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11 October 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

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 June 2018 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:

1.1 Sildenafil

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

In our view, a new Schedule 3 entry should have been prepared as proposed by the applicant.

In reviewing the summary of the ACMS advice, and the delegate's subsequent considerations, we note that:

- In finding that sildenafil did not meet the Schedule 3 SPF criteria, the ACMS and the Delegate placed too much emphasis on the risks associated with the substance and placed too little emphasis on the potential benefits of re-scheduling.

- The ACMS and the Delegate dismissed the recent and relevant decisions made by comparable overseas regulatory authorities on the public health benefit of increased access.

- The Delegate's reasons state that: "*There was no proposed Appendix M education or checklist material included in the application*" and that: *"Appendix M is not appropriate for*

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ED and sildenafil treatment given that ED is a symptom of other conditions which require medical practitioner diagnosis, monitoring and treatment." These two statements taken together are contradictory: indicating, firstly, that no Appendix materials were included and indicating at the same time that even if such materials were submitted they would not have been considered. The second statement on its own, seems to suggest a level of bias and prejudgment that is inconsistent with good decision making and we were surprised to see such a strong negative comment, when sildenafil had been put forward by the TGA as a case study at the second meeting of the Scheduling and Scheduling Policy ad-hoc working group, held in March 2018[1].

1.2 Budesonide

For the reasons outlined in our submission of 10 May 2018, ASMI supports the Delegate's interim decision to amend the Schedule 2 entry for budesonide to increase the dose per actuation from 50 to 64 micrograms; and remove the limit of 200 actuations.

1.6 Paracetamol combined with ibuprofen

ASMI does not support the Delegate's interim decision regarding Paracetamol combined with ibuprofen.

For the reasons outlined in our submission of 10 May 2018, the Schedule 3 and Schedule 4 entries should have been revised as proposed by the applicant. Such revisions would have better reflected the current scheduling principles and would have been a move towards closer alignment with the New Zealand scheduling of the combination.

2.4 Astodrimer sodium

ASMI supports the creation of a new Schedule 3 entry for astodrimer sodium as a better alternative to the Schedule 4 entry originally proposed by the TGA. Given the "minimal risk" and "low toxicity" of the substance and given the straightforward identification and treatment of Bacterial Vaginosis, we agree with the ACMS that the substance "May be suitable for future Schedule 2 listing".

ASMI supports the creation of a new Appendix H entry for astodrimer sodium.

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

[1] https://www.tga.gov.au/sites/default/files/medicines-scheduling-and-scheduling-policy-ad-hoc-working-group-meeting-two.pdf

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