

SUBMISSION

Wednesday, 22 May 2024

AMA submission to proposed amendments to the Poisons Standard - ACMS, ACCS & Joint ACMS-ACCS, JUNE 2024

By email: medicines.scheduling@health.gov.au

As the peak body representing medical practitioners in Australia, the AMA's submission will only comment on ACMS and joint ACMS-ACCS proposals.

Intravenous potassium salts

The AMA supports the creation of a Schedule 4 entry for preparations of potassium salts for injection or infusion.

Sulfonamides

The AMA supports the proposed amendments to the current Schedule 4 entry for sulfonamides which is intended to clarify the status of sulfonamides when used in a variety of settings, including therapeutically and industrially.

Sildenafil

The AMA does not support the down-scheduling sildenafil, as we did in 2017, 2018 and 2020. Downscheduling should only occur where there is strong evidence it is safe to do so, and there is demonstrated patient benefit and safety in dispensing the medication by this method. There is no new publicly available information to demonstrate this is the case.

Erectile dysfunction (ED) is a marker of the state of the blood vessels in other parts of the cardiovascular system and should be thoroughly investigated before phosphodiesterase inhibitors are prescribed. This is best investigated by the patient's usual medical practitioner in a consultation where this issue can be teased out and, if appropriate, alternatives discussed.

There are a range of potential causes of ED, including use of other prescription medicines and psychological issues. These issues only be addressed by medical practitioners in a consultation where they can make a complete diagnosis, monitor the ongoing use of medicines and to understand the risks and benefits inherent in prescribing, based on the individual's full medical circumstance.

Allowing sildenafil to be accessible over the counter would send a signal to consumers that it is much lower risk than it is, particularly for those cohorts already using it recreationally.¹ The risk profile is significant and requires a proper consultation with a medical practitioner to assess risks and discuss

¹ Wanjari and Late (2023) "Use of Sildenafil in young adults: a growing health problem" *Pan Afr Med J*.

potential, and serious, adverse reactions associated with use of sildenafil, and the significant range of contraindications.

Sildenafil has serious adverse interactions with a range of other medicines.² A community pharmacist will not know a patient's usual medicines, whereas a patient's regular general practitioner will also know the full range of medicines currently prescribed, why those particular medicines were prescribed, and be able to discuss safe alternative approaches knowing the full medical history of the patient.

The AMA notes that the consultation paper references the desire to limit the ordering of sildenafil from "unregulated internet-based sources". While the AMA shares these concerns, there is no evidence making it available over the counter will discourage this activity. The implication is that access is causing this behaviour and making it available over the counter will address this. The reality is that stigma is likely a significant driver for using unregulated internet-based sources.³ It seems unlikely that an individual who is reluctant to discuss the issue with a doctor in a private consultation would be willing to do so with a pharmacist in a public retail setting.

The AMA is also seriously concerned about the precedent that would be set by down-scheduling a medication with a significant risk profile due to the behaviour of some consumers. The issue requires a response, but it should be through strategic engagement and education. The AMA would be happy to engage with discussions on strategies to address recreational use and access through unregulated internet-based sources with the TGA and other stakeholders.

Contact

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² Mayo Clinic (2024) [Sildenafil](#) (oral Route).

³ Foster, Pomerantz, Bell, Carvalho, Lee and Lee (2022) "[Victims of virility: Honor endorsement, stigma, and men's use of erectile dysfunction medication](#)" *Psychology of Men & Masculinities*