Medicines Australia

Better health through research & innovation

Transparency Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
DUE DATE: 13 February 2019

Dear Sir/Madam

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)

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) 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)'.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact our sector.

Our detailed feedback on the guidance is contained in Attachment 1 including answers to the specific questions included in the consultation paper.

Our response includes suggestions for changes to provide better clarity on requirements which will support practical implementation as well as identifying key areas of concern.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments. Please feel free to contact Betsy Anderson-Smith if you would like further clarification on any aspect of our submission (banderson-smith@medaus.com.au).

Yours sincerely

Dr Vicki Gardiner
Director, Policy and Research
Medicines Australia

Page	Item	Comments and Rationale
-	**General Comments**	Medicines Australia believe that there is value in having the option to impose additional conditions that will support risk mitigation and quality use of medicines (QUM) for relevant Schedule 3 (S3) substances seeking down scheduling from Schedule 4 (S4). Overall, Medicines Australia supports the proposed criteria and framework for Appendix M.
Q1	**Specific criteria for inclusion in Appendix M – 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?	• Whilst Medicines Australia support the proposed Appendix M criteria to facilitate QUM, consideration needs to be given to mitigate the potential for the additional Appendix M controls (e.g. in the form of additional assessments, documentation etc) becoming a perceived barrier to supply. Medicines Australia believes that clinical factors should be the main drivers that influence a pharmacist's choice of therapy. • The use of checklists by pharmacists would be beneficial in determining whether the sale of recently down-scheduled S4 to S3 medicines is appropriate for the patient. This approach aligns with other countries that have successfully down-scheduled certain medicines such as New Zealand, the UK, and parts of the USA. • When appropriate the proposal for pharmacists to successfully complete specific training on the provision of the medicine will ensure that there is a strong competency-based education program in place. This will allow pharmacists to work in their central QUM role and reduce the burden on medical practitioners. Pharmacists are highly accessible and ideally placed to take on the increased responsibility for dispensing recently down-scheduled S3 medicines. • The use of electronic software will be beneficial in terms of supporting a central record of information, and also will enable systems to connect through My Health Record so that relevant information from a medical practitioner can be relayed to the pharmacist in electronic format if required. • As scheduling is in the control of states and territories, to ensure that the states and territories adopt Appendix M, it is recommended that representation of the Scheduling Committee be re-evaluated to ensure appropriate representation and expertise in patient counselling in the pharmacy setting.
Q2	**Accompanying guidance for Appendix M** • Is this sufficient level of detail for completion of an application?	Medicines Australia believe that the Scheduling Policy Framework, the Scheduling Handbook, and the Application Form to Amend the Poisons Standard are the appropriate documents to enable Appendix M updates, and that the updates described are helpful to sponsors.

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	• 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?	• An explanatory guidance together with examples of proposed patient information or materials to ensure appropriate use of the product such as clinical decision-making guidelines, and record keeping requirements for pharmacists would assist the applicant in preparing a down-scheduling application. • The TGA should ensure that the level of detail in the guidance is similar to the MHRA 'Legal Classification Changes' Guide. This would help the applicant ensure that they address all the required criteria in their application.
Q3	**Monitoring, compliance and enforcement of Appendix M** • Are these provisions adequate for monitoring, compliance and enforcement of Appendix M criteria? • What alternative measures might be considered?	• Medicines Australia acknowledge and agree that responsibility to monitor for compliance and enforcement of Appendix M lies with State and Territory Drugs and Poisons Units and the Pharmacy Board. • Public awareness campaigns that educate patients on the expected level of pharmacist interaction required to supply an S3 medicine will assist with public understanding that the supply of S3 medicines is dependent on multiple factors, including a pharmacist's clinical assessment and fulfilment of any Appendix M criteria.