australian healthcare & hospitals association

the voice of public healthcare

Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)

Submission to the TGA

1 April 2019

ahha
australian healthcare & hospitals association
the voice of public healthcare®

OUR VISION

A healthy Australia, supported by the best possible healthcare system.

OUR MISSION

To conduct research, educate and influence the healthcare system to achieve better health outcomes, improved patient and provider experience, greater equity and sustainability.

OUR GUIDING PRINCIPLES

Healthcare in Australia should be:

Effective

Accessible

Equitable

Sustainable

Outcomes-focused.

OUR CONTACT DETAILS

Australian Healthcare and Hospitals Association

Unit 8, 2 Phipps Close
Deakin ACT 2600

PO Box 78
Deakin West ACT 2600

P. 02 6162 0780
F. 02 6162 0779
E. admin@ahha.asn.au
W. ahha.asn.au

facebook.com/AusHealthcare
@AusHealthcare
linkedin.com/company/australian-healthcare-&-hospitals-association

ABN. 49 008 528 470

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INTRODUCTION

The Australian Healthcare and Hospitals Association (AHHA) is pleased to provide this submission to the consultation on the *Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)*.

WHO WE ARE

AHHA is Australia's national peak body for public hospitals and healthcare providers. Our membership includes state health departments, Local Hospital Networks and public hospitals, community health services, Primary Health Networks and primary healthcare providers, aged care providers, universities, individual health professionals and academics. As such, we are uniquely placed to be an independent, national voice for universal high-quality healthcare to benefit the whole community.

SCOPE OF REVIEW

AHHA acknowledges that this consultation is separate to work being undertaken concurrently to enable greater advertising of medicines containing Schedule 3 medicines; to identify potential Schedule 3 substances that may be suitable for advertising; and to identify suitable candidates for consideration for switch from Schedule 4 to Schedule 3 (including pro-active down scheduling). Feedback is therefore focused on the practicality, reasonableness and utility of the proposed framework for Appendix M criteria and related guidance.

OVERARCHING VIEW

AHHA supports the Scheduling Policy Framework as the mechanism for setting out the national policy for applying access restrictions on all 'poisons', with poisons scheduled according to the risk of harm and the level of access control required to protect consumers.

AHHA supports a nationally unified, but regionally-flexible approach, in imposing legislative controls in the supply of poisons. Support for this approach recognises the differences faced in different jurisdictions that impact on providing safe and effective health care and achieving quality and equitable health outcomes. Jurisdictional differences include differences in individual and population health needs, public health issues, and health workforce availability and distribution.

AHHA recognises that scheduling decisions can improve self-management and the use of public health resources, provided risks such as inappropriate use and delayed diagnosis of serious conditions can be minimised.

AHHA believes that the use of Appendix M can support models of care that improve equitable and timely access to medicines and address population health needs safely, effectively and efficiently.

Consistent with the layout of the consultation paper, a more detailed response has been provided against the following areas:

1. Intent of Appendix M
2. Proposed criteria
3. The application
4. Monitoring, evaluation, compliance and enforcement of Appendix M

1. INTENT OF APPENDIX M

The 'Background' section of the consultation paper states 'the introduction of Appendix M was planned to facilitate appropriate over the counter (OTC) access for certain products that have a good case for broader community access, but are currently prescription-only in Australia and may present public health risks above those normally considered acceptable for S3 substances'.

AHHA supports this purpose for introducing Appendix M, as a mechanism to facilitate increased access to medicines.

It is also stated that 'it is envisaged that Appendix M will function in a similar manner to Appendix D, which specifies additional controls for particular S4 or S8 substances. Appendix M would specify additional controls to those normally applying to pharmacist-only medicines'.

While the similarities in the operational aspects of the controls for Appendix D and M are supported, AHHA notes that the intent for these appendices is different. Appendix D is focused on mechanisms that further restrict access, rather than facilitate access. AHHA recommends that these differences in intent are explicitly noted in communications when comparing the appendices to ensure that Appendix M is not used to unintentionally or unnecessarily restrict access.

AHHA also supports the intent stated in the consultation paper that Appendix M controls would not be routinely required for medicines that are rescheduled from S4 to S3, recognising that reclassification has occurred safely and successfully for medicines across a broad range of indications without a need to impose these additional regulatory controls.

Further, inclusion in Appendix M should not prohibit the same medicines being supplied as a S4 (Prescription only) medicine (i.e. without pharmacists complying with the additional controls). The cost of medicines may be prohibitive without subsidisation under the Pharmaceutical Benefits Scheme, and patient access should be retained.

2. PROPOSED CRITERIA

- Do you agree with the above criteria? If so why/why not?
- Do you foresee issues with implementation of any of these criteria?
- Are there additional criteria that should be included?

AHHA notes that the proposed criteria for Appendix M identify the additional controls that could be imposed with inclusion of a substance in Schedule 3, rather than criteria that would justify the need for imposing additional controls.

While such flexibility is supported, AHHA reinforces previous comments that focus is retained on the intent of the Schedule being to facilitate access, and not unnecessarily restrict access. Further, vested interests, e.g. of professional groups who may financially benefit from the proposed changes, should be considered by the committee when considering feedback on the proposed inclusion of substances in Appendix M.

