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Consultation: Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS/ACCS meetings, March 2020

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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 March 2020 meetings of the Advisory Committee on Medicines Scheduling (ACMS), the Advisory Committee on Chemicals Scheduling (ACCS) and the Joint ACMS/ACCS.

PSA's comments relate to the following items: 1.1 Ranitidine, 1.2 Selective serotonin reuptake inhibitors, 1.3 Fexofenadine, 1.4 Flurbiprofen, 1.5 Ondansetron, 1.6 Rizatriptan, 1.7 Melatonin, 1.8 Adapalene, 2.1 Arbutin, 3.1 Nicotine and 3.2 Pentobarbital.

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.

Recommendations

Ranitidine *– PSA recommends retention of current arrangements for exemption from scheduling for ranitidine, and inclusion of the proposed increase in pack size of ranitidine to 42 days' supply in Schedule 3.*

Selective serotonin reuptake inhibitors (SSRI) *– PSA has no objections to the creation of a new Schedule 4 group entry in the Poisons Standard for SSRIs.*

Fexofenadine *– PSA accepts that the proposed amendment is consistent with the existing exemption from scheduling for fexofenadine and aligns across the different available strengths. PSA has no objections to this proposal.*

Flurbiprofen *– PSA does not support the proposed amendments for flurbiprofen which would result in small packs of lozenges being exempt from scheduling.*

Ondansetron *– PSA believes ondansetron meets the scheduling factors for Schedule 3 substances in the context of the proposed amendment to create a new entry in S3, however, clarity of the indications under S3 is required. PSA does not support the inclusion of ondansetron in Appendix H.*

Rizatriptan *– PSA supports the inclusion of rizatriptan in Schedule 3, in alignment with the recent interim scheduling decisions for sumatriptan and zolmitriptan. However, PSA does not support the inclusion of rizatriptan in Appendix H at the present time.*

Melatonin *– PSA is not aware of any preparatory work on appropriate pharmacist training to fulfil the requirements of Appendix M and, as the peak health and advisory body for pharmacists, seeks urgent discussions with the applicant.*

Adapalene *– PSA believes adapalene may be appropriate for inclusion in Schedule 3 with the inclusion of Appendix M controls. However, PSA is not aware of any preparatory work on appropriate pharmacist training to fulfil the requirements of Appendix M. As the peak health and advisory body for pharmacists, PSA seeks urgent discussions with the applicant.*

Arbutin *– PSA supports the proposed limits and entries for alpha- and beta-arbutin in Schedules 4 and 6.*

Nicotine *– PSA does not support the proposal to extend the exception list for nicotine in Schedule 7 through the addition of a sub-paragraph, "in tobacco prepared and packed for heating".*

Pentobarbital *– PSA supports the deletion of the Schedule 4 entry of pentobarbital, when packed and labelled for injection, given the ongoing reported misuse and adverse outcomes in humans, and in line with coroners' recommendations.*

Comments on proposed amendments

1.1 Ranitidine

Summary of proposal

PSA understands amendments to the Poisons Standard are being proposed to allow the provision of oral dose forms containing 150 mg ranitidine and 300 mg ranitidine as follows:

- up to 16 days' supply outside of the pharmacy (i.e. unscheduled). This equates to an increase in pack size to no more than 32 tablets for 150 mg ranitidine and no more than 16 tablets for 300 mg ranitidine. The current limit is up to 7 days' supply.

- up to 42 days' supply as a Pharmacy Medicine (Schedule 2). This equates to an increase in pack size to no more than 84 tablets for 150 mg ranitidine and no more than 42 tablets for 300 mg ranitidine. The current limit is up to 14 days' supply.

PSA's comments

Ranitidine is substantially safe for use in short term treatment regimens. However, PSA believes that the proposed amendments to increase the pack sizes of ranitidine available outside of the pharmacy environment (i.e. unscheduled) and under Schedule 2 are not warranted.

