

30 October 2018

Advisory Committee on Medicines Scheduling (ACMS)  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

By email: [MedicinesScheduling@health.gov.au](mailto:MedicinesScheduling@health.gov.au)

To whom it may concern,

**Re: Submission on proposed amendment to the Poisons Standard – Paracetamol (modified release)**

NPS MedicineWise would like to thank the Advisory Committee on Medicines Scheduling for providing the opportunity to make a submission on the proposed upscheduling of modified release (MR) paracetamol tablets from Schedule 2 to Schedule 3 of the current Poisons Standard.

NPS MedicineWise is an independent, evidence based organisation primarily funded by the Department of Health to educate health professionals and consumers about the appropriate use of medicines and medical tests. NPS MedicineWise improves the way medicines and other medical technologies are prescribed and used in practice. We do this through behaviour change interventions, evidence based information to support decision making, educational programs which aim to address evidence-practice gaps, and targeted health communications campaigns.

Findings from our own review of the evidence for the safety of MR paracetamol are consistent with those highlighted in the background to the proposed upscheduling. Based on the greater risk of overdose of MR paracetamol compared with IR paracetamol, and lack of evidence based guidelines for management of overdose of MR paracetamol, we support the upscheduling of MR paracetamol from S2 to S3 'Pharmacist Only Medicine'. This will maintain access to these products in pharmacies, while providing the opportunity for checking patients' use and for counselling on safe and appropriate use, dose and additional risks. It will also ensure that the MR formulation is not mistakenly purchased in place of the IR formulation, which could contribute to dosing errors.

However, while we support the upscheduling of MR paracetamol from S2 to S3 it is important to highlight that this measure alone will not reduce the increased risk of death or serious liver injury in people who overdose (intentionally or accidentally) on MR paracetamol compared to IR paracetamol.

Other risk minimisation strategies (such as those identified as being taken in New Zealand and considered for Europe, including revision and promotion of overdose management guidelines) will be required. Upscheduling and other strategies to reduce the risk of MR paracetamol should be supported by awareness raising activities such as education for health professionals.

As the national implementation body for quality use of medicines, NPS MedicineWise is well placed to support any upscheduling through education of health professionals and pharmacists about safe use of paracetamol and management of MR paracetamol (including why it is different to immediate release paracetamol).

Thank you again for the opportunity to provide feedback. We are very happy to provide further clarification or guidance as needed and look forward to our continued collaboration with the TGA in the future.

Yours sincerely,



Bronwyn Walker  
External Relations and Policy Manager

