



01 April 2019

Transparency, Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Submission by The University of Sydney School of Pharmacy

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

Specific criteria for inclusion in Appendix M

Do you agree with the above criteria? If so why/why not?

We have concerns regarding “**Criterion 2:** Specific pharmacist training on the provision of the medicine may be required.” On page 9, the consultation states “A training package for provision of medicines containing each S3, Appendix M substance would be developed by the sponsor in conjunction with an appropriate provider, such as the PSA.” However, on page 8 it is stated “They [the training] could take the form of optional Continuing Professional Development (CPD) units developed by sponsors and approved by relevant organisations.” We note that there is potential ambiguity as to the level of involvement of the sponsor in the development of the training material. To mitigate against a conflict of interest (or perception thereof), we recommend that the training program should be independently evaluated and accredited (by an organisation who will not produce their own training), and who does not have a conflict of interest with the training developer and sponsor funding the training. Furthermore, we support the development of Australian Pharmacy Council (APC) standards for the accreditation of training programs.

Do you foresee issues with implementation of any of these criteria?

Criterion 5: Record keeping and information sharing, may have a degree of implementation difficulty. Current information sharing processes between community



pharmacists and general practitioners in the Australian health system are non-standardised and suboptimal. We agree that information sharing with GPs may be required as a condition for supply of a medicine listed in Schedule 3 Appendix M. We also agree that *MyHealth Record* is a suitable option to facilitate information sharing. We recommend that clear guidance be developed by relevant professional organisations (such as PSA, PGA, RACGP) to facilitate timely information sharing including in instances where a person does not have a *MyHealth Record*.

Are there additional criteria that should be included?

No

***The application to amend the Poisons Standard
Is this sufficient level of detail for completion of an application?***

No further comment

Are the proposed requirements for the application form reasonable?

No further comment

Does this level of guidance provide sufficient information and flexibility for future scheduling decisions in relation to Appendix M?

No further comment

Monitoring, evaluation, compliance and enforcement of Appendix M
Are these provisions adequate for monitoring, evaluation, compliance and enforcement of Appendix M criteria?

The University of Sydney School of Pharmacy supports a review of the existing competency standards framework by the Pharmacy Board to establish competence to comply with Appendix M controls, as part of the registration standards.

If the Board decides that there are additional competencies to comply with Appendix M controls, it is our opinion that these competencies should be included at the *General*



performance level and that, all pharmacists should be able to demonstrate competence at initial general registration.

APC Accredited programmes, as provided by Universities, for initial training as a pharmacist should include education and assessment of identified additional competencies to comply with Appendix M controls in their curricula. This condition would reduce variation in practice and ensure that competence is developed through programmes that are accredited by the Australia Pharmacy Council according to the National Registration and Accreditation Scheme (NRAS).

Please note that demonstrated competency by pharmacists on initial registration should not preclude the completion of specific training for each individual S3, Appendix M substance.

What alternative measures might be considered?

No further comments.

We thank you for a chance to contribute to this consultation.

Yours sincerely,

