Pharmaceutical Society of Australia

Consultation: Proposed amendments to the Poisons Standard – ACMS meeting #31, June 2020

MAY
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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred for scheduling advice to the June 2020 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

PSA's comments relate to the following items: oxymetazoline (1.1), eletriptan (1.2), clotrimazole (1.3) and sildenafil (1.4).

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 32,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Recommendations

Oxymetazoline *– PSA does not support the proposal to amend the Schedule 2 entry for oxymetazoline which would result in nasal preparations containing 0.05% or less being exempt from scheduling.*

Eletriptan *– PSA supports the inclusion of eletriptan in Schedule 3 and in Appendix H, in alignment with recent final scheduling decisions for sumatriptan and zolmitriptan.*

Clotrimazole *– PSA does not support the proposal to reschedule vaginal use preparations containing 1% or less of clotrimazole from Schedule 3 to Schedule 2.*

Sildenafil *– PSA supports the rescheduling of sildenafil to Schedule 3 with Appendix M controls, and an entry in Appendix H, as proposed. This view is based on relevant Appendix M criteria being addressed to fulfil risk reduction to an acceptable level, and an assessment that there is likely to be public health benefits.*

Comments on proposed amendments

1.1 Oxymetazoline

Summary of proposal

PSA understands amendments to the Poisons Standard are being proposed to exclude from Schedule 2, nasal preparations containing 0.05% or less of oxymetazoline.

PSA's comments

Oxymetazoline nasal sprays are used for their nasal decongestant activity for short term management of readily recognisable symptoms.

PSA makes the following comments:

- PSA is aware of anecdotal reports by pharmacists through their daily practice, that they do become aware, not infrequently, of overuse of intranasal decongestants when they have to intervene in cases of patients experiencing rebound congestion. The application of mandatory warning statements on product packaging does not prevent inadvertent misuse by patients. This is of reasonable concern to pharmacists and PSA does not consider a statement on packaging to limit use to 3 days to be adequate risk mitigation for the supply of decongestant nasal sprays through non-pharmacy outlets.

- Decongestant use must be carefully managed in older children (aged 6 to 12 years) requiring health professional advice.

- The use of decongestants generally in children under 6 years of age is not recommended due to reports of significant adverse effects. Even when an appropriate warning statement is

included in package labelling, pharmacists are aware that sometimes carers may misunderstand those instructions or not read the label as intended. Reinforcing messages around appropriate use is warranted to minimise any inadvertent administration to young children by carers.

The inherent safety of oxymetazoline is not being questioned. However, being aware that decongestant nasal sprays are sometimes used inappropriately by patients, pharmacists believe that this could be further exacerbated if oxymetazoline nasal sprays were to become available in an unregulated environment. It is in the interests of patients requiring the use of nasal decongestants that professional advice and opportunity for intervention is available at the place of supply.

Therefore PSA does not support the proposed exemption from scheduling of oxymetazoline nasal preparations.

1.2 Eletriptan

Summary of proposal

PSA understands this application seeks to reschedule eletriptan for oral use in tablets containing 40 mg or less per tablet and when in a pack containing not more than two dosage units from Schedule 4 to Schedule 3. Thus, new entries are proposed for Schedule 3 and for Appendix H.

PSA's comments

PSA notes the Delegate's recently published final decisions to create new Schedule 3 and Appendix H entries for sumatriptan and zolmitriptan.

PSA is not aware of any evidence to suggest eletriptan has a different safety profile or clinical characteristics to sumatriptan and zolmitriptan and guidance around clinical use for acute treatment for migraine is essentially the same for all triptans. Therefore PSA believes alignment in the scheduling of eletriptan with sumatriptan and zolmitriptan is justified.

PSA also notes the applicable rescheduling implementation date of 1 February 2021 for sumatriptan and zolmitriptan. PSA would support the same effective implementation date for eletriptan, if possible. This would support clarity and uniformity around regulatory changes for consumers and health professionals. It will also support PSA's work on the development and provision of practice support resources for the supply of this class of medicine as Pharmacist Only medicines.

In summary, PSA supports new Schedule 3 and Appendix H entries for eletriptan as proposed.

1.3 Clotrimazole

Summary of proposal

PSA understands this application seeks to reschedule vaginal use preparations containing 1% or less of clotrimazole from Schedule 3 to Schedule 2.

