Australian Government
Department of Health
Therapeutic Goods Administration

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)

Version 1.0, February 2019

TGA Health Safety Regulation

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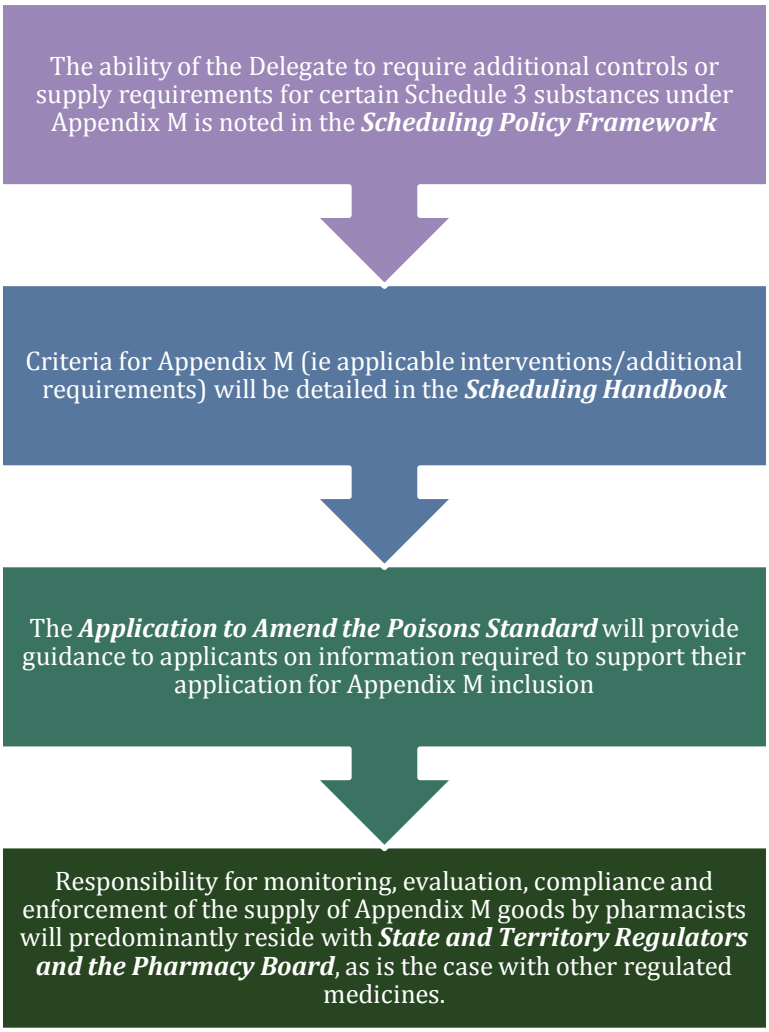
Executive summary

Following AHMAC endorsement, as of 1 January 2018 a provision for an Appendix M was included in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard). Appendix M appears in the Poisons Standard as of 1 February 2019. Appendix M provides for the imposition of additional conditions on Schedule 3 (pharmacist only) substances to support their down-scheduling ('switching') from Schedule 4 (prescription only). An *ad hoc* working group was formed in February 2018 to identify an appropriate regulatory framework to enable greater advertising of medicines containing Schedule 3 substances; to identify potential Schedule 3 substances that may be suitable for advertising; to identify suitable candidates for consideration for switch from Schedule 4 to Schedule 3 and to develop criteria for the use of Appendix M.

At a December 2018 meeting which was focussed on the last of these tasks, it was agreed that public consultation on the subject was appropriate. This paper outlines a potential framework for Appendix M criteria and related guidance. Your consideration and advice is sought on the practicality, reasonableness and utility of the proposed framework.



Purpose

The purpose of this consultation paper is to seek feedback on the proposed criteria, accompanying guidance and plans for monitoring of the supply of Schedule 3 (S3) Pharmacist only - Appendix M substances.

Appendix M is intended to include substances that have formerly been scheduled as Schedule 4 (S4) and have required a prescription by a medical practitioner, but if rescheduled to S3 could be dispensed by a pharmacist where specific strict controls are in place that ensure safe use. It is not intended that Appendix M controls would be routinely required for medicines that are rescheduled from S4 to S3.

