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1 April 2019

TGA Regulatory Reforms Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Sent via electronic submission: tgaregreforms@health.gov.au

Dear Sir/Madam,

Re: Proposed criteria and guidance for Appendix M

Thank you for the invitation to comment on the proposed criteria and guidance for Appendix M.

ASMI was involved in the ad-hoc Scheduling Working Group meeting of 11th December where Appendix M and proactive consideration for down-scheduling of S4 substances were discussed. We are pleased to have had the opportunity to review the consultation paper on specific criteria and guidance for Appendix M of the Poisons Standard.

Overview of ASMI position

ASMI is broadly supportive of the proposed criteria and guidance for Appendix M, as outlined in the consultation paper. We have reviewed the factors for consideration when placing substances in Appendix M, the proposed criteria, the notes on proposed accompanying guidance and monitoring, compliance and enforcement of Appendix M.

Background, purpose and intent of Appendix M

ASMI supports Appendix M and welcomes the development of guidance to assist applicants.

We note that pharmacists already play an important role in assessment of suitability for supply of S3 medicines, as well as provision of counselling and advice to consumers and we believe that Appendix M will strengthen these activities.

However, ASMI is also concerned that Appendix M may fuel some existing negative attitudes and perceptions regarding S4 to S3 rescheduling, which may make it difficult for Appendix M entries to be developed and accepted. A proposal to include an Appendix M entry with a rescheduling application should not be perceived as an admission that the scheduling factors for Schedule 3 cannot be met or that rescheduling is not appropriate. The intent of Appendix M should be to mitigate risk, that it enhances safety and appropriate provision of certain newly down-scheduled medicines, as well as facilitating innovation; Appendix M should not be perceived as an obstacle to rescheduling.

We agree with the TGA that Appendix M should not be routinely needed for proposed S4 to S3 switches, as stated on page 5 of the consultation paper.

We note that the consultation paper compares proposed Appendix M controls with those in Appendix D. While there may be some degree of similarity especially in terms of monitoring and compliance of the healthcare practitioners involved in prescribing, there are also some key differences. An Appendix D entry usually relates to specific contraindications or precautions of a medicine, that require warnings to consumers or control of prescribing. With Appendix M, sponsors and applicants have an important role in the design and implementation of Appendix M materials, especially training resources, dispensing protocols and patient resource materials as applicable to each specific submission. Many of these materials will by necessity be "product specific" rather than "substance specific" and may contain broader educational content.

Non-medical prescribing

ASMI agrees that Appendix M is different to non-medical prescribing and that the regulatory framework and controls will differ, as stated in the consultation paper (page 6). ASMI is concerned that some stakeholders view pharmacist prescribing as a substitute or preferred alternative to down-scheduling and ASMI would welcome more clarity on the differences between down-scheduling, pharmacist prescribing and emergency prescribing. There should be clear policy advice that pharmacist prescribing and emergency prescribing are different and these are not a substitute for S4 to S3 down-scheduling.

Based on member feedback, we would like to make the following further comments:

- ASMI welcomes the opportunity for sponsors to have open dialogue with the Scheduling Secretariat prior to the publication of the public notices of proposed changes to scheduling on the TGA website (page 5). Sponsors may require additional advice and assistance especially during the early stages of Appendix M implementation, and we welcome the opportunity for applicants to collaborate with the Scheduling Secretariat should this be required.
- In relation to an application for rescheduling of a substance from S4 to S3, we note that the Delegate can impose an Appendix M entry or decide to apply additional criteria on Appendix M on a case by case basis where warranted and on the advice of the ACMS (page 8). Any ACMS or Delegate-required inclusions of substances in Appendix M or amendment to any proposed Appendix M conditions should be done after consulting with the applicant, as it is the applicant who will need to decide whether or not to withdraw a particular application or to ensure that the training materials, as well as other pharmacist resources or product information can be prepared appropriately, in accordance with the ACMS or the Delegate's requirements.
- ASMI has reviewed the proposed criteria for Appendix M, and the grouping of these criteria depending on whether the activities can be directly regulated via States and Territories, or whether these can be developed into item-specific professional practice standards (page 9-10). We broadly support the inclusions in these sections. We would however appreciate some further clarity on how any proposed record keeping and information sharing requirements would be applied and monitored by the States and Territories and request consultation with all stakeholders prior to adoption of any Appendix M requirements that include these provisions.
- ASMI supports flexibility in the wording of the guidelines and criteria for Appendix M, with the expectation that sponsors / applicants can select or design relevant Appendix M entries on a case by case basis.
- The TGA should consider that some Appendix M entries could be time limited and that there should also be a mechanism for their amendment or removal, as experience with the new S3 / Appendix M entry increases over time. Sponsors or other applicants should have the option of applying for Appendix M controls to be amended or removed after sufficient experience and confidence with a new S3 / Appendix M entry has been gained.
- ASMI recommends that the scheduling application form (template) should be updated to include the proposed criteria and explanatory guidance for Appendix M, as well as Appendix H. It should be made clear in the application form template that an Appendix M entry is optional, depending on whether stricter and specific controls are needed to ensure safe use of the new Schedule 3 entry.
- We note that while a new Schedule 3 entry is substance based, any new Appendix M materials such as patient resources or pharmacist training materials are necessarily product based and will be

developed by sponsors / applicants before submission. ASMI's position is that consideration should be given to developing a process for ensuring that subsequent applications to register a new S3 medicine that has an Appendix M entry should have their Appendix M materials assessed, to ensure that these are of an equivalent quality and consistent with the initial applicant's Appendix M materials. This could be done either by the TGA as part of the new medicine registration process (or possibly by ACMS) as appropriate.

