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AMA submission – TGA/ACMS codeine schedule 4 proposal

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The Advisory Committee on Medicine Scheduling (ACMS) has not provided any summary of the evidence base underpinning the proposal to shift current Schedule 3 preparations of codeine to Schedule 4. No specific information about the current risks and harm, the problem that upscheduling would solve, or the expected impact on health care of the regulatory change has been provided

The AMA is therefore unable to provide a definitive view but makes the following observations.

The AMA agrees that codeine dependence is a real concern and that the side effects from taking excessive amounts can be very serious. There have been several recent studies indicating an increase in misuse and harm.

This may justify a decision by the ACMS to up-schedule some codeine preparations, particularly the higher dose and combination compound products. There is also some inconsistency in current regulation which could be addressed, for example, two Panadeine Extra tablets (the recommended dose) available over the counter is equivalent to one Panadeine Forte which requires a prescription.

However up-scheduling in isolation is unlikely to address the problems of misuse. Improved education about effective and safe pain management options for the public, pharmacists and general practitioners is also necessary.

The AMA continues to advocate for the implementation of the Electronic Recording and Reporting of Controlled Drugs system in each state and territory. This system would allow doctors and pharmacists to monitor in real time the prescribing and dispensing a range of medicines with the potential for misuse and harm, not only Schedule 8 medicines.

There are also alternatives to up-scheduling that could be considered, for example, introducing pharmacy requirements to record codeine dispensing in the same way as for pseudoephedrine.

It is also worth noting that a decision to up-schedule would likely lead to increased Medicare and PBS costs through more numerous medical practitioner consultations and prescriptions, at a time when the Government is seeking to reduce its outlays in these areas.

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