The aim of this consultation is to establish specific principles for when a S4 medicine could be considered for rescheduling to S3 with additional Appendix M conditions, and to establish a framework for the development of guidance to applicants on considerations and required information to be included in any application to reschedule goods from S4 to S3 with additional Appendix M conditions. It should be emphasised 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.

Please note that comment is not sought on the existing scheduling factors for S3 and S4 substances.

Background

In January 2018, a revised Scheduling Policy Framework (SPF) was published and came into force, including provision for a new Appendix M. Appendix M appears in the Poisons Standard from February 2019 with the heading "additional controls or supply requirements for poisons included in Schedule 3 to allow them to be provided by a pharmacist".

Conceptually, it is envisaged that Appendix M will function in a similar manner to Appendix D, which specifies additional controls for particular S4 or Schedule 8 (S8) substances. Appendix M would specify additional controls to those normally applying to pharmacist-only medicines. The introduction of Appendix M was planned to facilitate appropriate over the counter (OTC) access for certain products that have a good case for broader community access, but are currently prescription-only in Australia and may present public health risks above those normally considered acceptable for S3 substances.

While the responsibility for proposing specific Appendix M controls would rest with the applicant for rescheduling of a particular substance, given the special nature of Appendix M conditions the TGA Scheduling secretariat would engage in a dialogue with the applicant on these conditions prior to public consultation or consideration of the application by the Advisory Committee on Medicines Scheduling (ACMS).

As experience builds with the product provided in an OTC environment, the controls on particular products may subsequently be able to be modified.

Some examples of Appendix D Controls currently in place for prescription medicines include:

- Specific authorisation of certain types (specialties) of medical practitioners to prescribe
- Specific authorisation of individual medical practitioners to prescribe by State and Territory Health Department heads (or their delegates)

- Specific checks/ interviews of patients required prior to prescribing of the medicine
- Specific advice required to be provided to the patient (e.g. avoid becoming pregnant)
- Only the individual who is named on the prescription being legally able to possess substance

While some of these could reasonably be paralleled in Appendix M, others, such as restricting authorisation to specific practitioners, would require a different approach. For example, a parallel situation would be to require completion of particular training for pharmacist only medications.

Consideration of these issues has been part of the brief of an *ad hoc* working group formed in January 2018 to continue work on outstanding scheduling issues. This group comprises representatives from the states and territories, the medicines and chemical scheduling advisory committees, industry groups and professionals from the medicine, pharmacy and chemicals sectors as well as consumer representatives. The working group has met three times to date - 9 February, 6 March and 11 December 2018.

While discussion on the structure and use of Appendix M has progressed, it was agreed that further public consultation on this matter was warranted.

Factors for consideration of placing substances in Schedule 4 (prescription only) v Schedule 3 (pharmacist only)

All scheduling decisions include consideration of a standard set of factors, to ensure that application of public health risk and benefit considerations is consistent within each Schedule. The factors for each schedule are set out in the SPF (scheduling factors) and relate back to the matters required to be taken into account by section 52E(1) of the *Therapeutic Goods Act 1989* (the Act).

Pro-active down scheduling

An additional process considered by the *ad hoc* working group as part of the ongoing scheduling reforms relates to consideration of a process for pro-active down scheduling of S4 goods to S3. As part of this process, at the December 2018 meeting of the *ad hoc* working group, two lists of S4 substances that could be considered for pro-active down scheduling were presented by working group members. Discussion of this process and the lists of substances can be found on the TGA website under Scheduling News. These lists provide some examples of the types of substances that could be considered for the application of Appendix M conditions.

Non-medical prescribing

It is important to emphasise that the policy and legal intent of Appendix M requirements (where the substance would be an OTC medicine, but supplied with additional controls) is different to those around pharmacist prescribing and dispensing of S4 medicines where allowed by state and territory regulation (such as the influenza vaccine), or emergency supply provisions under Part 3 section 3.2 of the Poisons Standard.

