

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on the proposed amendment to the current Poisons Standard referred to the Advisory Committee on Medicines Scheduling (ACMS) meeting in March 2019.

Summary

Paracetamol (modified release) – terminology

- *PSA supports the proposal to amend the terminology for paracetamol from ‘slow release’ to ‘modified release’.*
- *PSA believes clear labelling on product packaging or broader information dissemination will be important for patients and carers who may not understand the meaning of the term ‘modified release’ or may be confused by the change from ‘slow release’ to ‘modified release’ in relation to their therapy.*

Paracetamol (modified release) – rescheduling

- *PSA supports the rescheduling of modified release paracetamol from Schedule 2 (S2) to Schedule 3 (S3).*
- *PSA believes consideration should be given to the possibility of up-scheduling paracetamol currently exempt from scheduling to S2.*
- *PSA suggests issues or factors relevant to the consideration of this proposal include:*
 - *the option of retaining smaller pack sizes in S2*
 - *likely impact on pharmacists’ practice with respect to additional S3 labelling requirements and providing information and reassurance to patients and carers*
 - *likely impact on patients if there is a change to scheduling or availability of their medicine (particularly if needed for chronic conditions), managing medicines appropriately to ensure continuity of established therapy, or the cost of the medicine if rescheduled.*
- *PSA suggests clear and consistent communication with patients and carers, and with prescribers regarding any changes to the scheduling and/or availability of paracetamol is needed so that confusion or concern can be minimised, and unintended changes to established therapy can be prevented.*

Proposed amendment

PSA understands the delegate of the Secretary proposes, in the Poisons Standard, to:

- amend the terminology from ‘slow release’ paracetamol to ‘modified release’ paracetamol, and
- up-schedule modified release tablets or capsules containing less than or equal to 665 mg of paracetamol from S2 to S3.

Terminology

The proposal to amend the terminology outlines that modified release paracetamol tablets are constructed in two layers, an immediate release layer and a sustained release layer. PSA notes the rationale provided that ‘slow release’ does not correctly describe the pharmacological action of the two-layer formulation and that the term ‘modified release’ is used in all the product information.

Overall PSA has no objections to amending the term ‘slow release’ paracetamol to ‘modified release’ paracetamol from a technical and regulatory perspective. However, some pharmacists have expressed concern to PSA that patients and carers may not readily understand the term ‘modified release’ and the change may be confusing. While counselling by the pharmacist will assist in this regard, PSA believes clear labelling on the product packaging and broader dissemination of information warrants consideration by the ACMS.

Rescheduling proposal

PSA is supportive overall of the proposed amendment for modified release paracetamol from S2 to S3. However, PSA requests the ACMS to take the following into account in the decision-making process.

Points raised in the proposal

- In the proposal a summary of risks provided includes that modified release paracetamol has “unpredictable and undefined pharmacokinetic profile” and that “current best practice guidelines do not completely address modified release toxicity”. Some pharmacists have queried these statements as it is felt that Australian clinical practice is adequately supported with respect to the management of paracetamol poisoning. For example, the current guidelines¹ for Australia and New Zealand indicate that:
 - possible changes to the paracetamol nomogram treatment line have been considered in the past (given there has been a change in the UK and Ireland) but remain unchanged in Australia as risks versus benefits in changing were not favourable, and

¹ Chiew AL, Fountain JS, Graudins A, et al. Consensus statement. Guidelines for the management of paracetamol poisoning in Australia and New Zealand – explanation and elaboration. Med J Aust 2015; 203:215–8. At: https://www.mja.com.au/sites/default/files/issues/203_05/Guidelines_paracetamol_Aus_NZ_2015.pdf

- the different management pathway required for modified release overdoses, including very large overdoses, is included in the guidelines.
- The proposal states that chronic suprathreshold overdose is also thought to be not uncommon and that this is likely largely due to confusion about the difference in dose between modified release and immediate release paracetamol. The availability of paracetamol in different dosage forms and types of formulation, in different combination products and for different indications, and being available from outlets with varying degrees of regulatory control are of significant concern to PSA and pharmacists. PSA strongly believes that the high utilisation rate and potential clinical risks associated with paracetamol mean that paracetamol-containing products should not be available in non-pharmacy outlets, particularly where information about medicines generally and advice on those medicines being purchased are not available to the patient or carer. PSA requests the ACMS to give consideration to the possible up-scheduling of paracetamol currently exempt from scheduling.

Impact on pharmacists

- It is noted that a change in scheduling (to S3) will have a substantially greater impact on pharmacists' practice in Queensland due to the additional labelling requirement. In this regard, whilst PSA recognises the sovereignties of states and territories we believe there should be, as far as practicable, national consistency in the regulation of medicines.
- More generally, pharmacists believe that many patients unaware of legislated requirements for S3 medicines will be confused or concerned, at least in the initial stages of implementation should there be up-scheduling to S3. This is likely to have a moderately significant impact on practice with additional workload for pharmacists to explain and reassure patients and carers, particularly those who regularly take modified release paracetamol.
- PSA is aware that there are 26 modified release paracetamol products currently on the Australian Register of Therapeutic Goods. PSA notes that many community pharmacies would generally choose to regularly stock a limited number of brands, partly based on the needs of the local demographic (although other specific brands can be procured if requested or required). In addition, PSA notes the brief feedback obtained from practising pharmacists which indicates that the use of modified release paracetamol is substantially greater than that of immediate release paracetamol with estimated proportions ranging between 50/50 and 90/10 (modified release / immediate release).

Possible impact on patients

- The applicant's proposal outlines that the continued availability of paracetamol in S2 in pack sizes of 96 poses an unacceptable risk to the Australian population. PSA's member pharmacists suggested the option of rescheduling modified release paracetamol to S3 with the exception of smaller pack sizes which could be retained in S2. However pharmacists also noted that a smaller pack size could pose an inconvenience to those who take modified release paracetamol for the relief of persistent pain associated with osteoarthritis. A smaller pack size would also generally increase the price per unit and this would be a further disadvantage for patients who rely on this therapy for basic physical activities of daily living.

- As outlined earlier, patients may express concern if modified release paracetamol is rescheduled. This may impact more on those who rely on this medicine for a chronic condition. Pharmacists are aware that a change to medicine availability can impact on patients in different ways. PSA strongly believes clear and consistent communication to patients would be required to minimise any confusion or concern, or unintended changes to established therapy.
- Pharmacists noted that many patients who take modified release paracetamol long term do so on their medical practitioner's recommendation. Therefore communication with prescribers will also be necessary if modified release paracetamol is rescheduled to ensure they are aware of changes impacting on patients.

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