- In the management of symptoms of gastro-oesophageal reflux, there are various patient factors for which referral to a medical practitioner would be recommended and a number of alarm symptoms which would require immediate referral. The range of these factors is reasonably extensive and PSA does not consider packaging and labelling to be adequate means of risk mitigation, particularly through non-pharmacy suppliers.

- Providing 16 days' supply of ranitidine in a pack with labelling of instructions to not take the medicine beyond 14 consecutive days does not promote quality use of the medicine.

- With the larger pack sizes of 42 days' supply, PSA believes S3 would be more appropriate and in the best interests of patients. Some pharmacists were unclear on the rationale for the proposed larger pack sizes, noting also that such quantities are in excess of currently listed ranitidine items under the Pharmaceutical Benefits Scheme. With regards to medium- to long-term use, the place in therapy of ranitidine (and other H_2-receptor antagonists) would need to be considered carefully in the context of a broader, holistic therapeutic approach to the management of symptoms of gastro-oesophageal reflux.

In summary, PSA recommends the following:

- retention of current arrangements for exemption from scheduling for ranitidine, and

- inclusion of the proposed increase in pack size of ranitidine to 42 days' supply in Schedule 3.

1.2 Selective serotonin reuptake inhibitors

Summary of proposal

PSA understands the proposal is to create a new entry for Schedule 4 for: *Selective serotonin reuptake inhibitors (SSRI) except when separately specified in these Schedules.*

PSA's comments

The notice outlines that a number of individual SSRIs are currently included in S4, however, the Poisons Standard does not contain a group entry for SSRIs.

PSA understands a group entry for SSRIs will:

- provide regulatory protections for consumers by capturing any future unnamed or unscheduled SSRI variants in S4

- help clarify the scheduling status of SSRIs and associated requirement for a prescription/order e.g. for travellers intending to enter Australia with an SSRI not specifically included in the Poisons Standard, or anyone intending to import under the personal importation scheme an SSRI not specifically scheduled in the Poisons Standard.

Given the seriousness, severity and frequency of adverse effects and drug interactions associated with SSRI use, and based on the intent of the proposal, PSA has no objections to the creation of a new S4 group entry for SSRIs.

1.3 Fexofenadine

Summary of proposal

PSA understands amendments to the Poisons Standard are being proposed to allow fexofenadine for the relief of seasonal allergic rhinitis symptoms to be exempt from scheduling as follows:

- for adults and children over 12 years of age, in packs containing 5 dosage units or less and not more than 5 days' supply, restricted by dosage unit and labelled with a recommended daily dose not exceeding 180 mg

- for children 6 years and over, in packs containing 20 dosage units or less and not more than 10 days' supply, restricted by dosage unit and labelled with a recommended daily dose not exceeding 60 mg.

No change has been proposed for the current exemption from scheduling for divided preparations for adults and children 12 years and over, in packs containing 20 dosage units or less and not more than 10 days' supply, and labelled with a recommended daily dose not exceeding 120 mg of fexofenadine.

PSA's comments

Fexofenadine is effective for the relief of symptoms of seasonal allergic rhinitis and substantially safe for use, including in children with mild symptoms or for intermittent use.

PSA notes the proposed amendment is consistent with the existing exemption from scheduling for fexofenadine and aligns across the different available strengths.

PSA has no objections to this proposal.

1.4 Flurbiprofen

Summary of proposal

PSA understands amendments to the Poisons Standard are being proposed to allow flurbiprofen in divided preparations containing 10 mg or less per dosage unit to be exempt from scheduling when:

- not labelled for the treatment of children 12 years of age or less, and
- in a primary pack containing not more than 16 dosage units.

Currently these limits are captured in Schedule 2.

PSA's comments

Flurbiprofen as outlined in this proposal would capture the small to medium size packs of lozenges which are currently available in Australia for the relief of pain, swelling and inflammation associated with severe sore throats.

Flurbiprofen lozenges, currently in Schedule 2, require the inclusion of advisory statements in the package labelling cautioning against use in pregnancy.

