[redacted]

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting November 2019

Comments by The Pharmacy Guild of Australia to the proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling

1. **Mometasone**
2. **Sumatriptan**
3. **Zolmitriptan**
4. **Caffeine**

Date 17 October 2019

[redacted]

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[redacted]

1. MOMETASONE

This application would allow for the supply of mometasone topical preparations for dermal use containing 0.1 percent of less in packs containing 15 g or less as Schedule 3.

The proposed Appendix M entry would ensure that mometasone for dermal use would only be supplied to patients whose conditions have already been diagnosed or reviewed by a medical practitioner in the last 6 months.

This application was considered by the ACMS at its 26th meeting in March 2019 and we provided support for this application[1]. However, at that stage we were not aware of any particular proposed Appendix M wording.

Given the suggested Appendix M wording included in this application we would once again support this application.

We would suggest only a slight modification of the wording to be consistent with other substances with an Appendix M listing, such as the triptans, also being considered at this meeting.

APPENDIX M – Suggested wording

> *MOMETASONE - to be dispensed by a registered pharmacist who has assessed a patient's symptoms and verified that a formal diagnosis has been made by a medical practitioner (or periodic review of the condition) within the last 6 months and that mometasone has previously been prescribed. 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.*

Appendix M Criteria

1. Specific pharmacist training on the provision of the medicine

A training package would be developed for the goods in question, covering the nature and use of the medicine, conditions being treated and alternative treatments where relevant, risk factors and guidance on when to refer for medical assessment. The training package would also provide guidance on the use of any supporting materials.

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 to reschedule a substance to S3 with Appendix M conditions. Ideally, this would be done in tandem with the development of professional practice standards addressing expected Appendix M conditions. Accreditation of training through existing pharmacy profession pathways is desirable.

We do not believe that it is necessary to include the phrase *"Specific pharmacist training on the provision of this medicine is required"* in the Appendix M wording. Pharmacists already know about corticosteroid dermal preparations and the treatment of corticosteroid responsive skin conditions. Despite what other submissions might suggest pharmacists are trained to differentiate between varied skin conditions and they are well aware of the pharmacology of topical corticosteroids having specialised in pharmacology

[1] https://www.tga.gov.au/sites/default/files/public-submissions-scheduling-matters-referred-acms-26-accs-24-and-joint-acms-accs-21-meetings-held-march-2019-pga.pdf

and drug chemistry in their Bachelor of Pharmacy degree or equivalent. Dermatology and the treatment of skin conditions is a topic covered in the pharmacy courses of study at Universities in Australia. For example, at The University of Sydney Pharmacy Course the subject *"Musculoskeletal, Dermatological and Senses PHAR3826*"[2] covers:

> *"the therapeutics of musculoskeletal, dermatological and special senses including the pharmaceutical sciences that underpin the pharmacological therapies. This unit will also include the epidemiology, pathophysiology and clinical features of musculoskeletal, dermatological and special senses disorders. Topics covered include: wound care, arthritis including rheumatoid and osteoarthritis, dermatitis, sunscreens, gout, photochemotherapy, pain, glaucoma, ethics and decision making, TDM cyclosporine, and NSAIDS. Through the use of case-based learning, students will participate in the interpretation, application and dissemination of pharmaceutical and pharmacotherapeutic concepts and knowledge. On completion of this unit of study students will be able to apply an understanding of the pharmaceutical sciences to optimising the pharmacological and non-pharmacological therapy of patients with musculoskeletal, dermatological and special senses disorders"*

Other Pharmacy Courses in Australian Universities would have equivalent subjects that cover dermatological conditions, their differential diagnosis and treatment. Pharmacists know when they can treat a skin condition and when to refer to a medical practitioner.

We would also remind the Delegate and ACMS members that pharmacists under current scheduling arrangements are already able to initiate hydrocortisone treatment from their own assessment of a patient's condition which would require a similar approach in differential diagnosis when considering whether mometasone is appropriate for a patient's condition.

This does not mean that there could not be refresher training provided to pharmacists and in fact we have recently released a CPD accredited course titled "*Choosing an appropriate topical corticosteroid for the management of atopic dermatitis."* Pharmacists are expected as part of their registration to complete 40 CPD points per year. As part of these CPD requirements, pharmacists as registered health professionals undertake an annual learning plan and would make an assessment whether any further professional development is required in this area and relevant for their practice. This CPD course, whilst not expressly about mometasone, would include the necessary information to ensure a pharmacist could provide continuing treatment with mometasone to a patient already diagnosed by a medical practitioner. In fact, we believe that pharmacists should be able to provide this substance with the education they already have.

