Pharmaceutical Society of Australia

Therapeutic Goods Administration

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

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration on the consultation draft of *Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)*.

Through this consultation, PSA has commented on the proposed details and utility of the framework for Appendix M criteria and related guidance, from the perspective of the pharmacy profession. It is a priority for PSA to consider what principles may be appropriate for when a *Prescription Only* (S4) medicine could be considered for rescheduling to a *Pharmacist Only* (S3) medicine with additional Appendix M conditions to ensure patient safety, quality use of medicines and optimal health outcomes for patients.

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 31,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Responses to selected sections of the consultation paper

Proposed criteria

The consultation paper states that “Appendix M will function as a ‘stage down’ provision to enable down scheduling on S4 substances in a controlled and monitored fashion, where doubt exists as to the safety of doing so”. In order to facilitate safe and appropriate rescheduling of S4 medicines to an S3 Appendix M category, PSA supports the proposal to have criteria which may be common to all Appendix M related applications as well as criteria which are substance specific.

PSA also supports the need for separate types of criteria, those that are regulation based and others which are considered to be accepted standards or requirements for the professional practice of pharmacists.

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

To support safe and appropriate rescheduling of S4 substances, substance specific criteria that would permit S3 Appendix M supply need to be legislated at State and Territory level. Therefore PSA believes that, based on the evidence and rationale presented by the applicant, Group 1 criteria would need to capture and regulate factors such as:

- limitations on duration, quantity and/or frequency of supply of the S3 Appendix M substance (and associated packaging and labelling requirements for S3 supply)
- if relevant, articulation of the need for formal diagnosis or periodic review of the condition by a medical practitioner
- any additional S3 Appendix M conditions that may be imposed on a case by case basis.

While certain factors (such as those listed above) may be regulated through legislation, PSA would have a role in assisting regulators through contribution of expert professional advice on the likely impact of rescheduling on pharmacists’ practice.

It is reasonable to expect that Group 1 criteria would reference the need for pharmacists to practise in accordance with legislation when involved in the handling and supply of a medicine containing an S3 Appendix M substance. However, specific details relating to professional decision making and pharmacist practice (e.g. drug interactions to be considered, or information to be provided about side effects) are more appropriate for inclusion as Group 2 criteria (see below).

To elaborate on the above, PSA suggests that the detail currently listed under point 1 (*Specific advice by the pharmacist (patient education) is required*) and point 2 (*Specific pharmacist training on the provision of the medicine may be required*) of Group 1 criteria should reside under Group 2. The requirement under Group 1 then could be to state that pharmacists are required to comply with relevant guidelines and standards in the handling and supply of medicines containing particular S3 Appendix M substances. This approach is recommended by PSA as it aligns with what is generally recognised and accepted by the profession to ensure consistent and high standards of professional practice.

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

PSA, as the peak professional pharmacy body and the largest provider of high quality education, training and practice support for pharmacists in Australia, has a core role in ensuring pharmacists meet contemporary standards of professional and ethical practice. PSA therefore has a fundamental role in the co-design and co-delivery of relevant materials to support the effective implementation of medicine scheduling changes and other associated activities.

Factors relating to pharmacists' professional practice

It would appear to PSA that there is possibly a misperception in the consultation paper of what is considered to be appropriate "training" for pharmacists in the context of S3 Appendix M medicines.

It is PSA's view that the proposal that "pharmacists would be required to successfully complete [this] training prior to being eligible to provide each substance under Appendix M" is not appropriate. Pharmacists are medicines and medication management experts and are accountable for their own scope of professional practice. Setting an expectation that there would be a need to undertake "training" for every substance included in S3 Appendix M is unreasonable.

Pharmacists would already be familiar with the S3 Appendix M molecule but, prior to the rescheduling, it would have been dispensed as an S4 medicine. Therefore a more appropriate expectation and priority would be to support pharmacists around the change in the clinical scenario that they will encounter and how best to handle and supply the S3 Appendix M medicine.

Through its core professional standards and training roles, PSA believes this could be more effectively achieved through, for example:

- reinforcing the professional standards applicable to the provision of non-prescription medicines and therapeutic devices (e.g. PSA's *Professional practice standards*, Standard 4) and highlighting the pharmacist's accountability under this framework

- providing professional guidance tailored for the particular S3 medicine (for example, see next section, *PSA's S3 guidance documents*)

- designing and developing practice support tools (e.g. factsheet, checklist, patient information) to facilitate best practice in the provision of the rescheduled S3 Appendix M medicine in an S3 supply environment

- raising profession-wide awareness on the rescheduling of the specific substance from S4 to S3 Appendix M, the resulting impact on pharmacists' practice and professional obligations of pharmacists.

It is important that there is flexibility allowed in how these implementation support resources are designed and packaged. Given its expertise in this area, PSA will have a primary role in advising what components are necessary, and how they are constructed and delivered to pharmacists in the context of the rescheduled substance.

It is also vital that this is done in a holistic manner. Hence, although guidance around the specific S3 Appendix M medicine is central to the guidance provided to pharmacists, there would also be consideration and information provision from a broader perspective of the relevant condition or disease.

PSA's S3 guidance documents

As the standards setting body, PSA is responsible for the development and maintenance of guidelines and standards for pharmacists in the delivery of health services. The section below under the heading ***Provisions for monitoring, evaluation, compliance and enforcement of Appendix M criteria*** provides additional information on the professional practice framework for pharmacists.

As mentioned earlier and as part of its core remit, PSA produces guidance documents for the provision of selected S3 medicines. These are published in the *Australian pharmaceutical formulary and handbook*, a core reference text listed in the Pharmacy Board's guidelines. PSA expects that similar guidance documents would be relevant and appropriate for the handling and supply of S3 Appendix M medicines.

