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15 April 2019

Pharmacy Board of Australia
AHPRA
GPO Box 9958
Canberra
ACT 2601

Submitted via email: PharmBAfeedback@ahpra.gov.au

Dear Sir / Madam,

Re: Pharmacy Board of Australia – Feedback on pharmacist prescribing

Thank you for the opportunity to comment on the Pharmacy Board of Australia discussion paper on pharmacist prescribing.

About ASMI

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines). ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

ASMI is committed to expanding and promoting Quality Use of Medicines (QUM), which is central to the National Medicines Policy.

Scope of the consultation

ASMI supports the stated key objectives of the Pharmacy Board of Australia and we agree that there is a need to:

- improve access to healthcare, including medicines,
- increase patient choice, and
- mitigate ongoing rural and remote workforce shortages.

Our comments in this response go to the areas within ASMI's scope, namely consumer healthcare and access to medicines.

Medicines Scheduling and Pharmacist Prescribing

Currently, pharmacists manage medicines in Schedule 3 of the Poisons Standard. These medicines are also referred to as Pharmacist Only Medicines, the safe use of which requires professional advice but should be

publicly available from the pharmacist without a prescription. There are also newly-introduced provisions for additional controls in the Poisons Standard for Appendix M entries for Schedule 3 medicines:

> *"Additional controls over access and training for substances in Schedule 3 may be required through inclusion in Appendix M, particularly where the potential for severe and possibly irreversible injury may occur without the user being aware of exposure and/or where the pattern of use of the substance poses a significant risk from direct or indirect public exposure"*.[1]

ASMI recommends that any framework that is developed for pharmacist prescribing should be clearly differentiated in scope, so that there is no conflation with existing Schedule 3 and Schedule 3/Appendix M, which also allow for pharmacists to make autonomous decisions on suitability of a medicine for a patient.

ASMI is concerned that some stakeholders view pharmacist prescribing as a less risky substitute or preferred alternative to switch/down-scheduling (Schedule 4 to Schedule 3). Pharmacist prescribing is not a substitute for S4 to S3 down-scheduling and this should be reinforced with the adoption of any model of pharmacist prescribing. There should be clear policy advice that pharmacist prescribing is different and is not a substitute for S4 to S3 down-scheduling where appropriate.

Emergency prescribing and pharmacist prescribing

ASMI recommends that the differences between existing emergency prescribing provisions, which are governed by States and Territories in their respective legislation, and pharmacist prescribing are clearly differentiated to a model of pharmacist prescribing.

The role of Schedule 3 / Schedule 3 Appendix M medicines

ASMI is of the firm view that Schedule 4 to Schedule 3 switch/down-scheduling (with or without Appendix M) is the most appropriate and widely available mechanism for pharmacists to extend their expertise in providing healthcare advice and appropriate medicines to consumers. Schedule 3 Pharmacist Only medicines provide pharmacists with a unique opportunity not available in many other countries (such as the UK, USA and other European and Asian countries) to develop their expertise with newly switched medicines and add value to public health.

There should be clear distinctions between the different pathways through which pharmacists can provide medicines without a prescription. Either of the independent and co-dependent pharmacist prescribing models described in the discussion paper are not substitutes for, and should not be alternatives to, increased access to Schedule 3 medicines.

The major advantage of pharmacists is their accessibility. Schedule 3 medicines are managed by all pharmacists under their existing scope of practice, a feature that may not be applicable to the pharmacist prescribing models, which will require specialized training and accreditation.

ASMI recommends that any future mechanism that is developed to enable pharmacist prescribing should clearly define the differences between pharmacist prescribing, emergency supply and medicines that could be suitable for inclusion in Schedule 3.

As part of recent reforms to the Scheduling Policy Framework, the TGA established a Scheduling Working Group, comprising representatives from the States and Territories, the medicines and chemical scheduling advisory committees, industry groups and professionals from the medicine, pharmacy and chemicals sectors as well as consumer representatives. Among other issues, the TGA's Working Group discussed possible candidate medicines for potential consideration for down-scheduling ('switching').

1. AHMAC Scheduling Policy Framework for Medicines and Chemicals v.1 January 2018 https://www.tga.gov.au/sites/default/files/ahmac-scheduling-policy-framework-medicines-and-chemicals.pdf

The driver for this change is to facilitate better access to medicines and support greater Self Care. The Working Group noted that similar stakeholder groups had provided advice of this type to regulators in UK, Ireland, Denmark and Singapore. The outcomes from the TGA Scheduling Stakeholder Workshop have been published on the TGA website, see https://www.tga.gov.au/scheduling-news. Clear descriptions of the suitability of the various supply pathways is important for industry when considering whether to apply for the down-scheduling of any medicine.

Recommendations

In conclusion, ASMI is of the view that Australian pharmacists already make a significant contribution to public healthcare through a broad range of services. They are highly trusted by consumers and are well-placed to play a greater role in the delivery of primary healthcare, particularly in the areas of Self Care, health literacy and consumer access to prescription and non-prescription medicines. We commend the Pharmacy Board for its discussion paper and its request for an evidence-based examination of the different models of pharmacist prescribing, and recommend that any pharmacist prescribing model that may be adopted should be clearly defined in scope and clearly differentiated from the existing Schedule 3 / Appendix M provisions and emergency supply provisions.

This would assist pharmacists, other healthcare professionals, consumers and industry in having an accurate understanding of these different supply provisions that can be used by pharmacists.

We look forward to the continuing discussion on this issue and the publication of the outcomes of this consultation.

Yours sincerely,

Julie Viatos
Quality Use of Medicines Manager