Skin conditions and their treatment are a staple part of a community pharmacist's work as they are often the first health professional that a patient will speak to. A community pharmacy is where most consumers will have their prescriptions dispensed.

There are a number of pharmacy organisations that will see the opportunity to develop mometasone educational materials should the Delegate approve the application as they are continuously producing educational modules for pharmacists.

[2] https://sydney.edu.au/courses/units-of-study/2020/phar/phar3826.html

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

This condition provides the ability to require the use of clinical decision-making aids by pharmacists, such as questionnaires, checklists or guidelines, in determining the appropriateness of supply of the product as an S3, Appendix M good. This condition also provides the ability to specify, for example, that face to face interviews should be conducted and if appropriately private interview spaces are available and how frequently, whether internet or phone sales are not permitted, or that specific assessments, reasonably available in a pharmacy setting (e.g. blood pressure checks), must be conducted, where such conditions are considered appropriate for the substance in question.

We believe that a pharmacist can verify that a patient has previously been prescribed this substance either by interviewing the patient or by consulting the patient's My Health Record or the pharmacy dispense records. In some cases the patient may in fact have a labelled tube of product with their name and the prescribing doctor's details, the date of dispensing and the pharmacy that dispensed the product. As of September 2019 the My Health Record had a 90.1% National Participation Rate. There are 4,770 pharmacies are participating in the My Health Record which is almost 83% of all pharmacies in Australia[3]. The My Health Record will transform the quality, experience and value in Australia's healthcare system to enhance patient self-management and improve outcomes. The My Health Record is the future of health care in Australia. It is available to all health care professionals today and should be embraced to provide the better health care that Australian taxpayers expect as a return on their investment.

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

This criterion covers information that may be considered essential to provide to patients, either verbally or in writing, at the time of supply. This could include information about side effects, drug interactions, health conditions that are contraindicated with the use of the substance, and education as to why supply might be restricted, the condition being treated and when to seek advice from a medical professional.

A patient provided with this substance under the Schedule 3 Appendix M mechanism would already have consulted a medical practitioner regarding their condition and have trialled mometasone. They would have been counselled by the medical practitioner and the pharmacist when they have their first prescription dispensed. If they find they require continuing supplies of mometasone but cannot consult with their doctor they can discuss their condition with the pharmacist who can provide the necessary advice and continuing treatment under the Schedule 3 Appendix M criteria. We do not believe that specific advice or patient education needs to be mentioned in the Appendix M criteria.

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

This criterion provides the ability to further refine the patient population and intended use of the substance, but specifying maximum durations of supply is beyond the existing capacity to specify indication, strength and quantity in the Poisons Standard. Any such restrictions would be tailored to the substance in question and incorporated into professional practice standards.

The Appendix M criteria state that the patient must have had a formal diagnosis or review of their condition within the last 6 months. This will provide a limitation on the length of time that a patient can continue treatment without a review by a medical practitioner. This Schedule 3 Appendix M criteria will allow access to mometasone for patients who have a flare up of their condition or run out of mometasone before their next appointment. A pharmacist will verify the number of supplies of this substance using the patient's My Health Record to ensure that the patient is using it appropriately.

[3] https://www.myhealthrecord.gov.au/sites/default/files/my_health_record_dashboard_-_28_july_2019.pdf

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

This criterion would apply to substances where initiation of the medicine and/or changes to dosing or product should be best made after a diagnosis by a medical practitioner. Pharmacist supply is appropriate if the condition being treated can be stable for extended periods of time and ongoing supply of the medicine, once treatment has been established, does not require frequent monitoring by a medical practitioner.

The Appendix M entry states that a pharmacist must verify that the patient has had a formal diagnosis and/or a periodic review. This could be done by using the pharmacy dispense history or if the patient is not known to the pharmacist, the My Health Record could be consulted.

6. Record keeping and information sharing

Record keeping may apply to any substances for which Appendix M criteria were considered appropriate. In some cases, a record of supply of the goods by pharmacists (for example, through inclusion in dispensing software), would be considered a sufficient measure for record keeping purposes. The need for information sharing about the supply of a substance with other health practitioners (subject to patient consent) would be determined on a case by case basis, but could be achieved through use of My Health records.