While some of the potential controls may be similar, there may also be the need for specific differences in the regulatory controls for the two types of provisions.

Pharmacist competency

Pharmacy stakeholders, including the profession, have collaborated on the development of, and periodic review of, the competency standards framework for pharmacists. The safe and effective delivery of pharmacy services is supported by professional practice standards and guidelines, such as those developed and published by the Pharmaceutical Society of Australia (PSA) and The Society of Hospital Pharmacists of Australia (SHPA).

The Pharmacy Board

The Pharmacy Board of Australia (the Board) is the regulator of pharmacists in Australia and acts to protect the public by ensuring that only suitably qualified and competent pharmacists are registered. The role of the Board as a regulator of pharmacists is one component of the complex regulatory environment governing pharmacist practice, which includes regulation by a range of entities including pharmacy registering authorities and state and territory health departments.

Under the Health Practitioner Regulation National Law (the National Law), the Board is responsible for developing registration standards for pharmacists and may develop codes and guidelines to guide pharmacists. The Board's guidelines address issues requiring clarification from a regulatory perspective such as complying with the National Law when advertising regulated health services, or addressing public risk about a specific practice issue. For example, the Board has published guidance about compounded medicines, in particular the compounding of sterile injectable medicines, to ensure product quality, safety and efficacy. The Board's 'Guidelines for the compounding of medicines' highlight risks that need to be carefully assessed and managed and are not a protocol for compounding. The practice standards on compounding developed by the PSA and SHPA, relevant legislation and published information in text books and journals and any other relevant published guidance (for instance, from other regulators) are an important primary source of information about the delivery of such services.

The Board also has responsibility for managing notifications (complaints and concerns) about pharmacists and pharmacy students. Expected standards of practice are informed by the professional practice standards and guidelines published by pharmacy organisations such as the PSA and SHPA, relevant legislation and additional information published by relevant regulators, and the codes and guidelines published by the Board. These may be used as evidence of what constitutes appropriate professional conduct or practice for pharmacy in proceedings under the Health Practitioner Regulation National Law (the National Law) or a law of a co-regulatory jurisdiction against a health practitioner.

Pharmaceutical Society of Australia

The 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. The 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.

The PSA, as the profession's standards-setting body develops its own codes, guidelines and standards. These cover aspects of professional and ethical practice by pharmacists. PSA's documents are referred to by the Pharmacy Board when outlining its expectations. In its public protection role, the Board may also refer to or use as evidence PSA's documents when considering cases relating to pharmacists' professional conduct or behaviour.

Specific criteria for inclusion in Appendix M

Appendix M entries will include both the substance that has been rescheduled to S3 and the additional requirements that relate to that substance. As is the case with other appendices to the Poisons Standard, Appendix M criteria should be well defined, but allow for the flexibility to address specific safeguards that may be required for individual substances. It is proposed to have a set list of common criteria, some or all of which could be applied to each new substance considered for addition to Appendix M, depending on the specific risks identified as requiring additional controls to manage risks in down scheduling to S3. In addition (or in place of specific criteria) the Delegate can impose additional criteria on Appendix M substances on a case by case basis, where warranted and on the advice of the ACMS. It is not intended that Appendix M controls would be routinely required for medicines that are rescheduled from S4 to S3.

In general, novel medicinal substances that have not benefited from a minimum period in widespread general use are typically scheduled as prescription-only substances, and it is anticipated that this practice would continue. Thus Appendix M would normally only be considered for rescheduling purposes, not for newly-scheduled substances.

Where pharmacist training is referenced in the criteria for Appendix M, it is envisaged that this will be focussed on the specific substance and associated conditions in question and that training requirements would be relatively concise, easily accessible and not onerous in nature in most cases. They could take the form of optional Continuing Professional Development (CPD) units developed by sponsors and approved by relevant organisations. This training would be developed on a case by case basis for each Appendix M entry.

It will be important for pharmacists to emphasise the ongoing role of pharmacist/ prescriber collaboration in healthcare management of individuals. The importance of patients advising their doctor of all medicines they are currently taking, including OTC and complementary medicines should be emphasised.

