinols (THC)	ASCEPT agrees with the proposed changes
Alkyl nitrites	ASCEPT agrees with the proposed changes

ASCEPT will not be providing comments to scheduling advice to ACCS #23 or the Joint ACMS-ACCS #19



Yours sincerely,



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