1 April 2019

[redacted]

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

Dear [redacted]

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

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional, for-purpose organisation for over 5,300 leading pharmacists and pharmacy technicians working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use.

SHPA welcomes the opportunity to make a submission to the TGA on proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only) and has the following comments to make on the questions outlined in the consultation paper.

Introductory remarks

The TGA is an internationally respected regulator of medicines and medical devices due to its rigorous processes and requirements which seek to protect the Australian public, support the quality use of medicines and are independent of commercial interests. Amendments to medicines scheduling in Australia should always be made on quality use of medicines and medication safety principles and informed by evidence. Whilst the opportunity for applicants to down-schedule medicines from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only) can be used for ulterior motives outside of TGA's remit, SHPA is pleased to hear that the usual consultation processes will still apply for any scheduling amendments, allowing health professionals and members of the public to provide their views on applications.

SHPA reiterates concerns made in previous submissions to the TGA around the suitability of the retail environment of community pharmacies and their practices, to support appropriate supply and quality use of medicines, especially for Schedule 4 (Prescription only) medicines that are down-scheduled to Schedule 3 (Pharmacist only).

SHPA understands that a list of seven medicines that are targets for potential down-scheduling have been presented to the TGA. Given these medicines are currently Schedule 4 (Prescription only) in recognition of their risk to the public if misused and the seriousness of the conditions which they treat, the community pharmacy environment needs to be meet consumer expectations of health service requirements to support the quality use of medicines.

Many retail pharmacies do not have private consultation rooms, which are essential given some of the medicines presented to the TGA for pro-active down-scheduling are for urinary tract infections and erectile dysfunction. Furthermore, whilst records of Schedule 4 (Prescription only) medicines supply is a legal requirement, it is not a mandatory legal requirement to record supplies of Schedule 3 (Pharmacist only) in most jurisdictions, which is a potential risk for a patient's other healthcare providers who will not have a full and accurate medication profile for their patients.

The Society of Hospital Pharmacists of Australia
PO Box 1774 Collingwood Victoria 3066 Australia
(03) 9486 0177 | shpa.org.au | shpa@shpa.org.au | ABN: 54 004 553 806

Proposed Criteria – Do you agree with the criteria? If so why/why not?

Group 1: Criteria that could be directly regulated via State and Territory legislation

1. Specific advice by the pharmacist (patient education) is required

Specific patient education and counselling by pharmacists at the point of medicines supply is a fundamental requirement of all current Australian pharmacy guidelines and practice standards. SHPA is concerned that the existence of this criteria might infer specific advice for supply of non-Appendix M Schedule 3 (Pharmacist Only) medicines is not required.

2. Specific pharmacist training on the provision of the medicine may be required

It is expected that for certain potential Appendix M medicines, specific pharmacist training would be appropriate. SHPA recommends that there should be a national oversight to record which pharmacists have completed certain training for Appendix M medicines. of those who have completed the training be established rather than a state-based repository. This would ensure that information on completed training can be easily accessible by pharmacists and employers.

However, depending on the number of Appendix M medicines that have this criterion, this could potentially become difficult to regulate efficiently. As such, it must be considered and justified as to why further specific pharmacist training beyond undergraduate training, is required. Additionally, the criterion should explicitly outline whether or not training needs to be repeated at certain intervals, by pharmacists to ensure accurate up to date information is always provided to patients.

3. Additional conditions may be imposed

SHPA will respond to additional conditions on a case-by-case basis where applicable.

Group 2: Criteria that could be developed into item-specific professional practice standards, which must be complied with as a condition of supply of an Appendix M good.

4. Suitability of individual patient for supply of medicines containing an S3, Appendix M substance to be assessed by the pharmacist

SHPA supports the use of clinical decision-making tools in determining the supply of Schedule 3 (Pharmacist only) medicines. However, the examples given including questionnaires, checklists and guidelines do not state which stakeholders will or should develop these tools and clinically validate them to ensure quality use of medicines.

Furthermore, the use of questionnaires and checklists currently used in the community pharmacy environment as clinical decision tools, are not fully supported by dispense records where a supply occurs, or consultation summaries in community pharmacy software. This is even more important as the healthcare sector transitions to the digital era where it is the consumer expectation that the supply of these medicines and the pharmacy care provided will be uploaded to a patient's My Health Record. Thus, the current paper-based questionnaires and checklists used in community pharmacies does not meet the sector's or consumer expectations.

5. Record keeping and information sharing

SHPA agrees information should be shared with General Practitioners if clinically appropriate and patient consent has been provided. As outlined in our response above, SHPA has concerns about the community pharmacy sector's capacity for record keeping practices that support the transition to digital health and are in line with patient expectations. It should also be noted that even if this information is uploaded to a patient's My Health Record, the patient is still able to hide information from specific clinician groups.

6. Limitations on duration, quantity and/or frequency of supply

SHPA supports this criterion in principle to reduce potential overuse or abuse of medicines. The limitations mentioned in this criterion need to be complemented with real-time prescription monitoring and information sharing for it to be effective. Without such monitoring, individuals would be able to visit multiple pharmacies and obtain supplies on a frequent basis, as mentioned in this option.

