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Codeine and Sildenafil scheduling proposals

AMA submission to the TGA Advisory Committee on Medicines Scheduling – proposals to up-schedule codeine and down-schedule sildenafil

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The AMA supports maintaining the current scheduling of codeine and sildenafil at this time.

Codeine

The AMA supports retaining the existing scheduling for codeine; it does not support the proposal to up-schedule codeine from Schedule 4 to Schedule 8 in circumstances when it is in:
- divided preparations containing more than 12 mg of codeine per dosage unit; or
- undivided preparations containing more than 0.25 per cent of codeine.

Considerable analysis and public consultation went into the recent codeine up-scheduling decision. The AMA is not aware of any new evidence supporting additional up-scheduling. The current scheduling arrangements should remain unless there is new data supporting another change. It is unlikely that data on the impact of the new scheduling arrangements will be available for some time.

Regarding the argument that up-scheduling codeine will allow better monitoring, while the Commonwealth has sought to focus real time prescription monitoring systems on Schedule 8 medicines, the reality is that state governments may use these systems as they wish. This has been demonstrated by the Victorian Government's decision to include Schedule 4 codeine preparations in its list of prescription medicines that will be monitored under *SafeScript*.

Sildenafil

The AMA opposes the application to down-schedule sildenafil from Schedule 4 to Schedule 3 in divided preparations for oral use containing 50 mg of sildenafil per dosage unit in packs of not more than 8 dosage units.

The AMA lodged a submission last year opposing an application to down-schedule sildenafil. No new, publicly available, information appears to have been provided to substantiate or justify another application, following the TGA's rejection of the previous application.

The AMA repeats its reasons for opposing the down-scheduling of sildenafil below.

Erectile dysfunction (ED) is complex medical condition not a simple health issue.

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.

ED may also be caused by many other prescription medicines.

It is also crucially important to explore whether there are psychological causes of ED which can be a very significant reason for presentation.

The above issues cannot be addressed by answering a simple check list of questions posed by a pharmacist.

It is argued that men will be more likely to seek help with ED problems if they can access medicines over the counter at a pharmacy, rather than make an appointment with their general practitioner. However accessing these medicines from a pharmacist does not avoid initiating a conversation about ED issues. Conversations with men regarding erectile dysfunction can be very difficult to initiate where there is not a well-developed therapeutic relationship between doctor and patient. It is most unlikely that a pharmacist delivered checklist will facilitate the confidence and trust and emotional security to entertain such a delicate discussion.

Once ED issues are broached, a consultation with a general practitioner will ensure that a full health assessment is undertaken, risk factors are identified and holistic advice is provided. A medical practitioner consultation to obtain a prescription of sildenafil also provides an opportunity to screen for diabetes mellitus and sexually transmissible infections, as well as undertake unrelated but important health prevention activities.

The Advisory Committee on Medicines Scheduling (ACMS) will also be well aware that sildenafil is known to have serious adverse interactions with a range of other medicines. While theoretically a pharmacist may know about a patient's usual medicines, 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. A pharmacist identifying a potential adverse drug interaction will, in any event, have to refer the patient to their general practitioner.

ACMS will also be aware of the potential, and serious, adverse reactions associated with use of sildenafil, and the significant range of contraindications.

The AMA does not have confidence that a pharmacist-administered questionnaire, even supported by additional training provided by the sponsor, will mitigate the risks to patient safety or ensure dispensing and use that is consistent with quality use of medicines principles. Relying on pharmacists to control the use of low-dose codeine products was unsuccessful in stemming the increase in codeine-related deaths post 2010.

It should also be noted that pharmacists will gain financially from the dispensing of these medicines; there is an inherent conflict of interest.

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