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Consultation: Proposed amendments to the Poisons Standard - Advisory Committee on Medicines Scheduling meeting, November 2019

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred for scheduling advice to the November 2019 meeting of the Advisory Committee on Medicines Scheduling (ACMS).

PSA's comments relate to proposed amendments to mometasone, zolmitriptan and sumatriptan.

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.

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Comments on proposed amendments

Mometasone

Details of the proposal

This proposal seeks to create new Schedule 3 (S3) and Appendix M entries and amend the Schedule 2 (S2) entry for mometasone in the Poisons Standard as follows:

> **S3** – *Mometasone as the only therapeutically active substance in preparations for dermal use containing 0.1% or less of mometasone in packs containing 15 g or less except when included in S2.*
>
> **Appendix M** – *The medicine (mometasone) should only be supplied if the patient has had a formal diagnosis by a medical practitioner (or periodic review of the condition) within the last 6 months and specifically recommended mometasone. This is to be determined by a patient questionnaire. Specific pharmacist training on the provision of this medicine is required.*
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> **S2** – *Mometasone in aqueous nasal sprays delivering 50 micrograms or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short term prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years and over.*

Proposed Schedule 2 entry

This proposal seeks to add to the S2 entry an upper limit to the pack size of aqueous nasal sprays with other limits on strength and maximum daily dose remaining unchanged. With regards to the proposal to add 'when packed in a primary pack containing 200 actuations or less', PSA notes through the **published interim decision** of a delegate of the Secretary that this was supported. It was outlined that, at usual recommended adult doses, a delivery device containing up to 200 actuations (of 50 micrograms/spray) would permit 50 days of prophylaxis and treatment and/or 100 days of maintenance. The inclusion of an upper limit for S2 supply was also considered to require the patients to return to a pharmacy for resupply and possible consultation with a pharmacist. Thus, PSA has no objections to the proposed amendment in the context of the reasons cited.

However, the conditions in the S2 entry include "… for the short term prophylaxis or treatment of allergic rhinitis for up to 6 months…". On further review, PSA notes that the TGA recently communicated (albeit in the context of the Appendix M criteria consultation) advice from States and Territories that "limits on frequency and duration of supply are not within their power to legislate". Therefore PSA seeks clarification on whether the reference to "for up to 6 months" is still appropriate for inclusion in the S2 entry of the Poisons Standard for mometasone, and if so, how this condition is expected to be fulfilled in practice.

Proposed new Schedule 3 and Appendix M entries

Interim decision

An application proposing new entries for mometasone in S3 and Appendix M of the Poisons Standard was considered by the ACMS in March 2019. The **published interim decision** cited that the proposal was not accepted primarily because risk mitigation measures to support an entry in S3 through Appendix M controls could not be clarified.

In deciding to not reschedule mometasone from Schedule 4 (S4) to S3, the delegate provided comments on issues including "that the diagnosis, management or monitoring of the medical condition is such that it requires medical intervention before the mometasone is used". PSA takes this opportunity to present its assessment and views as follows.

Delegate's comment	PSA's response
Consumers and/or pharmacists are not best placed to perform a differential diagnosis in the supply of mometasone (e.g. fungal infections, herpes zoster, infection).	The Counselling guides published in the Australian Pharmaceutical Formulary and Handbook (a reference text mandated by the Pharmacy Board of Australia) provide pharmacists with information about other causes of skin conditions including infections. Pharmacists already practise within a framework that requires differential diagnosis of other skin diseases.
Retention of mometasone in S4 will support better patient outcomes as any failures in the treatment of conditions with existing mild to moderate potency over-the-counter corticosteroids will be a signal that medical intervention is required.	PSA produces guidance documents for the provision of specific Pharmacist Only Medicines (S3). An S3 guidance document for pharmacists on mometasone would cover all aspects of professional practice including conditions where mandatory or conditional referral is appropriate. Pharmacists are already used to considering and referring patients who have not responded to existing/prior therapy.
Mometasone is classified as a Class III (potent) topical corticosteroid and there are systemic adverse events associated with medically unsupervised and inappropriate use.	As noted by the delegate, pharmacists are already familiar with corticosteroids. Pharmacists currently already advise patients about appropriate use of topical corticosteroids. In an S3 Appendix M scenario, PSA's training and/or S3 guidance document will appropriately address additional factors including systemic adverse events associated with medically unsupervised and inappropriate use. (contd.)

