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26 October 2018

Adjunct Professor Paul Brent
Chair, Advisory Committee on Medicines Scheduling
Department of Health
MDP 71, GPO Box 9848
Canberra, ACT 2601

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Dear Adjunct Professor Brent,

Re: Proposed rescheduling of Modified Release Paracetamol from S2 to S3

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide feedback and comments on the Advisory Committee on Medicines Scheduling's (ACMS's) proposed amendment to upschedule modified-released paracetamol from Schedule 2 (Pharmacy only) to Schedule 3 (Pharmacist only).

The RACGP believes a change from Schedule 2 to Schedule 3 is unlikely to protect children from accidental ingestion or protect adults from intentional overdose. It may be more appropriate in the first instance to work with emergency department physicians and general practitioners (GPs) working in emergency departments to alert them to the need to consider overdose with modified-released paracetamol that may not be apparent in early blood testing. While the use of modified-released paracetamol can have longer toxic effect in patients, there is little difference to the usual practices of paracetamol overdose, and well within the remit of any emergency department.

Although there is evidence to suggest concern, national studies and the Therapeutic Goods Administration's (TGA's) Adverse Drug Reaction System (ADRS) database has found that the risk of death and rate of adverse events from the inappropriate use of modified-released paracetamol is actually very low.[1] The Australian study quoted by the ACMS documentation does not support the ACMS's claim that modified-released paracetamol is substantially 'less safe' than immediate-released paracetamol.

The RACGP believes there is a lack of evidence to suggest that oversight by pharmacists will lead to improved patient outcomes, especially improved drug safety. Experience with mystery shoppers[2] demonstrates significant variability in pharmacists' advice. Hence, any decision to upschedule should be accompanied by a commitment to monitor its effect.

The RACGP appreciates the complexities of the issues involved; however, on balance, such a step may have unintended consequences on patients, including reduced access and cost implications because of the supply environment.

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Thank you once again for the opportunity to provide feedback and comments. We look forward to hearing about the progress and outcomes of this consultation.

Yours sincerely,

[redacted]

Dr Harry Nespolon
President

References

1. Tovell AM, McKenna K, Bradley C, Pointer S. Hospital separations due to injury and poisoning, Australia: 2009–10. Canberra: Australian Institute of Health and Welfare, 2012.
2. Hussainy SY, Stewart K, Pham MP. A mystery caller evaluation of emergency contraception supply practices in community pharmacies in Victoria, Australia. Aust J Prim Health 2015;21(3):310–16.

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