

medicines.scheduling@tga.gov.au

RE: Proposed amendments to the Poisons Standard - ACMS meeting, November 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 and quality use of medicines.

SHPA has the following comments to make with respect to proposed amendments to the Poisons Standard.

Cardarine (GW501516), Stenabolic (SR9009) and other synthetic REV-ERB agonists

SHPA does not support the proposed Schedule 4 Prescription Only entry for cardarine (GW501516), Stenabolic (SR9009) and other synthetic REV-ERB agonists. SHPA understands that these medicines are used to alter gene expression and can be used as a physical performance enhancer. Clinical evidence of purported health outcomes such as reduced obesity and diabetes through altering gene expression is scant, of low quality and only produced in mice subjects¹. Human studies of this medicine have not been published. Thus, SHPA believe it is not appropriate for this medicine to receive a Schedule 4 entry.

SHPA has no remarks on the simultaneous application for a Schedule 9 Prohibited Substance entry for these medicines.

Cathinones, methylone (MDMC) and alpha-pyrrolidinovalerophenone (alpha-PVP)

SHPA does not support proposed Schedule 4 Prescription Only for methylone (MDMC) and alpha-pyrrolidinovalerophenone (alpha-PVP), noting that that they are synthetic psychostimulants associated with overdoses, suicides and illicit use. SHPA notes that in New South Wales, alpha-PVP was explicitly banned in 2013 after synthetic psychostimulants were determined to be the cause of death in a teenager².

SHPA does not support amending the Schedule 9 Prohibited Substance entries for cathinones, methylone (MDMC) and alpha-pyrrolidinovalerophenone (alpha-PVP), and believe these to be appropriate. SHPA notes that cathinones are illegal in many other countries such as the United States of America, the United Kingdom, Sweden and New Zealand.

Clotrimazole

SHPA does not support the proposal to downschedule clotrimazole for vaginal thrush from Schedule 3 Pharmacist Only to Schedule 2 Pharmacy Medicine, which would allow for patients to self-select topical antifungal treatments for vaginal candida infection.

It is imperative that patients presenting with vaginal disorders are consulted by a pharmacist to ensure that the diagnosis and treatment is appropriate and/or necessary, and to ensure referrals to doctors are made when appropriate. Trigger points for referrals to physicians are diabetic patients, patients under 16 and over 60 years of age, pregnant women, and patients taking immunosuppressants.³ A consultation with a pharmacist is also important to rule out common differential diagnoses such as bacterial vaginosis which requires treatment with antibiotics.

Orphenadrine

SHPA does not support the downscheduling of orphenadrine from Schedule 4 Prescription Only to Schedule 3 Pharmacist Only. Orphenadrine has very limited role in pain management,^{4,5} poor efficacy and patients rapidly develop tolerance to this medicine. An SHPA member reported providing care to a patient who had overdosed on orphenadrine resulting in ischaemic bowel and the formation of a stoma.

Ibuprofen

SHPA supports the proposals to

- Delete the exemptions for ibuprofen in Schedule 2 Pharmacy Medicine which allow it to be sold in supermarkets
- Restrict the pack size of ibuprofen 200mg in Schedule 2 Pharmacy Medicine to 30 dosage units, down from 100 dosage units

These proposals would reduce the incidence of self-selection of ibuprofen to treat pain or muscular inflammation, and allow for patients to appropriately receive counselling and guidance from pharmacists when accessing treatment in a pharmacy setting. Two comprehensive review of NSAIDs conducted by the TGA in recent years acknowledged the cardiovascular, hepatotoxicity and pregnancy risks associated with these medicines^{6,7}. Thus, it is appropriate that access to these medicines are restricted further to ensure appropriate review by a pharmacist.

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

Yours sincerely,



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Chief Executive Officer

References

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