AHHA supports the breadth of options that are proposed in the criteria and that may be considered by the Advisory Committee on Medicines Scheduling (ACMS) when considering inclusion of a substance in Appendix M. Where training requirements are imposed, AHHA recommends that there be consideration of equitable access to training so that such requirements do not further exacerbate inequitable access to health care, e.g. disadvantaging those in rural and remote areas or vulnerable groups. There should also be an expectation of consistency in training requirements and cross-recognition of completion between states/territories, wherever possible, so as not to impose additional unnecessary burden on pharmacists practising across multiple jurisdictions.

3. THE APPLICATION

- Is this sufficient level of detail for completion of an application?
- Are the proposed requirements for the application form reasonable?
- Does this level of guidance provide sufficient information and flexibility for future scheduling decisions in relation to Appendix M?

Australia is recognised as less active in reclassifying medicines from prescription to non-prescription than other countries, in particular New Zealand.[1,2] The application process should ensure that barriers to initiating reclassification of medicines are not exacerbated.

AHHA recommends that any proposed material or training should not need to be developed as part of the application process, but rather the application should describe the proposed:

- objectives and parameters for the material or training that are anticipated will mitigate risk;
- the development and approval process that will be utilised; and
- mechanisms to support equitable access by pharmacists to the material or training.

The ACSM may then provide advice on the conditions imposed, and requirements to support their implementation, as part of their recommendation for the substance's inclusion in Appendix M.

[1] Gauld, N, et al (2015) Widening consumer access to medicines: a comparison of prescription to non-prescription medicine switch in Australia and New Zealand. PLoS ONE vol. 10, iss. 3: e0119011.

[2] Gauld, N, et al (2015) Why does increasing public access to medicines differ between countries? Qualitative comparison of nine countries, Journal of Health Services Research & Policy, vol. 20, iss. 4, pp. 231-239.

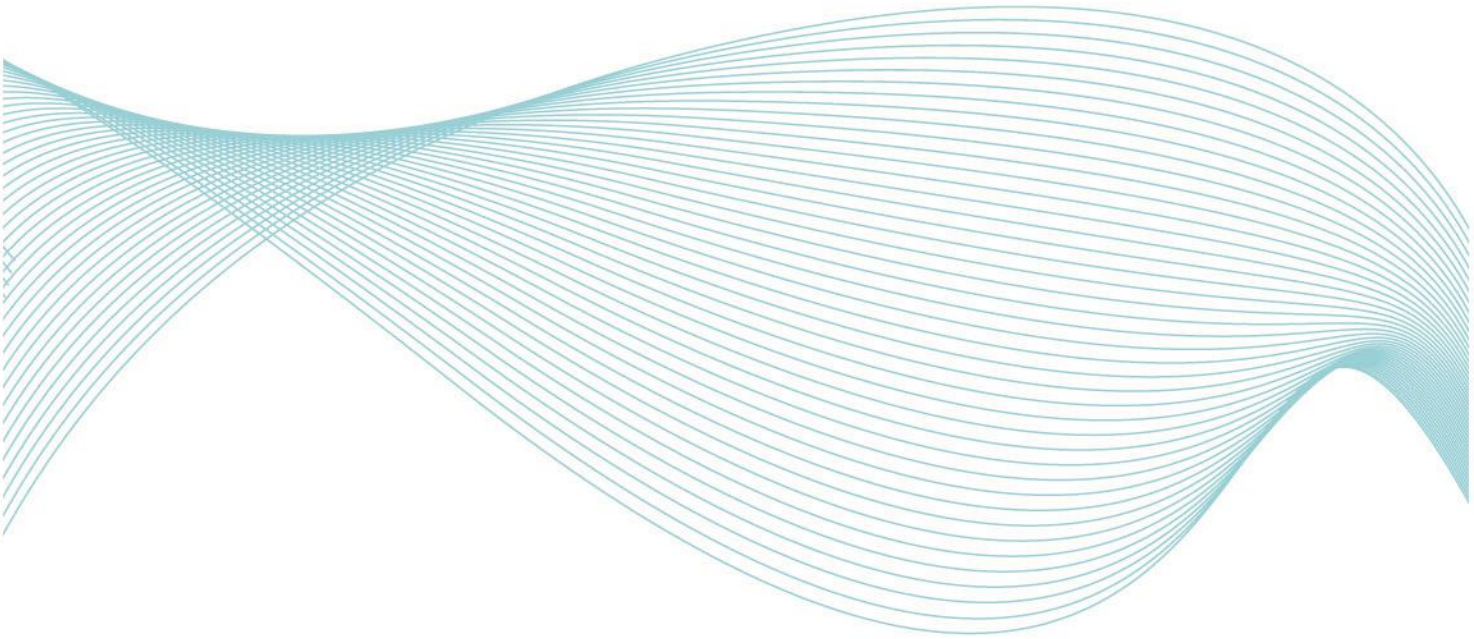
4. MONITORING, EVALUATION, COMPLIANCE AND ENFORCEMENT OF APPENDIX M

- Are these provisions adequate for monitoring, evaluation, compliance and enforcement of Appendix M criteria?
- What alternative measures might be considered?

With the introduction of this new policy initiative, AHHA recommends the TGA provide a consolidated report on compliance with Appendix M requirements on an annual basis. This may include consolidating and publishing relevant:

- Findings from monitoring by State and Territory Drugs and Poisons units
- Notifications made to the Pharmacy Board of Australia.

Findings from monitoring and evaluation can be used to inform the ACMS on the appropriateness of their use of Appendix M, supporting consideration of the inclusion of existing medicines and future applications. The findings will also support stakeholder understanding and use of Appendix M in facilitating access to medicines.



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ABN. 49 008 528 470