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5 March 2018

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au and Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, November 2017

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 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

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

1.6 Ibuprofen

For the reasons outlined in our submission of 6 October 2017, ASMI supports the Delegate's interim decision that the current Schedule 2 and Schedule 3 entries for ibuprofen remain appropriate.

1.9 Clotrimazole

ASMI does not support the Delegate's interim decision regarding clotrimazole.

In our view the schedule entries and appendices F and H should have been amended as proposed by the applicant.

The Delegate has missed an opportunity to improve access by women to a safe and effective treatment.

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Clotrimazole is available over-the-counter (without mandatory pharmacist intervention) in more than 70 other countries (and is available as a general sale item – GSL - in the US and the UK). The Delegate has therefore also missed an opportunity to bring the Australian scheduling of clotrimazole into alignment with scheduling in comparable markets.

2.2 Salts of boric acid

ASMI does not support the Delegate's interim decision regarding the salts of boric acid.

As indicated in our submission of 6 October 2017 (and despite comments to the contrary in the interim decision) there *are* products on the Australian market which will be affected by the decision (one of our members has advised us that their existing dental adhesive product will require re-formulation).

As identified in our submission of 6 October, an appropriate transition period would be 24 to 30 months, so as to allow affected manufacturers to:

a. investigate alternative ingredient(s), and
b. develop new formulations, and
c. perform the required testing to ascertain the optimal formulation, and
d. manufacture test batches, and
e. perform the associated stability / quality control on test batches
f. All before going to market

The final scheduling decision will not be published until 10 April 2018 and manufacturers cannot reasonably act until that final decision is known. The 1 October 2018 implementation date is therefore manifestly inadequate as it allows less than six months for the affected manufacturers to develop and produce re-formulated products. The advice from our affected member is that:

> *"Exploration of on an alternative formulation that would give a comparative or improved product with greater bonding and strength requires at least 2 years of study and testing."*

The interim decision appears to have no impact on the many complementary medicines which include borax below the 6mg per daily dose cut-off.

2.3 Polihexanide

Polihexanide is included in the TGA's Permitted Ingredients list and in the TGA eBS ingredients list; it is allowed as an excipient in over the counter and listed medicines for topical dermal use, in a concentration of 0.3% or less. The Delegate's interim decision to align the Schedule 6 entry with this 0.3% limit will therefore have no impact on the scheduling of therapeutic goods and to that extent, ASMI supports the interim decision.

3.5.1 1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives

This substance is not entered in the TGA eBS ingredients list, nor is it entered in the TGA Permitted Ingredients List. The Delegate's interim decision will therefore have no impact on the scheduling of therapeutic goods and to that extent, ASMI supports the interim decision.

3.6 Phenyl methyl pyrazolone

This substance is not entered in the TGA eBS ingredients list, nor is it entered in the TGA Permitted Ingredients List. The Delegate's interim decision will therefore have no impact on the scheduling of therapeutic goods and to that extent, ASMI supports the interim decision.

Thank you for the opportunity to comment on the above interim decisions.

Please contact me should you have any further queries.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

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