PSA's comments

PSA notes that the scheduling of clotrimazole for vaginal use was considered in 2017–2018 with Schedule 3 confirmed to be the appropriate entry. From the current pre-meeting notice it is not clear whether the applicant has new information, evidence or initiative that would now support a rescheduling to Schedule 2.

If these medicines are rescheduled to Schedule 2 and able to be self-selected by consumers (except in Western Australia and Queensland), pharmacists have expressed concern about whether these therapies would be used appropriately. In a study[1] investigating the accuracy of patient self-diagnosis of vulvovaginal candidiasis (VVC), it was reported that 53% of women seeking to purchase a topical antifungal for treatment of presumed VVC were confirmed to have another infectious cause such as a urinary tract infection, or their symptoms were not secondary to infection.

While this proposal relates to clotrimazole vaginal use preparations, the use of all forms of antimicrobials must be considered holistically from the perspective of antimicrobial stewardship. Thus PSA is concerned, for example, that clotrimazole has consistently been reported to be the second most commonly prescribed antimicrobial in aged care settings.

In view of the reasons outlined above, on balance, PSA does not support the proposal to reschedule vaginal use preparations containing 1% or less of clotrimazole from Schedule 3 to Schedule 2.

1.4 Sildenafil

Summary of proposal

The proposed amendments to the Poisons Standard for sildenafil are to create a new entry for Schedule 3 with Appendix M controls, and Appendix H. The details are as follows:

- **Schedule 3, new entry** – Sildenafil in divided preparations for oral use containing 50 mg of sildenafil per dosage unit in packs of not more than 4 dosage units in accordance with the requirements of Appendix M.
- **Appendix M, new entry** – Sildenafil where the pharmacist providing professional advice:
    - Has demonstrated achievement of competency through completion of an accredited training course that meets the requirements set out in the Pharmaceutical Society of Australia competency-based education framework for supply of sildenafil as a Pharmacist Only medicine; and
    - Complies in all respects with the relevant professional practice standards, and the Pharmaceutical Society of Australia professional practice guidance for supply of sildenafil as a Pharmacist Only medicine; and
    - Confirms a PDE5 inhibitor has previously been prescribed by a medical practitioner for the patient for treatment of erectile dysfunction; and

[1] Hilmi SC, Mccloskey JC, Tenni P, Hughes JD. Vulvovaginal candidiasis in Australia: Let's take a look 'down under'. Sexual Health, 2007; 4(4):298.

- Documents the supply of sildenafil in a clinical information system in accordance with professional practice guidance.

- **Appendix H, new entry**.

PSA's comments

Appendix M criteria

PSA has reviewed each of the Appendix M criteria in the context of sildenafil, as summarised below.

1. Specific pharmacist training on the provision of the medicine.

PSA has canvassed a possible outline of a competency-based education framework that would be used to develop an appropriate training package for pharmacists relevant to the supply of sildenafil as proposed in this application. The training package is expected to cover topics including the nature and use of the medicine, conditions being treated and alternative treatments where relevant, risk factors and guidance on when to refer for medical assessment.

2. Suitability of the individual patient for supply of the medicine must be assessed by the pharmacist

In the context of this proposal, PSA has developed draft outlines of a competency-based education framework and a professional practice guidance document for the supply of sildenafil as a Pharmacist Only medicine. These will frame PSA's work in developing resources to enable a pharmacist to assess a patient presenting with a request for sildenafil, and to ensure safe and appropriate supply.

3. Specific advice (patient education) is required on supply of the medicine

Pharmacists have a professional obligation to provide information and counselling to the patient to support safe, appropriate and quality use of the medicine. This requirement is comprehensively detailed in relevant professional practice standards issued by PSA (e.g. provision of non-prescription medicines; counselling).

PSA has also determined (through consideration of draft outlines of a competency-based education framework and a professional practice guidance document) that required information will include: indication, contraindications and precautions, drug interactions, treatment expectations, adverse effects, referral criteria and reasons for referral.

4. Limitations on duration/quantity and/or frequency of supply

The indication of the medicine, and the strength and quantity for the (proposed) Schedule 3 entry are specified in the pre-meeting notice.

The professional obligation of a pharmacist to consider the safety and appropriateness of therapy for a patient is outlined in relevant professional practice standards issued by PSA.

PSA will provide professional practice guidance to pharmacists in relation to the age of the patient, the recommended dose, maximum daily dose and frequency of use through a PSA training package and professional practice guidance for the supply of sildenafil as a *Pharmacist Only* medicine.

