[redacted]

10 May 2018

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir or Madam,

Email to:

Notice inviting public submissions under subsection 42ZCZK/42ZCZL of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACCS, ACMS and ACCS/ACMS Meetings, June 2018

We refer to the notice inviting public comment under Regulation 42ZCZK/42ZCZL of the *Therapeutic Goods Regulations* and would like to provide comment on the ibuprofen paracetamol combination scheduling proposals that will be referred to the June 2018 meetings of the ACMS.

Ibuprofen combined with paracetamol.

> *To amend the Schedule 3 entry for paracetamol to allow the Schedule 3 primary pack size, when combined with ibuprofen, to be increased from 30 to 50 dosage units; and amend the Schedule 4 entry to reflect this change.*

Comments

- RB support the proposal to increase the pack size of the Schedule 3 entry from 30 to 50 dosage units. RB also continues to support retaining a scheduling cut-off based on the number of dosage units (as opposed to a scheduling cut-off based on a number of days' supply).

- Considering current ibuprofen paracetamol combination products in the market, the proposed increase in pack size from 30 to 50 dose units in Schedule 3 represents 6 days' supply at the maximum labelled dose for Maxigesic tablets and 16 days' supply at the maximum label dose for Nuromol and generic tablets. By comparison, the existing pack size limits in Schedule 2 for paracetamol and ibuprofen packed separately represent 12 and 16 days' supply per 100 pack respectively.

- The total amount of paracetamol and ibuprofen present in the proposed 50 pack in Schedule 3 will be less than half the amounts present in the existing Schedule 2 packs of these ingredients presented separately.

- Consumers using Nuromol as directed on the product label will take less than half the maximum recommended dose of paracetamol and ibuprofen used separately. This 'active-sparing' effect is in line with the Quality Use of Medicines (QUM) principles in Australia's National Medicines Policy.

- Paracetamol and ibuprofen individually both have a long history of use in Australia, and are well tolerated and have favourable safety profiles. The low risks associated with these ingredients are such that they are unscheduled in small pack sizes.

- The current Australian ibuprofen paracetamol combination products are a logical replacement for the low dose codeine paracetamol and codeine ibuprofen combinations that switched to Schedule 4 on 1 February 2018.

- The fixed dose combination of paracetamol and ibuprofen in Nuromol offers greater analgesic efficacy at a lower dose while maintaining the acceptable safety profile of each substance used separately.

- The labelling of these products contains appropriate warning statements, as per the TGA Medicines Advisory Statement Specifications (MASS 2017) to facilitate appropriate use. Pharmacists are also available at the point of supply to provide advice and referral if needed.

In addition, the proposed increase in Schedule 3 pack size for paracetamol combined with ibuprofen will:

- Allow pharmacists to exercise greater discretion in managing clients with acute intermittent strong pain (e.g. from migraine headache).
- Reduce the pressure on GPs resulting from demand for larger packs of stronger analgesics from patients with a legitimate need for treatment of acute intermittent strong pain.
- Provide consumers with access to an economical, effective and safe medication for the relief of acute intermittent strong pain (e.g. from migraine headache), subject to consultation with a pharmacist.
- Avoid unfairly penalising consumers who do not have ready access to a GP (e.g. due to location, mobility, economic or other issues) and need options for treating acute intermittent strong pain.

Conclusion

RB supports the proposal for amendment of Schedules 3 and 4.

Yours sincerely,

RB

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