As an additional consideration, the nature of Appendix M and the additional controls placed in it are such that there are likely to be circumstances in which the substance cannot be provided as pharmacist only, either because the patient or pharmacist does not satisfy the additional controls. To ensure needed substances remain available, the Delegate could decide that the substance should also remain in S4. The effect of these provisions is such 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. The removal of Appendix M conditions, if and when considered appropriate, could be achieved through the usual mechanisms i.e. by direct decision of the Delegate, or following an application to amend the Poisons Standard by any applicant.

In considering criteria for Appendix M, it is important to note that the Poisons Standard, including Appendix M, is given legal effect by State and Territory legislation. Therefore, criteria should be framed in such a way as to allow for ready adoption by States and Territories through their usual processes. It is recognised that some of the criteria suggested below might more appropriately be considered the domain of professional practice standards, to be adopted by pharmacy professional and peak bodies, while others can be readily translated into State and Territory legislation. Accordingly, the suggested criteria are separated into two groups; criteria that could be directly regulated; and criteria that could be captured through a requirement to comply with specific professional practice standards as developed for each Appendix M item.

Proposed criteria

A range of potential criteria for application to Appendix M substances has been identified. The Delegate and the ACMS (in advising the Delegate) may require that one, some or several of these criteria be applied under an Appendix M entry for the Schedule 3 substance.

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

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

   This criterion identifies advice on mandatory warnings to be applied to medicines containing S3, Appendix M substances when they are supplied. Information may be required to be provided to the patient about side effects, drug-drug interactions and/or health conditions that are contraindicated with the use of the substance, including advice on when to seek medical review. This may be required to be provided as oral and/or written advice.

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

   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. This could be modelled on existing specific pharmacist training packages, such as those on provision of emergency contraception. Minimum requirements for training packages will be described in the application for rescheduling. Pharmacists would be required to successfully complete this training prior to being eligible to provide each substance under Appendix M. It is anticipated that individual pharmacists, business owners and the training provider, including e.g. the sponsor and the PSA, would retain records of the pharmacists who have completed training.

3. Additional conditions may be imposed

   Appendix M would also contain the general provision that the Scheduling Delegate may impose additional controls on substances on a case by case basis where deemed necessary, on the advice of the Advisory Committee on Medicines Scheduling. Depending on the nature of any additional controls, these might be directly implemented by States and Territories, or could be incorporated into professional practice standards, as for Group 2.

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

   This would include use of clinical decision making tools such as questionnaires, checklists or guidelines by pharmacists in determining whether supply of an S3, Appendix M substance is appropriate. These would cover information about general health conditions, patient characteristics, existing medications and co-morbidities pertinent to the substance in question and clearly state relative and absolute contraindications to supply, including relevant patient exclusions. Full assessment might be required on each supply or at periodic intervals (e.g. once a year, every third supply etc.).

5. Record keeping and information sharing

   Pharmacists would be required to retain patient questionnaires or records of interview and related data on supply of S3, Appendix M goods for a specified period. Records and related data could include:

   - all material and information used to support pharmacist decision making in supply of an Appendix M good, and
   - any other evidence of compliance with Appendix M criteria as relevant (e.g. demonstrate use of labels, patient information sheets , information sharing practices with GPs).

   It is not expected that systems for real-time data collection and sharing (for example, as used currently for pseudoephedrine) would typically be required for S3, Appendix M goods, although this is an option that could be considered by the Delegate in specific cases.

   A requirement to share information relating to the supply of goods with the patient's GP could also be considered on a case by case basis. Information sharing could be through any agreed method by the pharmacy and relevant GPs, including, but not limited to, use of MyHealth Records or direct, electronic communication with the practice, and would be subject to all applicable legislative restrictions, including patient consent for the sharing of information.

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

   While the maximum quantity (and strength) of doses containing particular substances able to be supplied per pack can be specified in the Schedule 3 entry for an S3, Appendix M substance, it is proposed the S3, Appendix M entry could specify additional limitations on duration, quantity and/or frequency of supply of products containing an S3, Appendix M substance. This could potentially form part of state and territory regulation or be considered as a component of good pharmacy practice.

