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Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (prescription only) to Schedule 3 (Pharmacist only)

AMA submission to the TGA

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The AMA does not support the down-scheduling of medicines unless 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.

The AMA's view is that if additional supply requirements or controls are required in order for pharmacists to safely dispense a medicine, then it is – by definition – unsafe and inappropriate to down-schedule that medicine.

The AMA opposed several applications to down-schedule oral contraceptives, vardenafil and sildenafil for these reasons. Each time, these applications were subsequently rejected by the Advisory Committee on Medicines Scheduling, despite the applicants proposing additional controls such as patient screening tools that pharmacists would be required to implement before dispensing.

Nothing has changed regarding these medicines, the risks to patients, the community pharmacy environment or the Australian context. It is highly concerning therefore that these medicines are being used in stakeholder meetings as examples of medicines that may be down-scheduled in the future through listing under Appendix M.

Of even greater concern is that these examples – where rejection of down-scheduling on safety grounds has occurred after examination of individual medicines – should be a strong argument to continue to take a careful approach to down-scheduling. Instead, the proposal is an illogical blanket approach in the opposite direction with no reasonable basis and potential major risks to patient safety.

The additional 'criteria' proposed in the TGA's consultation paper are inadequate to support safe pharmacist dispensing of the types of medicines to which they would need to be applied.

Checklists, questionnaires and guidelines are not equivalent to a physical examination which can only be performed by a medical practitioner who also has a range of diagnostic tools available to them to support the decision to prescribe, not to prescribe, or importantly, to prescribe or recommend an alternative safer, more effective treatment appropriate for that individual.

The proposed limitations on duration, quantity and frequency of supply will not prevent patients seeking supply from an alternative pharmacy. It is not correct to say that the risk is equivalent to a patient seeking supply from an alternative medical practice. It is manifestly easier and quicker to walk a few hundred metres to obtain supply from a nearby pharmacy where no appointment is needed than to 'doctor-shop'.

It is unacceptable that there be a proposed criteria that a pharmacist could dispense a medicine only after a formal diagnosis or periodic review by a medical practitioner. A medicine requiring this level of medical practitioner involvement should never be down-scheduled. There is nothing different in this scenario to the model of prescribing described in the *Health Professional Prescribing Pathway* approved by Health Ministers in 2013. If the TGA pursues this approach, it is essentially allowing pharmacists to prescribe medicines outside a nationally agreed governance framework for expanding the prescribing of non-medical health practitioners.

Finally, it is extremely concerning that there will, in effect, be no compliance or enforcement mechanisms except through a complaint being brought to the Pharmacy Board or the relevant State/Territory government agency. Without any monitoring or reporting mechanisms in place it is likely that non-compliance will only come to the attention of these bodies when a patient suffers an adverse event.

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