Delegate's comment	PSA's response
Mometasone is classified as a Class III (potent) topical corticosteroid and there are systemic adverse events associated with medically unsupervised and inappropriate use. (contd.)	Topical corticosteroids are commonly classified based on potency. This is a useful clinical guide, however, pharmacists are aware that patient factors and substance characteristics will influence the choice of corticosteroid in relation to their safety and potential benefits. It is important to look beyond the potency classes with regards to therapeutic options. For example, mometasone and methylprednisolone aceponate are both in the 'potent' category but there are variations in their recommended uses[1] – methylprednisolone aceponate 0.1% ointment or fatty ointment can be used on the face but mometasone furoate is not recommended. The proposed S3 pack size limit (15 g) will also minimise the risks associated with inappropriate use.
Inappropriate application of topical mometasone to the face can lead to significant skin problems including corticosteroid induced rosacea on the face (perioral dermatitis) and skin atrophy.	Similarly, PSA's training and/or S3 guidance document will address information on precautions and contraindications, appropriate dosing and application, and other counselling points. Tailored information about precautions and appropriate use of mometasone is core advice that a pharmacist would provide to the patient/carer. This would include, for example, avoiding use on the face.

According to the **published interim decision**, the delegate noted that data suggest mild corticosteroids in S2 and S3 appear to be supplied and used appropriately. Further, that mometasone 0.1% or less in packs containing 15 g or less may meet the scheduling factors for S3. However, rescheduling to S3 was not seen to be justifiable given the following:

- the lack of clarification of risk mitigation measures (through Appendix M controls)
- no identifiable evidence of demand or unmet need for a higher potency corticosteroid to be available without a prescription medicine
- no clear argument that S3 mometasone would offer additional benefit to the community given existing provisions allow for three days emergency supply for a previously diagnosed condition in the absence of a prescription at the time of supply.

As outlined above, the delegate has needed to balance several factors before concluding that mometasone should remain in S4. One issue that concerns PSA is that emergency supply provisions appear to have been cited as one reason why mometasone should not be rescheduled to S3. PSA would contend that the objectives and arrangements for emergency supply provisions in state and territory legislation are entirely different to the purpose of considering whether a substance is suitable for inclusion in S3.

[1] Dermatitis. In: eTG complete. Me bourne: Therapeutic Guidelines; 2019.

Assessment against Appendix M criteria

The following table provides PSA's comments on the applicability of Appendix M criteria (as published in the ***Scheduling handbook: guidance for amending the Poisons Standard***) to mometasone.

Appendix M criteria (numbered) and PSA's comments (dot points) – Mometasone

1. **Specific pharmacist training on the provision of the medicine**

   - The published wording of the proposed new Appendix M entry stipulates that "specific pharmacist training on the provision of this medicine is required".

   - The Scheduling handbook clearly outlines the expectation that an applicant seeking to reschedule an S4 substance to S3 with Appendix M conditions will conduct preliminary discussions with the pharmacy profession. Thus, as the only Australian Government-recognised peak national professional pharmacy organisation, PSA expects it would be approached and consulted on any Appendix M application. PSA has not been approached by any person or organisation in relation to the mometasone proposal.

   - Further, under this criterion it is stated that "applicants are advised to work with an appropriate pharmacy body to develop a suitable training package and related support materials, for submission as part of their application… ideally… in tandem with the development of professional practice standards…". As the recognised standards setting body for the profession and the largest provider of high quality professional education and training for pharmacists, PSA expects to have a substantive role in determining the applicability of this criterion to the substance (mometasone) and, if pharmacist training is required, the design of the training materials. PSA is keen to assist and work in collaboration with the applicant but, to date, has not been approached by the applicant of this proposal.