   Examples of conditions that could be applied include: that the substance be supplied from a particular pharmacy not more than twice in a 12 month period; or not more than 20 tablets to be supplied at one time; or for no longer than 6 months without evidence of appropriate clinical review; or not without evidence of stable disease not requiring dose adjustments for at least 6 months. It is recognised that the patient could seek supply from an alternative pharmacy. This is a risk for any patient consultation process and could be mitigated by the provision of advisory information under the first criterion, to ensure patient awareness of the risks of inappropriate use of the substance in question, or that a continued need to use the Appendix M good in excess of the restrictions on OTC supply would indicate a need for medical review. If such measures were considered inadequate mitigation for the risks posed, it is likely the substance in question would remain S4 only.

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

   For some substances, it may be appropriate that they only be supplied if the patient has had a formal diagnosis or periodic review of the condition by a medical practitioner within a specified timeframe. Assessing this could form part of the patient interview or questionnaire, and include consideration of recent prescriptions, specialist referrals or notes or any other documentation held by the patient. Determining an acceptable level of evidence to confirm whether a patient has a formal diagnosis or has been recently reviewed would be guided by professional practice standards, but ultimately be at the discretion of pharmacists on a case by case basis.

- 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?

Accompanying guidance for Appendix M

There are three main documents in which applicants can find information about requirements for rescheduling applications: the SPF, the Scheduling Handbook (the Handbook) and the Application to Amend the Poisons Standard itself [the Application]. Proposed changes to each to address Appendix M guidance are discussed below.

The Scheduling Policy Framework

The SPF states:

> *"The Secretary may, in consultation with ACMS, require additional controls or supply requirements for certain Schedule 3 substances to enable them to be provided by a pharmacist. This Appendix is intended to facilitate down scheduling from Schedule 4 to Schedule 3 where, for example, there is community need for access to a medicine but additional controls and oversight, including by the dispensing pharmacist are needed.*
>
> *The substance and proposed intervention/additional requirement(s) will be listed in the Appendix.*
>
> *All proposals for inclusion in Appendix M must be referred to ACMS and undergo public consultation."*

Appendix M is further explained in a note to the Scheduling Factors for S3 which states:

> *"Additional controls over access and training for substances in Schedule 3 may be required through inclusion in Appendix M, particularly where the potential for severe and possibly irreversible injury may occur without the user being aware of exposure and/or where the pattern of use of the substance poses a significant risk from direct or indirect public exposure."*

It is not anticipated that any changes will be made to the SPF.

The Scheduling Handbook

The Handbook provides further guidance on the application of the SPF. At present, regarding rescheduling applications, the Handbook states:

> *"Rescheduling applications are only made in relation to substances that have an existing (individual substance or class) entry or entries in the Poisons Standard.*
>
> *When considering a rescheduling application the Secretary will decide:*
>
> - *the scope of the entry and the schedule(s) in which the substance is to be included*
> - *which other parts of the Poisons Standard may also apply to the substance"*

It is proposed that the Appendix M criteria would be included in the handbook.

The application to amend the Poisons Standard

The application form specifies information required for consideration of scheduling and rescheduling amendments. Information regarding claims against the requirements of the scheduling policy framework is already provided for in Part 2.1 of the form, which specifies criteria that must be addressed in detail by the applicant in order for their application to be considered by the advisory committee. It is proposed that further criteria would be added to the form by adding a new Part 2.3, which would require an application for rescheduling of an item to S3, Appendix M to address in detail how the applicant proposes to meet Appendix M criteria.

