



26 October 2018

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

Dear Therapeutic Goods Administration,

**RE: Proposed amendment to the current Poisons – ACMS meeting, March 2019**

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional, for-purpose organisation for leading pharmacists and pharmacy technicians working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA believes that any changes to the scheduling of medicines should be driven and underpinned by the principles of consumer safety, evidence-based medicine and quality use of medicines. SHPA has the following comments to make with respect to proposed amendments to the Poisons Standard.

**Paracetamol (modified release)**

SHPA supports the proposed amendment of terminology in the Poisons Standard from 'slow release' paracetamol to 'modified release' paracetamol to accurately reflect the pharmacological action of this formulation of paracetamol.

SHPA supports the up-scheduling of modified release tablets or capsules containing less than or equal to 665 mg of paracetamol from Schedule 2 to Schedule 3 of the current Poisons Standard. The up-scheduling will ensure patient counselling on appropriate dosing and the risks associated with overdose, whether intentional or accidental.

While the proposal to TGA does not discuss pack sizes for modified release paracetamol, SHPA believes this should be considered by the TGA as the proposal seeks to make these changes to curb both intentional and accidental overdoses. Modified release paracetamol is currently marketed in pack sizes of 96 tablets, containing almost double the median ingested dose of the Australian Toxicology Monitoring (ATOM) Study - Australian Paracetamol Project.<sup>1</sup> Changes in legislation in the United Kingdom where the reduction of paracetamol pack sizes was followed by a significant reduction in deaths due to paracetamol overdose<sup>2</sup>. This harm minimisation strategy can be implemented in the Australian context in order to reduce the harms associated with modified release paracetamol.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on [jdewever@shpa.org.au](mailto:jdewever@shpa.org.au).

Yours sincerely,

A handwritten signature in black ink that reads 'Kristin Michaels'.

Kristin Michaels  
Chief Executive



**The Society of Hospital Pharmacists of Australia**

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## References

- <sup>1</sup> Chiew, AL., Isbister, GK., Page, CB., Kirby, KA., Chan, BSH., Buckley, NA. (2018) Modified release paracetamol overdose: a prospective observational study (ATOM-3). *Clin Toxicol (Phila)*. 2018 Sep;56(9):810-819.
- <sup>2</sup> Hawton, K., Bergen, H., Simkin, S., Dodd, S., Pocock, P., Bernal, W., Gunnell, D. and Kapur, N. (2013). Long term effect of reduced pack sizes of paracetamol on poisoning deaths and liver transplant activity in England and Wales: interrupted time series analyses. *BMJ*, 346(feb07 1), pp.f403-f403.



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