5. Need for formal diagnosis or periodic review of the condition by a medical practitioner

One of the proposed Appendix M criteria for sildenafil is that "a PDE5 inhibitor has previously been prescribed by a medical practitioner for the patient for treatment of erectile dysfunction".

PSA's professional practice guidance for pharmacists will include requirements relating to prior treatment and medical review.

6. Record keeping and information sharing

The supply of sildenafil as a Schedule 3 medicine must be recorded in a clinical information system. This is proposed in an Appendix M criterion.

Documentation requirements will be further articulated through PSA's training package and support materials, including the PSA professional practice guidance.

Communication or information sharing requirements will also be outlined for pharmacists.

7. Additional criteria may be imposed

No additional criteria that would apply to sildenafil as Appendix M controls were identified by PSA.

Potential public health benefits

In rescheduling a substance from Schedule 4 to Schedule 3, it is essential that appropriate risk mitigation strategies are applied. In the context of this application for sildenafil, PSA believes the inclusion of Appendix M controls provides the appropriate degree of risk reduction and also creates possible public health benefits as outlined below.

- **Broader patient benefits.** The availability of sildenafil following an assessment by a suitably-trained pharmacist offers benefits of improved access for the patient and supports the patient with continuity of therapy. Regular contact with a health professional (a pharmacist) supports the patient with better health management overall. The pharmacist provides information and advice to the patient, helps monitor the patient's response to therapy, proactively identifies any potential adverse outcomes, and refers the patient to a general practitioner, if required. This helps address the challenge of the patient visiting a doctor once, and then not returning for subsequent follow-up consultations. This is an important consideration particularly for the demographic of men experiencing erectile dysfunction, those over 40 years of age, who are known to be most likely to not make regular visits to their doctor.

- **Access to public health initiatives.** The scope of practice of a pharmacist and the health services that can be delivered through community pharmacies mean that patients are able to receive vaccinations, health checks (such as blood pressure and blood glucose measurements), and receive up-to-date information on key health priorities. A greater proportion of the population receiving health services and health advice has positive implications for public health initiatives. If vaccination is used as an example, we know that less than 40% of at-risk people over 18 years of age are considered to be fully immunised. Frequent contact with pharmacists, who are able to deliver a vaccination service, can help deliver public health messages and improve public health initiatives.

- **Building health awareness.** Inclusion of sildenafil in Appendix H will highlight erectile dysfunction to the general public. Erectile dysfunction is often symptomatic of more serious conditions. It is also a condition which is frequently unreported by patients. Building awareness

of, and normalising conversations about, erectile dysfunction will facilitate more people in the target group to visit their general practitioner, with a potential benefit of receiving a diagnosis for any significant health conditions.

- **Access to safe and high-quality sildenafil medicines.** PSA is aware that the Therapeutic Goods Administration (TGA) has invested significant efforts to educate consumers about the public health risks and possible harmful effects that counterfeit medicines pose. Counterfeit products containing (or claiming to contain) sildenafil, mostly sourced online, have been the subject of many TGA safety alerts. This is not a primary reason to reschedule sildenafil. However, PSA notes that greater access to sildenafil medicines which are registered on the Australian Register of Therapeutic Goods, having met relevant standards of safety, quality and efficacy, can be regarded as a positive flow-on benefit for Australian patients.

Implementation issues

An important consideration of this application is around the implementation of a positive rescheduling decision.

PSA has been in discussion with pharmacist colleagues in New Zealand who have had several years of experience in implementing sildenafil supply arrangements similar to the Australian Pharmacist Only medicine arrangements. PSA understands they have faced several difficulties in having multiple sponsors (of sildenafil) each creating their own training requirements for pharmacists as well as a variety of implementation and practice support tools.

In the Australian practice context, PSA believes it is fundamentally important that there is consistency in approach in all aspects but particularly around pharmacist education and training, as well as practice implementation requirements such as recording of supply.

Thus PSA is confident that the Appendix M criteria of this proposal with the inclusion of a single competency-based education framework is the correct approach. This does not preclude training being made available by more than one provider but will ensure content is aligned to an agreed framework.

Summary

In summary, PSA supports the rescheduling of sildenafil to Schedule 3 with Appendix M controls, and an entry in Appendix H, as proposed. This view is based on relevant Appendix M criteria being addressed to fulfil risk reduction to an acceptable level, and an assessment that there is likely to be public health benefits.

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