Explanatory guidance to the section could include relevant advice such as:

- All criteria (1-7) must be addressed. The applicant should outline what measure(s) they think would be appropriate to meet each criteria. If the applicant thinks a particular criterion need not be applied to their product, they need to provide justification for its omission.
- Samples of any proposed patient information or advisory material should be provided with the application.
- A preliminary version or comparable example of any proposed material related to ensuring the appropriate use of the product, such as training material, clinical decision making guidelines, questionnaires or professional advice for pharmacists must be included for evaluation. Evidence of consultation and/or collaboration with relevant professional colleges or associations (for example, the PSA) should also be included.
- Training material must include:
  - Information on relevant health conditions and indications for the substance in question (including, where relevant, any known alternative non-drug treatments for the relevant health conditions to enable the provision of fully informed, appropriate clinical advice)
  - All known side effects, adverse effects and drug interactions, including relative and absolute contraindications for supply
  - An outline of any related patient information materials produced as part of the Appendix M criteria
  - Guidance as to when patients should be referred for medical assessment, including advice on common co-morbidities which might require further evaluation by a medical practitioner
- Record keeping and information sharing requirements for pharmacists would generally be expected to be consistent for all entries and determined by State and Territory Drugs and Poisons units in consultation with other key stakeholders, including the Pharmacy Board. Applicants would only be required to indicate if additional/alternative arrangements were considered necessary or advisable for a particular substance, and if so, to detail what these should be and why they were necessary.
- If an applicant foresees that there may be an objection to down scheduling their substance that is not addressed by the other criteria, they may suggest additional criteria for risk mitigation under criterion 3, for consideration by the delegate and ACMS in their scheduling decision.

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

Monitoring, evaluation, compliance and enforcement of Appendix M

Monitoring and evaluation

Monitoring of Appendix M items will be important for ensuring compliance with its provisions by pharmacists (individual compliance) and evaluating the impact of these controls on public health and safety (program evaluation). Responsibility for monitoring and evaluation of individual compliance would lie predominantly with State and Territory Drugs and Poisons units under existing capabilities for evaluating compliance with scheduling requirements. Program evaluation may be undertaken by partners such as State and Territory Drugs and Poisons units or the TGA where deemed appropriate.

Compliance and enforcement

Compliance with *general* competency to supply under Appendix M

The Pharmacy Board has developed registration standards for the pharmacy profession. These are distinct from the professional practice standards for pharmacists, such as those published by PSA and SHPA, which articulate the expected standards of professional behaviour of pharmacists when delivering pharmacy services.

The Board's *Registration standard: Continuing professional development* sets out the annual CPD obligations of pharmacists to competently and safely provide services to the public. When renewing their registration annually, pharmacists are required to declare that they have met the minimum annual CPD requirements specified in the registration standard. The Board's registrations standard and guidelines do not specify particular CPD activities to be completed and pharmacists must assess their CPD needs and complete suitable activities to address those needs.

It is possible that specific competency requirements could be set by the Pharmacy Board to establish competence to comply with Appendix M controls, as part of their registration standards. It will first be necessary to review the existing competency standards framework to ascertain whether or not it currently articulates the competencies that are necessary for supply by pharmacists of medicines in Appendix M. If additional competencies are identified, it will be necessary to consider how pharmacists might meet those competencies e.g. through additional education and training, and whether this can be achieved through pharmacists' compliance with the Board's *Registration standard: Continuing professional development* or by a relevant authority (e.g. a health department) setting specific education and training and any other requirements.

If additional competencies for the general provision of Appendix M goods were developed, failure of a pharmacist to maintain those competencies would be a matter for the Pharmacy Board to consider and redress.

Compliance with *specific* Appendix M conditions for individual items, including completion of any item-specific training packages prior to supply

Under the proposed arrangements, ensuring that pharmacists have complied with specific Appendix M controls and responding to breaches would be a joint responsibility under existing provisions between State and Territory Drugs and Poisons units and the Pharmacy Board, either of whom could take independent action appropriate to the specifics of the case in question. This would include assessment of compliance with professional practice standards, as a condition of supply of Appendix M goods under State and Territory legislation.

- Are these provisions adequate for monitoring, evaluation, compliance and enforcement of Appendix M criteria?
- What alternative measures might be considered?

What will happen after the consultation?

Based on consultation responses, a final position paper will be developed outlining the suggested Appendix M changes and forms, in particular the proposed criteria for Appendix M. Changes will be implemented and stakeholders notified via the TGA website by mid-2019.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Transparency Reforms and Evaluation Support, Prescription Medicines Authorisation Branch	February 2019

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