We suggest that Appendix M wordings for different substances be as consistent as possible and we have recommended wording that is similar to that in the triptan applications. We believe that it is good clinical practice for the pharmacist to label the product and to record on the patient's My Health Record to ensure there is a history for all health care practitioners and the patient to consult. The Australian taxpayer has made a large investment in the My Health Record and we believe that it is incumbent on every health care practitioner to embrace this new technology for the benefit of all Australians' health care needs.

7. Additional criteria may be imposed

This criterion provides the flexibility for the Secretary to impose additional conditions on a substance to be rescheduled, if the need for a condition is identified that is not captured by the preceding criteria.

Not Applicable.

Appendix H

With regards to a proposed Appendix H entry we note the *Guidelines for advertisements for medicines containing Schedule 3 substances*[4] states the following must be considered by the Delegate:

1. Is there potential for abuse, inappropriate use and/or diversion that may be exacerbated by advertising?

The Appendix M wording ensures that a patient must have previously been diagnosed with a dermal condition suitable for treatment with mometasone within the last 6 months. This requirement will ensure that there is no potential for inappropriate use or diversion that would be exacerbated by advertising. This is not a medicinal preparation that would be subject to abuse as such.

[4] https://www.tga.gov.au/sites/default/files/guidelines-advertisements-medicines-containing-schedule-3-substances.pdf

2. Are there potential interactions with the substance (drug-drug, drug-food) that require increased patient education to ensure safe use and therefore patient choice could be adversely influenced by advertising?

There are no potential interactions with mometasone that will not have already been addressed by the medical practitioner at the 6 monthly consultation. As with all Schedule 3 medicines the pharmacist must ensure that there is a therapeutic need and that the patient has already been prescribed this medicine previously by a medical practitioner in accordance with the Appendix M criteria. Advertising will not adversely influence a patient but it will act as a reminder that they can access continuing treatment should they have a flare up of their condition.

3. Are there additional risks associated with the dosage form that may impact on safe use that may be exacerbated by advertising?

There are no additional risks associated with the dosage form that may impact on safe use that will be exacerbated by advertising. Only patients that have a formal diagnosis and have previously used this substance will be eligible for access. Advertising will act as a reminder that they can access treatment for their condition should they experience a flare-up of their condition and cannot consult with their medical practitioner in a timely fashion.

4. Is there any other information that may be relevant, for example the substance has sedating properties, or there are safer alternatives available and therefore patient choice could be adversely influenced by advertising?

The substance does not have sedating properties and the choice of alternatives has already been made by the medical practitioner when making the formal diagnosis. The patient will have already been provided a prescription by the doctor on original diagnosis and this Schedule 3 Appendix M mechanism simply provides access to this substance for those patients who require ongoing or urgent treatment of their condition. There is still a requirement in the Appendix M wording for 6 monthly assessment by a medical practitioner.

Summary

As previously stated in the submission to the 26th ACMS (March 2019) meeting we believe that this substance meets the scheduling criteria for Schedule 3 substances. We suggest wording for Appendix M that would be similar to other substances that are being considered for Schedule 3 – Appendix M for consistency.

2. SUMATRIPTAN

Overview

We agree that it would be appropriate for consumers to access these sumatriptan under the proposed Schedule 3 Appendix M criteria. The Appendix M criteria will ensure that consumers who have previously been diagnosed and treated with a triptan will be able to purchase from a pharmacy without having to have a prescription.

The risks and benefits of the use of a substance

Risks

We note that at previous meetings of the NDPSC the Committee raised the following issues:

- **There is no suitable validated diagnostic tool available to pharmacists to accurately diagnose migraine**

  We believe that the Appendix M listing for sumatriptan in which the pharmacist will verify the diagnosis of migraine by checking the patient's My Health Record for the prescription and dispensing of sumatriptan will adequately address this issue.

  As of April 2019 90.1% of Australians are participating in the My Health Record.[5] If the patient does not have a My Health Record or has no previous prescription and dispensing of sumatriptan then they can attend a general practitioner for further investigation of their condition

  If the pharmacist does verify previous prescription and dispensing of sumatriptan they are able to supply sumatriptan and must make a record of this supply on the patient's My Health Record for the patient.

  We note that in New Zealand the [redacted] has developed a Migraine Questionnaire which could be modified to include My Health Record information.