The Database of Adverse Event Notifications includes four reported cases in the last two decades where flurbiprofen (lozenge) was the single suspected medicine that caused a number of adverse effects including rash, oedema, paraesthesia, chest discomfort and hallucination.

The use of low dose flurbiprofen in adults is known to be generally safe and effective for symptomatic relief of sore throats. However, in addition to pregnancy being a contraindication, the use of flurbiprofen requires caution in other health conditions such as stomach ulcer, asthma, heart failure and renal or hepatic impairment. Flurbiprofen may also interact with other medicines such as anticoagulants, diuretics, oral corticosteroids and angiotensin II receptor antagonists.

Given the range of precautions required with the use of flurbiprofen, PSA does not believe that risk mitigation through labelling is adequate and therefore, flurbiprofen lozenges must be available through a setting where professional advice can be accessed.

In summary, PSA does not support the proposed amendments for flurbiprofen which would result in small packs of lozenges being exempt from scheduling.

1.5 Ondansetron

Summary of proposal

Amendments to the Poisons Standard are being proposed to create new entries in Schedule 3 and Appendix H. The proposed entry for S3 is: *Ondansetron for human therapeutic use in divided preparations containing 4 mg or less in packs containing not more than 4 dosage units*.

PSA's comments

Ondansetron is currently included in Schedule 4 and indicated for the prevention and treatment of nausea and vomiting induced by cytotoxic therapy and radiotherapy. Off-label use is widely reported. Ondansetron is listed in *Therapeutic Guidelines* as a common antiemetic with general use for initial management of acute nausea and vomiting in adults. The lowest effective dose of ondansetron should be used with the total daily dose generally ranging from 8 mg per day, up to a maximum of 32 mg per day.

Schedule 3 criteria

Considering the relevant scheduling factors, PSA believes ondansetron is suitable for inclusion in S3:

- Ondansetron is substantially safe with pharmacist intervention to ensure its quality use. Patients can readily identify the symptoms to be treated and the pharmacist can verify the patient's needs and suitability. The pharmacist will also provide counselling in relation to any other risk factors and additional or associated care for the management of acute nausea and vomiting.

- The proposed amendment will limit the availability of ondansetron under S3 to a small pack size (maximum of four dosage units) of the lowest available strength (4 mg (or less) per dosage unit). Thus the potential for ongoing use without pharmacist intervention or deliberate misuse is low.

PSA has a role in developing an S3 guidance document for ondansetron if it is included in S3. The guidance document will be designed to support pharmacists to fulfil their professional obligations in the handling and provision of ondansetron as an S3 medicine. Generally S3 guidance documents cover professional obligations, clinical considerations, referral pathways, treatment options, counselling points and other requirements such as record keeping and communication.

Clear guidance on the indications for S3 is required given off-label use is widely reported even though current S4 indications are limited. This will have an impact on the development of PSA's S3 guidance document.

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

PSA would welcome the opportunity to work with the applicant to ensure timely development and implementation of required professional resources.

Appendix H

Given the lack of experience with ondansetron as a non-prescription medicine in Australia, PSA does not support the inclusion of ondansetron in Appendix H.

Summary

PSA believes ondansetron meets the scheduling factors for S3 substances and therefore supports the proposed amendment to create a new entry in S3, however, clarity of the indications under S3 is required. PSA does not support the inclusion of ondansetron in Appendix H.

1.6 Rizatriptan

Summary of proposal

PSA understands this application seeks to reschedule rizatriptan 5 mg in pack sizes of two tablets for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms. New entries are proposed for Schedule 3 and Appendix M, as follows, and for Appendix H.

- **S3** – Rizatriptan 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 5 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets.

- **Appendix M** – Rizatriptan – 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 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 dispensing software, and include the patient's name, address and directions for use and date of supply. 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.

PSA's comments

PSA notes the Delegate's interim decisions, recently published, based on the advice of the ACMS from the November 2019 meeting. The two substances, sumatriptan and zolmitriptan, were deemed to be appropriate for inclusion in S3 based on reasons which included the following:

- Time critical access to these medicines is crucial for the management of migraine symptoms. Sumatriptan and zolmitriptan are substantially safe with pharmacist advice and availability as S3 will improve timely access and patient outcomes.