In Australia, the current practice for provisions of Schedule 3 (Pharmacist only) medicines shows that most of these transactions and consultations are not recorded on the retail pharmacy's dispensing software, even though professional practice guidelines may suggest otherwise. While counselling aims to mitigate the inappropriate use of medicines, individuals can, and often, choose not to adhere to advice and can potentially result in adverse events resulting in a hospital admission. The appropriate limitations on duration, quantity and/or frequency of supply for Appendix M medicines will need to be considered very carefully on a case-by-case basis in order to ensure that there is no potential for abuse.

7. Need for formal diagnosis or periodic review of the condition by a medical practitioner

SHPA supports this criterion, however it is difficult to implement given current practices. Beyond a pharmacist recommending formal diagnosis or review of the condition by a medical practitioner, it is not possible for the pharmacist to know whether this advice is adhered to and that the patient presents to a medical practitioner for a consult. Furthermore, it would also be difficult for a patient to demonstrate that they have been reviewed by a medical practitioner before requesting an Appendix M medicine, unless they have evidence of a consultation or a prescription for that medicine – these are not common practices for Schedule 3 (Pharmacist only) medicine requests. SHPA believes that the My Health Record can potentially address these issues of transparency and information sharing, however practice change for both medical practitioners and pharmacists will be required.

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

SHPA will require providing a case-by-case response to each scheduling application for Appendix M to assess if there are foreseeable issues with implementation of any of these criteria.

In addition to the issues highlighted above, SHPA believes that in order to implement Criteria 1 and 2, a standardised approach much be taken to ensure that pharmacist education and training is nationally consistent. This would entail the same patient education resources and pharmacist training across all states and territories, ensuring that information provided to patients is consistent.

Furthermore, if the supply of certain Appendix M medicines hinges on the pharmacist undergoing specific training, issues around equity of access to trained pharmacists may arise. It would be important to consider the expectation of patients regarding access to these medicines from community pharmacies, particularly in rural and regional areas where some inequities in medicines access already exist.

Accompanying guidance for Appendix M and Scheduling Policy Framework

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

The application should also specifically discuss how the scheduling amendment will improve the quality use of medicines and provide a net positive in health outcomes for patients.

In order to strengthen the applications received by the TGA, SHPA suggests that the training materials in the application should include all short and long-term adverse effects to ensure that patients understand the importance of treatment duration and drug interactions.

Are the proposed requirements for the application form reasonable?

SHPA considers the proposed requirements for the application form to be reasonable, particularly the need for the applicant to address all seven criteria and explicitly state if any criterion is not applicable to the product.

However, SHPA will require providing a case-by-case response to each scheduling application for Appendix M to assess if the specific proposed requirements are appropriate.

Monitoring, evaluation, compliance and enforcement of Appendix M

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

SHPA recommends that individual compliance of Appendix M criteria could be captured by the National Competency Standards for Pharmacists in Australia 2016. This standard outlines the following competencies which would ensure quality and safe use of medicines:

- 3.1.1 Obtain relevant health and medicines information;
- 3.2.2 Provide primary care and promote judicious use of medicines;
- 3.2.3 Dispense medicines (including compounded medicines) in consultation with the patient and/or prescriber;
- 3.2.5 Provide counselling and information for safe and effective medication management; 3.2.6 Facilitate continuity of care including during transitions of care;
- 3.3.1 Undertake a clinical review;
- 3.3.2 Apply clinical review findings to improve health outcomes

A separate competency framework would not be needed as all applicable competencies are already included in the national standards, however, pharmacists would have to recognise that they may need particular training in order to supply the specific Appendix M medicine.

The consultation document states that "*Program evaluation may be undertaken by partners such as State and Territory Drugs and Poisons units or the TGA where deemed appropriate.*" Individual compliance has been described sufficiently, however, there is very little provided on how the program evaluation might be undertaken. SHPA believes that the program evaluation should be clearly outlined so it can be determined if Appendix M medicines are contributing to improved health outcomes and quality use of medicines.

Antimicrobials (including trimethoprim) should be deemed as unsuitable for Appendix M given the impact of antimicrobial use at a public health level, in addition to that at the individual patient level. Specimen pathology orders cannot be made or collected in a community pharmacy setting to ensure the appropriate investigations relating to antimicrobial supply are undertaken. Reducing the incidence of antimicrobial resistance is a national and global health priority and loosening access controls to these vital medicines can undermine actions to preserve the efficacy of antimicrobials. Australia already faces challenges for the treatment of urinary tract infections due to the increasing incidence of resistant strains of *E. coli.*, the most common cause of urinary tract infections. SHPA firmly believes that antimicrobials such as trimethoprim should not be down-scheduled and have an Appendix M entry.

SHPA would like to express interest in being represented on the Advisory Committee on Medicines Scheduling to contribute to appropriate and safe medicines scheduling decisions. If you have any queries or would like to discuss our submission further, please do not hesitate to contact [redacted]

Yours sincerely,

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