- Further clarity is needed on the role of the States and Territories and the Pharmacy Board of Australia, in monitoring for compliance to Appendix M especially given that the Appendices to the Poisons Standard are not uniformly adopted by all States and Territories.

Attached to this letter are ASMI's responses to the questions raised in the consultation paper.

Thank you for the opportunity to comment on this consultation.

We remain available to meet or discuss any of the above information should you require clarification.

Kind regards,

[redacted]

Questions raised in TGA Consultation paper

- **Do you agree with the criteria? If so, why/why not?**

ASMI agrees with the publication of a range of suitable criteria, that applicants may select on a case by case basis for a specific S4 to S3 rescheduling application.

Although ASMI supports the proposed criteria for Appendix M, we also note that some of these activities already form part of pharmacists' routine responsibilities for provision of Schedule 3 medicines as per the Pharmaceutical Society of Australia (PSA) pharmacists' professional practice standards, see the https://psastaging.alphasys.com.au/wp-content/uploads/2018/08/Professional-Practice-Standards-v5.pdf .

Pharmacists are routinely trained on new Schedule 3 medicines, and the PSA has published guidance protocols for provision of Schedule 3 chloramphenicol, emergency contraception, fluconazole, naloxone, orlistat, prochlorperazine, proton pump inhibitors and short acting $beta_2$ agonists.

These PSA protocols include some that are part of the TGA's proposed Appendix M criteria, such as information on advice on warnings to be given to patients and patient education (Group 1, no.1); patient selection/suitability of the patient (Group 2, no. 1); limitations on duration, quantity and / or frequency of supply (Group 2, no.6); as well as the need for formal diagnosis or advice on when a review of the condition by a medical practitioner is needed (Group 2, No.7).

Our point in relation to the above is that pharmacists already have a responsibility to manage S3 medicines and that is part of their training and scope of practice. ASMI therefore does not expect that Appendix M should be needed as part of every S4 to S3 down-scheduling, and it should be reserved for cases where there is a specific risk that is best mitigated through use of Appendix M.

ASMI does not expect that an Appendix M entry should be required for activities that are currently within the scope of pharmacists'existing scope of practice and professional practice standards, e.g. materials comparable with existing S3 supply protocols.

An Appendix M entry should instead focus on additional activities that may be required to manage specific risks in a S4 to S3 medicine down-scheduling and could include higher level activities such as record keeping and information sharing, assurance of a formal diagnosis or periodic review by a medical practitioner, as well as formal training or accreditation requirements.

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

ASMI believes that any new reform may have both foreseeable as well as unforeseeable issues that arise during implementation.

Monitoring and Compliance

ASMI is concerned that there is continuing uncertainty regarding the role of State and Territory Pharmaceutical Services sections in adoption, monitoring and compliance of Appendix M.

States and Territories are a key stakeholder in Appendix M, but applicants are concerned that there will be difficulty in obtaining advice or information on feasibility and potential implementation for an Appendix M entry that involves State and Territory monitoring and compliance activities.

Clarification of pharmacist prescribing and emergency supply

ASMI notes the statement in the consultation paper (page 6) that "*the policy and legal intent of Appendix M requirements is different to those around pharmacist prescribing and dispensing of S4 medicines where allowed by state and territory regulation...*".

Some stakeholders view pharmacist prescribing and emergency supply as preferred options for supply compared to S4 to S3 rescheduling. ASMI is concerned that Appendix M may fuel some of these perceptions that these pathways are more appropriate and preferred ways for consumers to access medicines, compared to S4 to S3 rescheduling.

ASMI would be keen for the TGA to provide more detail for applicants and other stakeholders so that there is an understanding of the differences between these different supply mechanisms in each of the States and Territories, and that these are not effective substitutes for S3 supply when appropriate.

Approach to Appendix M issues as they arise

As with any reform, various issues may arise during the implementation phase. There may be uncertainty on the part of applicants, as well as uncertainty in how the various agencies monitor ongoing compliance.

ASMI is keen for the TGA to be available to applicants who would like to discuss Appendix M options prior to submission.

We would also be interested in a review of Appendix M following its implementation and suggest that the TGA engage with industry to review learnings with Appendix M after an appropriate period of time has elapsed, e.g. after two years or two Appendix M entry implementations. This may provide the opportunity to refine criteria based on experiences of applicants and other stakeholders such as pharmacists, medical practitioners, States and Territories and other bodies responsible for monitoring and compliance.