  The use of the My Health Record to verify previous diagnosis of migraine and dispensing of sumatriptan is analogous to the Continued Dispensing[6] option where a pharmacist can supply a PBS maximum quantity of a statin or oral contraceptive pill if the patient has previously been dispensed these medicines.

- **Concerns about the safety of the substances particularly its cardiovascular and cerebrovascular side effects and high prevalence of these in the community**

  We note that in the submission to MedSafe by [redacted] in February 2006 *"the last decade's experience with triptans in more than half a billion people worldwide reveals a benign adverse-effect profile. Published reports and real-world experiences illustrate that these*

[5] https://www.myhealthrecord.gov.au/statistics

[6] https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/pbs-pharmacists/initiatives/continued-dispensing

drugs do not merit fears of triptan-induced cardiac consequences in appropriately selected individuals" [7]

- **Possibility of patients overusing**

  We note that the strength and pack size will be limited to 50 mg and a pack of 2 tablets with warnings to the patient not to take more than 2 tablets for the same attack. The patients My Health Record would assist the pharmacist to monitor usage.

  Patients who require higher strengths and larger quantities could still visit a medical practitioner for a prescription.

  The availability of the 50 mg in a pack size of 2 tablets will address the issue of supply in situations where a person with diagnosed migraines requires treatment and cannot get to a doctor e.g. in after hours or rural/remote areas.

- **Given their concerns surrounding the lack of a real public health need for increased access to the substance through down-scheduling and given the 'emergency supply' provisions already in place…**

  We note that pharmacists would not use the "emergency supply" provisions to supply a patient with a triptan.

  For example, in Queensland the emergency supply provisions in the Poisons legislation[8] states:

  194 Emergency sale of restricted drugs by pharmacist

  Despite section 193(1)(a), a pharmacist may sell a restricted drug to a person without prescription if the pharmacist reasonably believes—

  (a)an emergency exists; and

  (b) the person seeking the drug is under medical treatment requiring the use of the drug; and

  (c) it is essential to continue the treatment for the person's wellbeing.

Whilst some would argue that a triptan is essential to continue the treatment for a person's "wellbeing" we believe that there is some likelihood that some pharmacists would consider continuing treatment with an anti-hypertensive is an "emergency" rather than the provision of an analgesic. We do not agree with the argument that "emergency supply" provisions negate the public health need for increased access.

Sumatriptan has been available in New Zealand since 2006. As search on the MedSafe SMARS data base shows that there have been 84 reports on sumatriptan with 161 reactions since 1 Jan 2000[9].

A search on the DAEN[10] show that since 1 Jan 2000 there have been 81 number of reports with no cases where death was a reported outcome. See appendix 1 for DAEN report.

[7] Wenzel R, Dortch M, Cady R, Lofland JH, Diamond S. Migraine headache misconceptions: barriers to effective care. Pharmacotherapy 2004; 24(5):638-648.

[8] https://www.legislation.qld.gov.au/view/pdf/2014-10-01/sl-1996-0414

[9] https://www.medsafe.govt.nz/Projects/B1/ADRSearch.asp accessed 24 April 2019

[10] https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx accessed 24 April 2019

Benefits
Sumatriptan has been shown to be effective for migraines as per the clinical trials evidence in the TGA-approved Product Information.

The benefits of the 50 mg tablet in a box of 2 tablets will be that consumers will be able to access treatment when they cannot get to a medical practitioner for a prescription. The benefits of the triptans are best realised if they are used as soon as possible after the onset of a migraine. Consumers in New Zealand and the UK have been able to safely access sumatriptan without having to visit a doctor for a prescription for a number of years and we agree that Australians should have the same access to an effective and safe substance.

The purposes for which a substance is to be used and the extent of use of a substance

Sumatriptan as a Schedule 3 substance will be used by consumers who have previously been diagnosed with migraine and have previously been prescribed it by a medical practitioner.

Sumatriptan has been on the Australian market for many years and is a safe an effective substance.

It has been listed on the PBS for at least 20 years as a tablet and nasal spray.

