[redacted]

[redacted]

31 October 2018

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.gov.au

Dear Sir or Madam,

**Notice inviting public submissions under regulation 42ZCZK of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the ACMS Meeting, March 2019 (Paracetamol pursuant to regulation 42ZCZJ)**

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide the following comments on the paracetamol scheduling proposal that will be referred to the March 2019 meeting of the ACMS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to provide public comment in relation to ACMS agenda.

We wish to address relevant matters under section 52E of the *Therapeutic Goods Act* 1989.

Please find enclosed, under cover of this letter, ASMI's comments in relation to the paracetamol scheduling proposal that will be considered by the ACMS at the March 2019 meeting.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

[redacted]

**Paracetamol**

*To amend the terminology in the Poisons Standard from 'slow release' paracetamol to 'modified release 'paracetamol; and*

*To up-schedule 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.*

Introduction

While ASMI supports replacing the term "slow release" with "modified release" we do not support the proposed up-scheduling of modified release paracetamol from Schedule 2 to Schedule 3.

Safety

Paracetamol has a long history of use in Australia, is well tolerated and has a favourable safety profile. The safety profile of modified release (MR) paracetamol in normal therapeutic use is similar to that for immediate release (IR) paracetamol.

MR paracetamol has been available in Australia since 2001.

ASMI is unaware of any evidence of dependence, abuse, misuse or illicit use of either the IR or MR paracetamol products.

ASMI understands that only a very small proportion of overdoses with MR paracetamol have been due to unintentional overdose.

The TGA submission relies, in large part, on the Chiew et al 2018 study[1]. In relation to this study, ASMI notes that:

- There has only been one was one death reported in Australia in association with MR paracetamol (an 87 year old man who died from respiratory failure secondary to aspiration 30 h post-ingestion)
- There have been no deaths in patients who developed hepatotoxicity
- The authors have called for research into better treatment strategies (and not increased restrictions to access)

ASMI understands that the majority of patients who use MR paracetamol in Australia so do responsibly and with little risk of accidental overdose. The TGA's adverse event data does not show any signal to indicate an increasing risk with MR paracetamol in Australia and the NSW PIC data shows that calls related to intentional overdose with MR paracetamol have not increased.

[1] Angela L. Chiew, Geoffrey K. Isbister, Colin B. Page, Katharine A. Kirby, Betty S. H. Chan & Nicholas A. Buckley (2018) Modified release paracetamol overdose: a prospective observational study (ATOM-3), Clinical Toxicology, 56:9, 810-819

ASMI notes the following statement at page 25 of the TGA submission:

> *"…the TGA considers that up-scheduling to S3 will provide …. a barrier to the impulsive purchasing of MR paracetamol for the purposes of taking an overdose."*

We can find no evidence of such "impulsive purchasing" either in the TGA submission or the public domain. We would encourage the TGA to produce whatever evidence they possess in support of this statement.

International Experience

ASMI notes, that while the Australian and New Zealand overdose guidelines take a dose-based approach to the use of the antidote (acetylcysteine), the Swedish guidelines are based on a paracetamol blood level chart (a nomogram).

In our view, the Swedish experience is not relevant to the Australian regulatory environment (firstly because of the different approaches to treating overdose, and secondly because in Sweden, MR paracetamol was a prescription only medicine indicated for a wide range of acute and chronic pain states, in contrast to the over-the-counter indication in Australia for persistent pain associated with osteoarthritis).

ASMI notes that the Danish Medicines Authority[2] has already lifted the suspension on MR paracetamol (and other EU countries are expected to follow).

Benefits

There are real (demonstrated) benefits to three-times daily dosing with MR paracetamol[3].

The majority of patients who use MR paracetamol in Australia do so responsibly and with little risk of accidental overdose.

Impact of up-scheduling

Restricting access will present consumers with an unnecessary barrier, will increase costs and will increase inconvenience.

ASMI suggests that up-scheduling of MR paracetamol would not have had an impact on any of the adverse event reports discussed in the TGA submission where death was the outcome (see pages 24 and 25). In those cases, MR paracetamol was either prescribed or unlikely to have been the cause.

The TGA proposal also ignores the substantive risk mitigation measures that are already in place and there is nothing to suggest that up-scheduling will improve this already favourable position.

---

[2] https://laegemiddelstyrelsen.dk/da/nyheder/2018/depotformuleret-paracetamol-forbliver-paa-markedet-i-danmark/

[3] Ortiz, M., G. Calcino and F. Dunagan. Prescription usage patterns of two formulations of paracetamol in osteoarthritis: Australia-wide experience 2008-11; 2016 Aust Fam Physician 45(5),321-325.

In any event, there are better alternatives to up scheduling considering our best-practice approach to overdose treatment (these include improved product labelling, detailed pack leaflets, online information, improved education, etc.). ASMI understands that some affected sponsors have already begun to implement these improvements.

Up-scheduling will not provide benefits and will disadvantage the many people who are already using this product to protect the small minority who opt to use it for deliberate self-harm.

## Scheduling factors

MR paracetamol clearly meets all of the Schedule 2 scheduling factors:

1. The quality use of the medicine *can be achieved* by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist should be available to maximise the safe use of the medicine.

2. The use of the medicine *is substantially safe* for short term treatment and the potential for harm from inappropriate use is low.

3. The use of the medicine *is very unlikely to produce dependency* (at either the established therapeutic dose or supratherapeutic doses) and the medicine *is very unlikely to be misused*, abused or illicitly used.

4. The risk profile of the medicine *is well defined* and *the risks can be identified and managed by a consumer* through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.

5. The use of the medicine at established therapeutic dosage levels *is not likely to mask the symptoms or delay diagnosis* of a serious condition.

MR paracetamol should therefore remain in Schedule 2.

## Conclusion

For the reasons outlined above (and in accordance with the scheduling factors), ASMI does not support the proposed up-scheduling of MR paracetamol from Schedule 2 to Schedule 3.