2. **Suitability of the individual patient for supply of the medicine must be assessed by the pharmacist**

   - The clinical aspect of determining suitability (i.e. patient assessment) is covered by PSA's S3 guidance documents, for example: presenting signs and symptoms; trigger factors; differential analysis; age; prior episodes and treatment; medical, family and medication history; lifestyle factors; advance provision.

   - The S3 guidance documents outline details of the recommended procedure for pharmacists when considering (and supplying) specific S3 medicines. The systematic process helps pharmacists fulfil their professional obligations.

   - PSA also generally makes an assessment of pharmacists' professional practice needs for S3 and provides a suite of materials appropriate to support implementation (e.g. practice support tools) as well as relevant continuing professional development activities.

Appendix M criteria (numbered) and PSA's comments (dot points) – Mometasone

3. Specific advice (patient education) is required on the supply of the medicine

- PSA's S3 guidance documents extensively cover counselling points including: 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.

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4. Limitations on duration/quantity and/or frequency of supply

- PSA S3 guidance documents include information on limits on duration, quantity and/or frequency of supply consistent with the S3 entry of that substance in the Poisons Standard.
- As mentioned earlier, PSA has noted the advice of jurisdictions that they cannot legislate limits on frequency and duration of supply. Therefore PSA believes careful consideration of the practicalities of implementation is required so that pharmacists are able to fulfil their professional responsibilities without undue burden.

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

- The published wording of the proposed new Appendix M entry stipulates that "the medicine (mometasone) should only be supplied if the patient has had a formal diagnosis by a medical practitioner (or periodic review of the condition) within the last six months and specifically recommended mometasone. This is to be determined by a patient questionnaire".
- PSA agrees that an important consideration with the mometasone proposal is to ensure supply is not initiated by the pharmacist for an acute condition.
- PSA would require the opportunity to give this further consideration, in discussion with the applicant, to provide guidance on the most appropriate and effective way to meet this criterion in practice. For example, based on PSA's experience with other therapeutic substances, options other than a patient questionnaire could be canvassed. The nature, context and details of "periodic review of the condition" may also need to be considered.

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6. Record keeping and information sharing

- Record keeping requirements are outlined in PSA guidance documents for existing Pharmacist Only Medicines. The key documentation requirements that pharmacists must fulfil in the provision of a Pharmacist Only Medicine relate to specific standards in PSA's **Professional Practice Standards** and include:
  - Standard 1: *Fundamental pharmacy practice*, Criterion 1.5
  - Standard 4: *Provision of non-prescription medicines and therapeutic devices*, Criterion 4.9.

(contd.)

Appendix M criteria (numbered) and PSA's comments (dot points) – Mometasone

6. **Record keeping and information sharing (contd.)**

- Information sharing in the context of a person's medication management plan is covered, for example, by relevant privacy legislation, PSA's S3 guidance documents (developed for specific substances, classes of medicines and/or indications) and PSA's **Professional Practice Standards** under criteria relating to communication and collaboration:
  - Standard 1: *Fundamental pharmacy practice*, Criterion 1.9
  - Standard 9: *Collaborative care*, Criterion 9.2.
- PSA believes that existing professional responsibilities of pharmacists with respect to the handling and provision of Pharmacist Only Medicines would adequately cover S3 mometasone without additional controls under this criterion. It is envisaged that an S3 guidance document specifically developed for mometasone would include reference to options such as the use of dispensing software or the patient's My Health Record. Overall therefore, additional controls through Appendix M for record keeping and information sharing are not thought to be necessary.

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7. **Additional criteria may be imposed**

- At this stage, PSA is not aware of any additional conditions that may be required for mometasone to be rescheduled to S3. PSA understands that depending on the nature of any additional controls, these might be directly implemented by jurisdictions or they could be incorporated into or effected by a professional practice standard. Further consideration and overall assessment would be required once the applicant's intentions are clarified and PSA, as the peak professional body, is engaged in discussions.