We note that in previous considerations by the NDPSC a member stated "*that Schedule 3 status did not improve accessibility to the substance to diagnosed migraine sufferers who generally have a supply of sumatriptan with them from their doctor".* We contend that this is an unsubstantiated assumption and community pharmacies quite regularly have migraineurs who find themselves without a supply of sumatriptan. Pharmacists can provide these patients with such Schedule 3 preparations as metoclopramide+paracetamol ([redacted]) or prochlorperazine ([redacted]) but not sumatriptan. Further, the already available products under Schedule 3 for symptomatic treatment of migraine headaches largely aim to relieve nausea or vomiting associated with the headache, with paracetamol possibly only offering some relief against the headache itself. Having 50 mg x 2 tablets sumatriptan available as a Schedule 3 medicine would improve accessibility to this substance especially in after-hours situations or rural and remote areas where access to a GP is not possible.

We note that another member stated *"no-one was suggesting that pharmacists initially diagnose patients with migraines, but that the Committee should consider that patients who have been diagnosed are getting Authority prescriptions with repeats and it is these patients who come in on weekends asking for emergency supply."* We agree with these sentiments and a Schedule 3 entry with Appendix M would provide access to a safe and effective treatment for these patients.

The toxicity of a substance

We note that the Minutes of the NDPSC meeting raised the following toxicity issues:

- **The possibility of sumatriptan and serotonergic antidepressants causing serotonin syndrome**

As noted in the NDPSC minutes with respect to serotonin syndrome:

In response to the issue of ADRAC serotonin syndrome reports and the ADRAC Bulletin article in February 2004, XXXX noted that of the 161 cases of serotonin syndrome reported to ADRAC, not one had been associated with the use of a triptan, however XXXX also noted that there is potential for this syndrome to occur when a patient taking a serotonergic agent is prescribed another one. XXXX also stated that pharmacists are already aware of this potential and that the issue is not restricted to possible interaction with prescription drugs, as St John's wort has been associated with the syndrome.

XXXX pointed out that the Migraine Questionnaire would prompt customers to tell pharmacists about any other medications they were using and thus, the pharmacist would be aware if the patient was taking any other medications associated with serotonin syndrome. The pharmacist would then be able to counsel the patient in the symptoms of serotonin syndrome.

XXXX noted that in April 2006 the FDA requested all triptan manufacturers add class labelling for triptans regarding the concomitant use of SSRI/ SNRIs and the potential for serotonin syndrome. XXXX reviewed XXXX and found no causal relationship between sumatriptan use alone or concomitantly with SSRI/ SNRIs. However XXXX updated XXXX to reflect the FDA request. XXXX proposed that the wording in the OTC PI for sumatriptan be amended in line with the prescription PI, apart from the final statement in the Warning and Precautions section which would reflect the OTC use of the product. The new wording (underlined) of the proposed document would be "There have been rare postmarketing reports describing patients with serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) following the use of a selective serotonin reuptake inhibitor (SSRI) with sumatriptan .If concomitant use of sumatriptan and an SSRI/ SNRI is to be considered appropriate, migraneurs should be warned to see their doctor if they develop symptoms of serotonin syndrome XXXX

The experience of both the FDA and the Australian reporting systems appeared to indicate a low risk of serotonin syndrome in association with the use of sumatriptan together with an SSRI or SNRI. However, there is a strong theoretical risk of interaction between these drugs and warnings of possible SS are detailed in the relevant PI documents. Given this, it is possible that appropriate prescribing and avoidance of an interaction has contributed to the apparently low risk of SS with triptans when taken in combination with an SSRI or SNRI.

The possibility of a serotonin syndrome is low and this submission argues that it can be managed by the pharmacist by completing Migraine Questionnaire and verifying other medicines a patient is using by consulting the patient's My Health Record.

The dosage, formulation, labelling, packaging and presentation of a substance

We note that maximum quantity will be 2 tablets of 50 mg which will be sufficient for one episode of a migraine. This is the same as the quantity and strength available in New Zealand which has been available since at least 2007.

We also note that Appendix M will stipulate that the pharmacist will label the product with the patient's name and directions for use and the date of supply to ensure that the patient has it recorded on their My Health Record and they are made aware of the maximum dose and other necessary information.

The potential for abuse of a substance

A study by Sullivan et al[11] showed that sumatriptan has a low abuse potential. Given that the medicine has never been considered for Schedule 8 and is available without prescription in UK and NZ it is unlikely that there is a potential for sumatriptan to be misused or abused.

