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AMA submission to ACMS re Vardenafil and Sildenafil downscheduling proposal

The AMA strongly opposes the proposal to create new Schedule 3 entries so that low dose/small packs of Vardenafil and Sildenafil are available over the counter without a prescription from a medical practitioner.

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 vardenafil and 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 both vardenafil and sildenafil are 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 vardenafil and sildenafil, and the significant range of contraindications.

The AMA does not have confidence that a pharmacist-administered questionnaire 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.

Finally, Bayer submitted an application only last year to downschedule vardenafil but the ACMS recommended against any change to scheduling. The question must be asked - what has changed? If there is new evidence available, then this should be shared publicly so that stakeholders making submissions can be fully informed.

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