- The risk profiles of the substances are well defined, and the adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist and by the pack size

limitation. Access controls in place for an S3 medicine are appropriate and sufficient to mitigate the risk of misuse of sumatriptan and zolmitriptan, without their inclusion in Appendix M.

Thus, PSA believes the inclusion of rizatriptan, with the proposed amendments, in S3 is appropriate.

In the interim decisions for sumatriptan and zolmitriptan, PSA noted the proposed implementation date of 1 February 2021 to allow for regulatory changes and for "the development of education and training material to be provided to pharmacists". PSA appreciates the Delegate's consideration around this and would request similar arrangements for S3 rizatriptan. This will enable PSA to assess pharmacists' professional practice needs and develop relevant materials including a guidance document for the S3 indication of triptans to support pharmacists to fulfil their professional obligations in the handling and provision of these medicines.

The S3 guidance document would include clinical aspects of determining patient suitability (e.g. presenting signs and symptoms; trigger factors; differential analysis; age; prior episodes and treatment; medical, family and medication history; lifestyle factors; advance provision). It also generally covers counselling points such as: 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.

Other important professional considerations are also outlined in PSA's **Professional Practice Standards**, in particular, Standard 1: *Fundamental pharmacy practice*, and Standard 4: *Provision of non-prescription medicines and therapeutic devices*.

Appendix H

At this stage, given the lack of experience with rizatriptan as a non-prescription medicine in Australia, PSA does not support its inclusion in Appendix H. However, in the interim decisions for sumatriptan and zolmitriptan, PSA notes the Delegate included these substances in Appendix H after being satisfied that "there are no foreseeable potential impacts on public health that would preclude advertising… …directly to consumers".

Formulation

Rizatriptan is also available in a wafer form which is beneficial for patients who experience nausea associated with migraine. The wording of the proposed amendment makes specific reference to "tablets". PSA seeks clarification on whether "tablets" will capture the wafer forms or whether the wording should be amended to "divided preparations".

Summary

Overall, PSA supports the inclusion of rizatriptan in S3, in alignment with the recent interim scheduling decisions for sumatriptan and zolmitriptan. However, PSA does not support the inclusion of rizatriptan in Appendix H at the present time.

1.7 Melatonin

Summary of proposal

PSA understands this application seeks to reschedule melatonin 2 mg in modified release formulations. New entries are proposed for Schedule 3 and Appendix M, as follows, and for Appendix H.

> **S3** – *Melatonin in modified release formulations up to 2 mg for human use when supplied under the requirements of Appendix M.*
>
> **Appendix M** – *Melatonin – 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.*

PSA's comments

Melatonin 2 mg modified release formulation products are currently available and indicated as monotherapy for the short term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 years or over.

PSA believes melatonin meets the scheduling factors for S3 substances such as: being substantially safe with pharmacist intervention; not expected to produce dependency; not likely to mask the symptoms or delay diagnosis of a serious condition; and risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.

Appendix M criteria

PSA provides the following comments regarding the applicability of Appendix M criteria (numbered below) to melatonin.

1. Specific pharmacist training on the provision of the medicine

Melatonin for human use is currently included in Schedule 4. Given there is no experience in Australia of supply of melatonin as a non-prescription medicine, it is appropriate that specific training for pharmacist provision of melatonin is developed. This will include consideration of relevant risk mitigation steps and measures to ensure the quality use of melatonin.

To date, PSA has not been approached by any person or organisation which is outlined in the Scheduling handbook as a requirement in relation to 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.

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

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

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.

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.

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.

PSA notes that the proposed amendment does not include any quantity limits and suggests consideration of this is appropriate.

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

PSA will require the opportunity to give this criterion due consideration, in discussion with the applicant, once additional details of the proposed amendments are known. PSA has yet to determine if there is a requirement for a formal diagnosis by a medical practitioner or periodic review of the condition in the supply of melatonin as proposed.