The following was included in the [redacted] submission to MedSafe in Feb 2006[12]:

> *Long-term clinical trials (up to 2 years) with sumatriptan have not shown any evidence of tolerance, misuse or reports of chronic daily headache.[13] [14]*
>
> *The proposed Data Sheet for [redacted] Migraine Treatment states that no more than two 50 mg tablets (total dose 100 mg) are to be taken in any 24 h period and that the recommended dose of [redacted] Migraine Treatment should not be exceeded. It also includes a specific warning about the occurrence of chronic daily headache/exacerbation of headache with overuse of sumatriptan.*
>
> *In addition, migraineurs are advised to see their doctor if:*
> - *their typical headaches persist for longer than 24 h*
> - *they experience four or more migraine attacks per month*
> - *the pattern of their symptoms has changed*
> - *their attacks have become more frequent, more persistent, or more severe, or if they do not recover completely between attacks.*
>
> *These steps are expected to limit misuse in chronic daily headache or overuse (maximum number of tablets taken should not exceed six per month based on three attacks, each treated with two tablets) in the non-prescription setting and are considered to promote safe use of [redacted] Migraine Treatment. This guidance is in accord with a recent report suggesting that medication overuse and a high initial headache frequency are important risk factors for chronic headache.[15]*

Any other matters necessary to protect public health

A paper by Parkinson et al *"Cost-Effectiveness of Reclassifying Triptans in Australia: Application of an Economic Evaluation Approach to Regulatory Decisions"*[16] stated that "

> *Migraine is a common, chronic, disabling headache disorder. Triptans, used as an acute treatment for migraine, are available via prescription in Australia.*
>
> *An Australian Therapeutic Goods Administration (TGA) committee rejected reclassifying sumatriptan and zolmitriptan from prescription medicine to pharmacist-only between 2005 and 2009, largely on the basis of concerns about patient risk.*

[11] https://www.ncbi.nlm.nih.gov/pubmed/1333934

[12] https://medsafe.govt.nz/profs/class/Minutes/2006-2010/MCC35Sumatriptan.pdf

[13] Cady RK, Dexter J, Sargent JD, Markley H, Osterhaus JT, Webster CJ. Efficacy of subcutaneous sumatriptan in repeated episodes of migraine. Neurology 1993; 43(7):1363- 1368.

[14] Tansey MJ, Pilgrim AJ, Martin PM. Long-term experience with sumatriptan in the treatment of migraine. Eur Neurol 1993; 33(4):310-315.

[15] Katsarava Z, Schneeweiss S, Kurth T, Kroener U, Fritsche G, Eikermann A et al. Incidence and predictors for chronicity of headache in patients with episodic migraine. Neurology 2004; 62(5):788-790.

[16] https://www.ncbi.nlm.nih.gov/pubmed/30832967

Nevertheless, pharmacist-only triptans may reduce migraine duration and free up healthcare resources. The results showed that Reclassifying triptans will reduce migraine duration but increase AEs.

This will result in 337 quality-adjusted life-years gained at an increased cost of A$5.9 million over 10 years for all Australian adults older than 15 years (19.6 million). The incremental cost-effectiveness ratio was estimated to be A$17 412/quality-adjusted life-year gained.

Another paper by Millier et al *"Economic Impact of a triptan Rx-to-OTC Switch in Six EU Countries"*[17] concluded that:

"Given evidence of effectiveness and safety, and given the potential savings, a triptan Rx-to-OTC switch is a reasonable public policy decision."

Appendix M criteria[18]

1. Specific pharmacist training on the provision of the medicine

The Guild Learning and Development team would be happy to develop a training package that would cover the nature and use of the sumatriptan for migraine, alternative treatments where relevant, risk factors and guidance on when to refer for medical assessment.

The Guild Learning and Development team that has already written a CPD-accredited learning module titled *"Pharmacy Health Solutions: Migraine".* This course discusses the treatment of migraine, including contraindications and adverse effects.

The Learning Objectives are:

- Recognise the impact of migraine
- Identify the pathophysiology of migraine, including symptomatic presentation
- Recognise the differences between migraine and other headache presentations
- Discuss the treatment of migraine, including contraindications and adverse effects
- Outline the best practice treatment of migraine
- Recognise the role of the pharmacist in managing symptoms of migraine

There is also a unit titled *"[redacted] (erenumab) for the prevention of migraine: A guide for community pharmacists*. This course examines the symptoms, pathophysiology, and role of pharmacists in the treatment of migraine, and introduces erenumab – a monoclonal antibody for the prevention of migraine.