Each S3 guidance document (currently) provides details of the recommended procedure for pharmacists to follow when supplying specific S3 medicines. The guidance documents are structured in a logical stepwise manner to support professional decision making by the pharmacist.

The types of issues that current S3 guidance documents for pharmacists contain include the following:

Professional obligations	**Patient assessment**	**Recommendation**	**Counselling**
• professional standards • privacy considerations • duty of care • supply to a third party • appropriate recording and documentation	• advance provision • presenting signs and symptoms • trigger factors • differential analysis • age • prior episodes and treatment • medical, family and medication history • lifestyle factors	• treatment options and efficacy • contraindications and precautions • use in pregnancy and lactation • drug interactions	• dosage, administration, duration of therapy • storage • referral pathways, including need for immediate referral or conditional referral • self-care advice • treatment expectations • adverse effects • follow-up advice

Following a systematic process helps pharmacists fulfil their professional obligations. Pharmacists must meet all legislative requirements when supplying S3 medicines, and are expected to exercise professional judgement in adapting the information provided to the specific

presenting circumstances. Naturally, PSA believes that this type of process should extend to S3 Appendix M medicines.

Each guidance document will be tailored according to relevant parameters and approved indications for the S3 Appendix M substance. Consideration of the overall condition, ailment or disease is also vital.

Implementation related issues

The consultation paper explains that, conceptually, Appendix M is expected to function in a similar manner to Appendix D. However, this explanation has caused some confusion. Appendix D specifies controls deemed necessary to mitigate risks associated with particular S4 and Schedule 8 (S8) substances, and these controls are in addition to the general requirements of the relevant schedule (S4 or S8). By analogy, one could say that Appendix M lists additional controls necessary to mitigate risks associated with particular S3 substances. While this may be correct in terms of its overall effect, PSA understands that the primary purpose of Appendix M is subtly different because it is intended to specify principles (both core and substance specific) that could apply to facilitate consideration of rescheduling of a substance from S4 to S3. Thus PSA believes there is a need to amend the title of Appendix M and clearly state its purpose. This clarity is essential as it will impact on the utility and successful implementation of Appendix M.

In terms of the immediate implementation and ongoing operation of Appendix M, PSA believes that some issues need to be clearly articulated up front, for example, that:

- responsibility for proposing specific Appendix M controls would rest with the applicant for rescheduling of a particular substance
- the controls on particular products may subsequently be able to be modified based on experience gained with the provision of the product as an S3 medicine
- it is not intended that Appendix M controls would be routinely required for medicines that are rescheduled from S4 to S3
- sponsor-related obligations associated with a rescheduling of a medicine to S3 Appendix M (e.g. updating the Product Information) need to be met.

Details relating to potential applications

Would a substance be permitted to have more than one entry in Appendix M? Such a scenario may arise if, for example, a substance has multiple approved indications and different sets of ‘additional controls’ were deemed appropriate for the different indications.

If a situation arises where more than one application is lodged for S3 Appendix M at the same time (or similar period), how would the multiple applications be dealt with?

What, if any, incentives will there be for sponsor applicants in initiating a rescheduling application? PSA is aware that this is one of the considerations that can impact on whether or not a sponsor may proceed with an application.

The consultation paper states that “applicants will be expected to have canvassed the possible operation and implications of any proposed Appendix M conditions with relevant professional bodies and other stakeholders prior to submitting an application to down schedule their goods from S4, where Appendix M controls are anticipated”. To what extent would applicants need to demonstrate the pre-application consultation step, and what level or type of consultation is envisaged? Would these aspects be described and effected through legislation, or would it be a recommendation in the guidelines?

How will the inclusion of substances in S3 and Appendix M interface with Appendix H? Is it envisaged that the need to exclude the substance from being able to be advertised (i.e. listed in Appendix H) would be considered on a case-by-case basis?

Provisions for monitoring, evaluation, compliance and enforcement of Appendix M criteria

Pharmacists have an obligation to practise legally and ethically, and comply with statute law, guidelines, codes and standards. The professional registration of pharmacists includes the requirement to practise within the individual’s scope of practice and to meet annual continuing professional development requirements.

Relevant competency standards that would apply to pharmacists practising in a setting where S3 Appendix M medicines may be provided are already clearly articulated through the *National competency standards framework for pharmacists in Australia* (2016).

PSA is the custodian of the competency standards framework for pharmacists on behalf of the pharmacy profession, and also develops and publishes the *Professional practice standards*. Both of these important documents are endorsed by the Pharmacy Board of Australia. PSA also publishes the *Australian pharmaceutical formulary and handbook*, a reference text for pharmacists listed in the Pharmacy Board guidelines which “must be readily accessible and should be accessed by pharmacists during the clinical assessment, reviewing, dispensing and counselling processes”.

Thus there is a comprehensive framework of competency standards, professional practice standards and relevant practice resources embedded in legislation that pharmacists would need to comply with in the handling and provision of S3 Appendix M substances.

It is incumbent on every pharmacist to be aware of changes to medicine supply arrangements, and to understand and act on changes that affect their professional practice. Any lack of compliance with, or deviation from, expected standards of professional behaviour of pharmacists would constitute notifiable conduct to the Pharmacy Board of Australia.

Alternative measures for consideration

PSA would strongly encourage the implementation of appropriate pharmacovigilance arrangements to support the collection of data and information which would help to:

- assess the impact of rescheduling a substance from S4 to S3 Appendix M
- inform future modifications to Appendix M entries (e.g. removal of a substance from the list).

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