Appendix H

PSA notes the earlier **interim decision** that mometasone should not be included in Appendix H of the Poisons Standard on the grounds that there is a long history of over-the-counter availability of topical corticosteroids which the community is familiar with. It was also stated that "there may only be limited additional benefit from the advertising of a more potent option and the choice of agent is best managed through consultation with the pharmacist". PSA agrees with this assessment and rationale and therefore **supports mometasone to not be included in Appendix H**.

Summary

In summary, PSA believes that the proposed Appendix M controls **appear logical and appropriate** and the overall rescheduling proposal for mometasone is **appropriate from a patient safety perspective**. Pharmacists will continue to practise within the existing professional and ethical standards framework, and be guided by practice support resources, continuing

professional development and relevant additional training (to be determined).

However, in the absence of any discussion with PSA regarding the rescheduling to S3 through Appendix M controls and the apparent lack of preparatory work on a suitable pharmacist training package, PSA is **unable to support this proposal in its current form**. PSA **urgently seeks the opportunity to collaboratively work with the applicant**, consistent with the Appendix M requirements outlined in the Scheduling handbook.

Zolmitriptan and sumatriptan

The proposals to reschedule zolmitriptan and sumatriptan to S3 through Appendix M controls are similar in scope.

Details of the proposals

The proposals seek to create new S3 and Appendix M entries in the Poisons Standard as follows.

Zolmitriptan

> **S3** – *Zolmitriptan for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 2.5 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets.*
>
> **Appendix M** – *Zolmitriptan to be dispensed by a registered pharmacist who has assessed a patient's symptoms to be consistent with an acute, episodic migraine attack; and that assessment and supply is consistent with expected professional standards of practice and specifically related clinical support tools and resources; and that a history of migraine or acute migraine treatment has ideally been verified e.g. via the patient's My Health Record, or through previous prescribing/dispensing.*
>
> *The pharmacist will record the supply of this medicine in their dispensary software, and include the patient's name, address, date of birth and gender. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will upload a record of supply to the patient's My Health Record.*

Sumatriptan

> **S3** – *Sumatriptan for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 50 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets.*
>
> **Appendix M** – *Sumatriptan to be dispensed by a registered pharmacist who has assessed a patient's symptoms to be consistent with an acute, episodic migraine attack; and that assessment and supply is consistent with expected professional standards of practice and specifically related clinical support tools and resources; and that a history of migraine or acute migraine treatment has ideally been verified e.g. via the patient's My Health Record, or through previous prescribing/dispensing.*
>
> *The pharmacist will record the supply of this medicine in their dispensary software, and include the patient's name, address, date of birth and gender. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will upload a record of supply to the patient's My Health Record.*

Assessment against Appendix M criteria

In the following table, PSA has provided comments on the applicability of Appendix M criteria to zolmitriptan and sumatriptan (considered together, where possible, as 'triptans').

Appendix M criteria (numbered) and PSA's comments (dot points) – Triptans

1. **Specific pharmacist training on the provision of the medicine**

   - PSA agrees that specific pharmacist training on the provision of triptans will be required. PSA is concerned that it has not been approached by any person or organisation as outlined in the Scheduling handbook in relation to these Appendix M proposals. PSA expects to have a role in the provision of advice, design and implementation of a suitable training package. PSA is keen to assist and work in collaboration with the applicant.

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2. **Suitability of the individual patient for supply of the medicine must be assessed by the pharmacist**

   - The clinical aspect of determining suitability (i.e. patient assessment) is covered by PSA's S3 guidance documents, for example: presenting signs and symptoms; trigger factors; differential analysis; age; prior episodes and treatment; medical, family and medication history; lifestyle factors; advance provision.

   - As referred to earlier, PSA's S3 guidance document is designed to support pharmacists to fulfil their professional obligations in the handling and provision of specific S3 medicines. The systematic process nevertheless allows and expects the pharmacist to exercise professional judgement in the context of the specific clinical circumstances of the patient and their needs.