[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3868654/

[18] https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard

The Learning Objectives are:

- Describe the symptoms of migraine and its possible causes
- Discuss the burden of migraine and its prevalence in Australia
- Describe the mechanism of action of erenumab in comparison to current prophylactic treatment options
- Discuss the key product information for erenumab
- Discuss the clinical findings of erenumab in the prevention of migraine
- Identify the safety consideration for patients prescribed erenumab including common adverse events
- List the key counselling points that should be provided to patients prescribed erenumab
- Discuss the role that pharmacists can play in providing lifestyle advice and support to patients with migraine

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

We note that the application proposes a Schedule 3 entry that enables a registered pharmacist to supply these substances to patients who have had a history of use verified by the pharmacist using the patient's My Health Record or dispense software history. As with all Schedule 3 supply a pharmacist must determine a therapeutic need and by verifying previous prescribing and dispensing the pharmacist can be sure that the patient has been prescribed this substance previously. We suggest that a pharmacist may use questionnaires such as a modified [redacted] questionnaire as an aide memoire much as they use the PSA's Emergency Hormonal Contraception questionnaire.

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

As with all Schedule 3 medicines the pharmacist will determine therapeutic need for sumatriptan and in addition they will dispense and label the product with the dose. The pharmacist will provide any information that the patient requires bearing in mind that this will not be a new medicine for the patient because the pharmacist will have to verify that the patient has taken sumatriptan previously prescribed by a medical practitioner.

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

We note that the suggested Schedule 3 entry for sumatriptan is:

> 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.

The pack size is only 2 tablets of 50 mg which is sufficient for the treatment of an acute migraine attack. Patients requiring larger doses and increased quantities would still be able to consult with their medical practitioner for a prescription. The availability of a small pack size will accommodate those patients who cannot see their doctor for an acute attack e.g. on a weekend or after hours.

We note that the supply of these substances must be recorded by the pharmacist on the patient's My Health Record which will address the concerns some may have of the 'fragmentation of care".

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

We note that the suggested Appendix M wording requires that the pharmacist verify that the patient has been previously diagnosed with migraine and has been prescribed sumatriptan. The pharmacist could do this by verifying the patient's My Health Record or their dispense software. If the patient was not obtaining benefit from the substance then the pharmacist would refer the patient to their medical practitioner for re-assessment.

As the pharmacist will dispense the product and upload to the patient's My Health Record there will be no fragmentation of care because the patient's medical practitioner will have access to the patient's history. According to the Digital Health Agency[19] there is a National Participation Rate of 90.1% for the My Health Record. Those Australian's who choose to out of the My Health Record are still able to access sumatriptan by visiting their prescriber for a sumatriptan prescription. This is not unlike the Continued Dispensing initiative where pharmacists can continue treatment with the OCP or statin.

6. Record keeping and information sharing

We note that a pharmacist will not initiate treatment with sumatriptan and must verify previous prescribing and dispensing on the patient's My Health Record or their dispense software.

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. We believe that this will address the concerns that some have with the issue of "fragmentation of care".

Summary

We believe that a Schedule 3 entry with an Appendix M that ensures that the patient has had a formal diagnosis by a medical practitioner would be an appropriate change to scheduling. This would bring Australia into harmonisation with New Zealand where this substance has been available without prescription for some time without adverse consequences.

[19] https://www.myhealthrecord.gov.au/sites/default/files/my_health_record_dashboard_-_30_june_2019.pdf

3. ZOLMITRIPTAN

Overview

As with sumatriptan we agree that it would be appropriate for consumers to access these zolmitriptan under the Schedule 3 Appendix M criteria. The Appendix M criteria will ensure that consumers who have previously been diagnosed and treated with a triptan will be able to purchase from a pharmacy without prescription if they have been previously been diagnosed by a medical practitioner and trialled the substance.

The risks and benefits of the use of a substance

Risks

To consider the balance of risks and benefits of rescheduling zolmitriptan from a Schedule 4 medicine (S4) to Schedule 3 (S3), the following information is structured in alignment with the *'value-tree framework of benefits and risks for non-prescription drugs'* proposed by Brass et al.[20]

1. Risks:
    a. Misuse: unintended and/or intentional misuse with therapeutic intent
        i. Medication overuse headache (MOH)
    b. Accidental ingestion
    c. Intentional overdose
    d. Worsened outcome due to self-management
        i. Adverse drug effects
        ii. Risk of cardiovascular / cerebrovascular events
        iii. Medication interactions
        iv. Inaccurate / inappropriate assessment by pharmacist
2. Benefits:
    a. Improved access and improved clinical outcomes
    b. Improved public health
    c. Enhanced consumer involvement
    d. Economic benefits

1. Risks

The risks described below are followed by brief comments providing potential examples of steps for mitigation.