- **Are there additional criteria that should be included?**

ASMI believes that the criteria as described in the consultation paper are sufficiently flexible to enable applicants to select the most appropriate criteria from either Group 1 or Group 2, and we believe that applicants should have the flexibility to include other criteria under these headings should this be appropriate for an application.

- **Is this sufficient level of detail for completion of an application?**

Appendix M is not intended to be a mandatory component of every down-scheduling application. ASMI does not believe that overly prescriptive guidance is appropriate. We expect that every Appendix M application will be different, depending on the risks and benefits of the medicine. It is impossible to cover every possible element and criterion from the outset, nor should this be the aim of the guidance.

We are satisfied that the TGA's stated open approach to having dialogue with applicants will assist to resolve any uncertainties that applicants may initially encounter.

ASMI believes that sufficient detail has been provided at this point, and that the guidelines and application form can be updated over time, as experience with Appendix M applications grows.

One area of foreseeable concern is the lack of ability of applicants to canvass the operation and implications of any proposed Appendix M entry with all relevant stakeholders. This may be one of the most difficult aspects of the development of an Appendix M entry and the application process. Some key stakeholders cannot be "canvassed" (e.g. States and Territories) and ASMI is concerned that there may be unrealistic expectations around who and how many stakeholders should be consulted prior to an application, and whether not consulting with a particular group will be perceived as a weakness or deficiency in the application.

- **Are the proposed requirements for the application form reasonable?**

ASMI agrees that the application form should be updated by adding a new section 2.3 for Appendix M.

We note that the application form should also be updated to include the revised Appendix H arrangements.

Regarding the detail of the section titled "The application to amend the Poisons Standard" on page 12 of the consultation, we have the following comments:

- ASMI does not support the proposal that an application for Appendix M should address all criteria (1-7). The specific criteria section (page 8) states that "*It is proposed to have a set list of common criteria, some or all of which could be applied to each new substance….*" Additionally, the proposed criteria (page 9) states that "*A range of potential criteria for application to Appendix M substances has been identified. The Delegate and the ACMS may require that one, some or several of these criteria be supplied*…". The premise of the consultation paper is that Appendix M is not required routinely, and that applicants can select from a range of criteria depending on the specific safeguards that may be required. The discussion of the TGA Scheduling Working Group did not recommend that all criteria should be addressed, or that applicants need to justify criteria that are not addressed. This requirement is an unreasonable expectation that will make an Appendix M application more onerous and is at odds with the TGA's stated collaborative approach with applicants.
- ASMI agrees that samples of proposed patient information or advisory material ought to be provided by the applicant.
- ASMI agrees that a preliminary version or comparable example of proposed materials such as training materials, clinical decision-making guidelines etc. should be provided with the application.
- ASMI agrees with the description of information that should be included in the training materials.
- ASMI finds the 5th dot point (page 12) "*Record keeping and information sharing requirements for pharmacists would generally be expected to be consistent for all entries and determined by State and Territory Dugs and Poisons Units in consultation with other key stakeholders, including the Pharmacy Board*……" rather confusing. Applicants have very limited visibility on State and Territory record keeping requirements, and how States and Territories consult with the Pharmacy Board and other stakeholders. Applicants will require some level of assistance in understanding requirements and drafting Appendix M entries that are consistent and comply with the various State and Territory requirements. Applicants are legally prohibited from approaching States and Territories regarding rescheduling applications, and this may prove to be problematic for applicants who are seeking to understand requirements and draft consistent entries that satisfy State and Territory and Pharmacy Board requirements. This is an opportunity area where the TGA should provide assistance to applicants, especially in the early stages of implementation of Appendix M by providing detailed process clarity.
- The sixth dot point (page 12) refers to criterion 3, which is absent from the proposed criteria for Appendix M. This should be clarified or corrected. We suggest that this should simply refer to "any additional criteria" that may be required on a case by case basis.

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

ASMI believes that the level of guidance is adequate, and we support flexibility in the approach to Appendix M.

ASMI supports the approach put forward in the consultation, which includes two groups of different criteria from which applicants can select different options.

As stated above, there should be no expectation that all criteria should apply, and sponsors should not be required to justify the absence of any of these.

If the Delegate or ACMS believe that there are important reasons to include any additional criteria that may be absent from an application, then this should be discussed with the applicant prior to the publication of the meeting agenda or the interim decisions, as appropriate, and reasonable time allotted in the process framework which allows the applicant sufficient time to address any unforeseeable additional criteria, without impacting the time involved in the review of the application.

The publication of the Appendix M criteria as a guidance document also means that it can be updated as needed, and as experience with these applications develops over time.

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

ASMI believes that the provisions for monitoring, evaluation, compliance and enforcement of Appendix M appear adequate and would appreciate some additional advice from the various States and Territories on these matters. This is especially important as some States and territories reportedly do not adopt the Appendices in the Poisons Standard.