   - In addition, PSA will assess pharmacists' professional practice needs, and design and develop a suite of materials to support implementation (e.g. practice support tools) as well as relevant continuing professional development activities.

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3. **Specific advice (patient education) is required on the supply of the medicine**

   - PSA's S3 guidance documents extensively cover counselling points including: 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.

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4. **Limitations on duration/quantity and/or frequency of supply**

   - Existing PSA S3 guidance documents include information on limits on duration, quantity and/or frequency of supply consistent with the S3 entry in the Poisons Standard.

   - As mentioned previously, careful consideration of the practicalities of implementation is required so that pharmacists are able to fulfil their professional responsibilities without undue burden. This is in relation to those aspects that cannot be legislated by jurisdictions.

Appendix M criteria (numbered) and PSA's comments (dot points) – Triptans

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

- The proposed S3 availability of the triptans is for "patients who have a stable, well-established pattern of symptoms". PSA agrees with this as it indicates the requirement for a formal diagnosis by a medical practitioner or periodic review of the condition. Details of how the pharmacist would verify this (e.g. the patient's My Health Record, previous prescribing/dispensing) will be considered by PSA in the context of the design of appropriate pharmacist training. PSA will require the opportunity to give this due consideration, in discussion with the applicant, to provide guidance on the most appropriate and effective way to meet this criterion in practice.

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6. Record keeping and information sharing

- As mentioned earlier, record keeping requirements are clearly outlined in PSA guidance documents for existing Pharmacist Only Medicines; thus, this would apply to any new S3 / Appendix M substance. The key documentation requirements that pharmacists must fulfil in the provision of a Pharmacist Only Medicine relate to specific standards in PSA's **Professional Practice Standards** and include:
  - Standard 1: *Fundamental pharmacy practice*, Criterion 1.5
  - Standard 4: *Provision of non-prescription medicines and therapeutic devices*, Criterion 4.9.
- Information sharing in the context of a person's medication management plan is effected through several means including privacy legislation, PSA's S3 guidance documents (developed for specific substances, classes of medicines and/or indications) and PSA's **Professional Practice Standards** under criteria relating to communication and collaboration:
  - Standard 1: *Fundamental pharmacy practice*, Criterion 1.9
  - Standard 9: *Collaborative care*, Criterion 9.2.
- PSA has the expertise and responsibility to develop S3 guidance for zolmitriptan and sumatriptan which will include applicable record keeping requirements for pharmacists. The proposal outlines the means (e.g. dispensary software, patient's My Health Record) as well as the details (e.g. patient's name, address, date of birth and gender) to be recorded by the pharmacist. PSA will consider the options in greater detail in the context of designing appropriate pharmacist training in discussion with the applicant.

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7. Additional criteria may be imposed

- At this stage, PSA is not aware of any additional criteria or requirements that may be necessary.

Appendix H

Based on further discussions with the applicant, PSA may determine whether advertising of the triptans is appropriate. This will include consideration of whether advertising is likely to deliver benefits to patients and carers.

Other considerations

In many overseas countries, triptans have been safely and effectively rescheduled to non-prescription status for use in patients who have well established and stable pattern of symptoms of migraine attacks.

In Australia, PSA is aware of a recently completed study[2] in Western Australia which evaluated pharmacists' readiness and perspectives to manage migraine with non-prescription triptan medicines. PSA will further explore the outcomes of this study once published.

Summary

Overall, PSA believes that zolmitriptan and sumatriptan **can be included in S3 with additional controls**. The proposed Appendix M **controls are appropriate in mitigating the risks** associated with the provision of these triptans without a prescription. Pharmacists will continue to practise within the existing professional and ethical standards framework, and be guided by practice support resources, continuing professional development and appropriate additional training (to be determined).

However, in the absence of any discussion with PSA regarding this S3/Appendix M proposal and the apparent lack of preparatory work on an appropriate pharmacist training package, PSA **urgently seeks the opportunity to collaboratively work with the applicant**, consistent with the Appendix M requirements outlined in the Scheduling handbook.

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