6. Record keeping and information sharing

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 melatonin which will include applicable record keeping requirements for pharmacists. The proposal outlines the means (e.g. dispensary software, patient's My Health Record) and the details (e.g. patient's name, address, date

of birth, 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.

7. Additional criteria may be imposed

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

Appendix H

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

Summary

In the absence of any discussion with PSA regarding this S3/Appendix M proposal for melatonin 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.

PSA is also aware that there is a reasonable market in compounded melatonin, including higher strength products. Thus, it may be necessary to consider these additional implications.

1.8 Adapalene

Summary of proposal

PSA understands this application seeks to reschedule adapalene with new entries proposed for Schedule 3 and Appendix M, as follows, and for Appendix H.

> **S3** – *Adapalene in preparations for human external therapeutic use or human therapeutic or cosmetic use containing 0.1 per cent or less of adapalene.*
>
> **Appendix M** – *Adapalene – 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 verify that the patient is not intending to become pregnant, is pregnant or is breastfeeding. The pharmacist will upload a record of supply to the patient's My Health Record.*

PSA's comments

Adapalene is used in topical preparations for the treatment of comedo, papular and pustular acne of the face, chest or back.

Appendix M criteria

PSA provides the following comments regarding the applicability of Appendix M criteria (numbered below) to adapalene.

1. Specific pharmacist training on the provision of the medicine

Adapalene is currently included in Schedule 4. As this proposed amendment would result in adapalene being available as a non-prescription medicine in Australia for the first time, it is appropriate that specific training for pharmacists is developed.

To date, PSA has not been approached by any person or organisation which is outlined in the Scheduling handbook as a requirement in relation to 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.

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. Contraindications around pregnancy and cautionary use in breastfeeding would be captured in this consideration.

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. PSA also has a counselling guide for managing acne which provides pharmacists with advice on a holistic approach to care in acne treatment.

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

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.

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.

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

PSA will require the opportunity to give this criterion due consideration, in discussion with the applicant, once additional details of the proposed amendments are known. PSA has yet to determine if there is a requirement for a formal diagnosis by a medical practitioner or periodic review of the condition in the supply of adapalene as proposed.

6. Record keeping and information sharing

Record keeping requirements generally are 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 adapalene which will include specific record keeping requirements for pharmacists. The proposal outlines the means (e.g. dispensary software, patient's My Health Record) and the details (e.g. patient's name, address, date of birth, 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.

7. Additional criteria may be imposed

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

Appendix H

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

Summary

In principle, PSA believes adapalene meets the scheduling factors for S3 substances with the addition of Appendix M controls. However, in the absence of any discussion with PSA regarding this S3/Appendix M proposal for adapalene 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.

2.1 Arbutin

Background to the proposal

As stated in the notice, arbutin is not specifically scheduled in the Poisons Standard but is cross referenced to hydroxyquinone.

In June 2019, PSA expressed support for the inclusion (as proposed then) of arbutin in the Poisons Standard as specific entries in Schedules 2 and 4, and removal of the cross reference to hydroquinone. However, PSA noted that alpha-arbutin was reported to be much stronger in effect than arbutin or beta-arbutin.

PSA submitted its view that specific consideration was warranted on whether different or additional controls should be applied for:

- different arbutin derivatives for external use
- the use of oral arbutin preparations for urinary tract infections in males, and
- the recommended duration of use of oral arbutin preparations.

PSA did not object to the proposal to exempt arbutin-containing hair preparations and cosmetic nail preparations from scheduling in the concentration limits specified.

PSA's comments

In June 2019, PSA had also commented that, while the proposed limit for oral herbal preparations of 500 mg or less of arbutin per recommended daily dose appeared to be within acceptable range, reports suggested that:

- traditional use of arbutin can only be recommended for females
- the use of arbutin by men is only recommended when advised by a medical practitioner due to the risk of more severe infections (and not on the basis of traditional use), and
- there is also reference to the recommended time of use being limited to two weeks.

PSA is not aware of whether or not these reports have been taken into consideration by the Delegate.

