

Consumer Healthcare Products Australia

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5 March 2020

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au

Dear Sir/Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment

We refer to the notice inviting further comment under subsection 42ZCZP of the *Therapeutic Goods Regulations 1990* and would like to provide comment on the Delegate's Interim Decisions arising from the November 2019 meeting of the ACMS.

CHP Australia is the leading voice and industry body for manufacturers and distributors of consumer healthcare products, which includes non-prescription medicines. We strive to advance consumer health through responsible Self Care and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include improving health literacy, growing the consumer healthcare products industry and increasing access to medicines where appropriate.

CHP Australia has considered the Delegate's Interim Decisions and Reasons for Decisions and would like to comment on the following scheduling proposal:

Item 1.4 – Interim decision in relation to paracetamol (liquid formulations)

CHP Australia supports the Delegate's interim decision on paracetamol (liquid formulations) to the extent that current marketed products will not be affected by the decision.

However, we would like to reiterate our disappointment with the process in relation to this agenda item. The poorly worded proposal led to a great deal of unnecessary anxiety for industry stakeholders.

We were pleased to see the Delegate acknowledge the "ambiguity in the scheduling amendment as proposed which included both a concentration cutoff (50 mg/mL) and two different weight cut-offs (5 g and 50 g)", and we trust that the TGA will review and revise their drafting procedures so as to avoid any similar incident in the future.

As we described in our submission of 26 September, it was clear that an error had occurred in the drafting of the proposed change, and despite repeated requests to do so the TGA refused to correct the error. The result of such an ambiguous/erroneous/incomprehensible proposal was to create unnecessary effort/concern as stakeholders needed to prepare lengthy responses to all the potential interpretations/misinterpretations instead of simply responding to a clearly articulated proposal.

As we indicated at the time, we had no objection to the proposal to correct an administrative oversight by including an upper limit on the schedule 2 entry for liquid paracetamol products, we did, however, object to the ambiguous way that proposal had been worded.

Kind Regards

Steve Scarff
Regulatory and Legal Director