Overall, PSA supports the revised scheduling proposal for arbutin based on the separate considerations of alpha- and beta-arbutin.

3.1 Nicotine

Summary of proposal

The current entry for nicotine in Schedule 7 includes the following exceptions: (a) when included in Schedule 6, (b) in preparations for human therapeutic use, or (c) in tobacco prepared and packed for smoking.

The proposed amendment to this entry is to include an additional exception clause: *(d) in tobacco prepared and packed for heating.*

PSA's comments

PSA understands the applicant is seeking the proposed amendment as an initial step to enable heated tobacco products to be regulated and supplied in Australia, subject to tobacco control laws. The rationale cited is that heated tobacco products, as non-combustible alternatives to cigarettes, provide a less harmful alternative for individuals who do not choose to cease smoking.

The notice indicates that heated tobacco products are widely available internationally, largely regulated as tobacco products.

The applicant's approach is to demonstrate the less harmful effects of heated tobacco products compared to cigarettes. This may indeed deliver a more preferable option for those who do not choose to cease smoking.

PSA supports a harm reduction and harm minimisation approach to public and personal health. Although heated tobacco products may be less harmful alternatives to cigarette smoking, they contain nicotine and therefore it is vital that a range of factors is considered to determine their appropriateness. PSA makes the following comments.

- Heated tobacco products are being described as "likely to be less risky than smoking conventional cigarettes" however the comparator is a product which has substantial known risks to people's health.

- Concern has been expressed previously that preparations for use as a substitute for tobacco are still designed to deliver nicotine and this can pose health risks to both users and non-users of those products.

- Overuse of nicotine can lead to adverse effects. Nicotine dependence can develop rapidly, particularly in people of younger age.

- Although it is possible that some people may transition from cigarette smoking to the use of heated tobacco products and experience 'less' harm, the inherent risks associated with these products are concerning. Clearly from the perspective of pharmacists, strategies to encourage and support smoking cessation through a structured support program is preferable.

- The delivery of nicotine in aerosol may be considered or perceived to be a therapeutic product.

- PSA is not aware of the exact risk-benefit profile of heated tobacco products including the safety and health effects of long term use.

In summary, based on the available information, PSA is not supportive of the proposal to introduce an exception to the Schedule 7 entry for nicotine for "tobacco prepared and packed for smoking".

3.2 Pentobarbital

Summary of proposal

PSA understands the proposed amendments to the Poisons Standard for pentobarbital are to retain its Schedule 8 and Appendix K entries but to delete the Schedule 4 entry which specifies pentobarbital "when packed and labelled for injection".

The cross referencing of pentobarbitone to pentobarbital in the Poisons Standard is also to be retained.

PSA's comments

PSA notes the reasons for this proposal include reported misuse of injectable pentobarbital, involvement in suicides, and recommendations of several coroners to reschedule the S4 entry to S8.

The notice clarifies that no medicines currently on the Australian Register of Therapeutic Goods contain as an active ingredient, pentobarbital, the related substance pentobarbital sodium, or pentobarbitone sodium (the name used previously).

PSA is aware that this rescheduling proposal was considered previously in 2017 by the Joint Advisory Committee on Chemicals and Medicines Scheduling. It was reported that pentobarbital is a cheap and efficient medicine and a preferred agent for specific veterinary purposes, thus upscheduling was opposed by stakeholders on reasonable and practical grounds. Further, while the adverse effects on humans are well known and the use of injectable pentobarbital in suicides had been documented, it was reportedly regarded that the impact on intentional suicide was unclear but thought to be low when considering the available data of suicides and the people that were misusing pentobarbital for suicidal purposes. Thus, after balancing these factors, the Delegate's final decision was that the current scheduling for pentobarbital remained appropriate.

Given there have been additional reports of misuse and adverse outcomes in humans and further coroner recommendations to reschedule the S4 entry of pentobarbital to S8, on balance, PSA supports the deletion of the S4 entry of pentobarbital (when packed and labelled for injection).

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