A. Misuse: Unintended and/or Intentional Misuse with Therapeutic Intent Medication Overuse Headache

Medication overuse headache (MOH) is caused or propagated by frequently used medication taken for headache symptomatic relief.[21] Most patients with MOH have an underlying primary headache disorder that has not been managed effectively, which has lead them to over-using medication and further increasing risk of escalation to daily headaches.[21]

[20] Brass, E. P., R. Lofstedt, and O. Renn. 'Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit–Risk Assessment'. *Clinical Pharmacology & Therapeutics* 90, no. 6 (2011): 791–803. https://doi.org/10.1038/clpt.2011.231.

[21] Smith, Timothy R., and Jill Stoneman. 'Medication Overuse Headache from Antimigraine Therapy'. Drugs 64, no. 22 (1 November 2004): 2503–14. https://doi.org/10.2165/00003495-200464220-00002 .

The International Classification of Headache Disorders (ICHD-3) notes that MOH can occur in patients experiencing frequent episodic migraine (10-15 days/month), or with chronic migraine (headache occurring on ≥ 15days/month) and who have regularly used one or more medications for symptomatic relief for >3 months.[22]

The ICDH-3 further notes the specific risk of 'triptan-overuse headache' with the regular intake of one or more triptans (any formulation) on ≥ 10 days/month for >3 months; and 'non-opioid analgesic-overuse headache' as a consequence of regular use of one or more non-opioid analgesics on ≥15 days/month for >3 months.[21]

A comprehensive review of the clinical features, pathogenesis and management of MOH noted the risk of MOH with triptan use is comparable to that for simple analgesics and short-acting NSAIDs, but less than combination aspirin + paracetamol + caffeine products, or opioids.[21] The review states how MOH may occur with any medication that may be used for headache relief, including triptans, but that *"MOH due to triptans is not encountered with great frequency in clinical practice"*. However, the authors noted all triptans should be considered potential inducers of MOH with prolonged, regular use.[21]

Authors of a letter to the Editor of the MJA in 2016, in the midst of the codeine up-scheduling debate, called for a multidisciplinary approach to the prevention and management of MOH – noting the important role of pharmacists as the initial contacts for patients who self-medicate and may be over-using analgesics to discuss other treatment options (including migraine prophylaxis) with their GP.[23]

Of particular note of consideration with respect to the proposal to reschedule zolmitriptan, authors of a study of the diagnosis and treatment journey for patients attending a specialist headache clinic at the National Hospital for Neurology and Neurosurgery in London recommended:

> "*more frequent use of triptans instead of analgesics for episodic headaches and the early introduction of prophylactics with regular review and supervision during dose escalation at an early stage might reduce the tendency to develop chronic migraine and MOH"*[24]

Risk Mitigation

- The proposed rescheduling of 2 x 2.5mg zolmitriptan tablet packs limits the quantity of medication that may be supplied. This supports the primary intent of S3 supply being focussed on the management of an acute, i.e. episodic, migraine attack.

- Guidance in Consumer Medicines Information highlights the dosing of zolmitriptan should not be repeated for the same attack, and provides warnings about the risks of medication overuse headache.

[22] IHS Classification. '8.2 Medication-Overuse Headache (MOH)'. *ICHD-3 The International Classification of Headache Disorders 3rd Edition*. https://ichd-3.org/8-headache-attributed-to-a-substance-or-its-withdrawal/8-2-medication-overuse-headache-moh/.

[23] Stark, Richard J., Treasure McGuire, and Mieke L. van Driel. 'Medication Overuse Headache in Australia: A Call for Multidisciplinary Efforts at Prevention and Treatment'. Medical Journal of Australia, 1 September 2016. https://doi.org/10.5694/mja16.00492.

[24] Davies, Paul T.G., Russell J.M. Lane, Theresa Astbury, Manuela Fontebasso, Jill Murphy, and Manjit Matharu. 'The Long and Winding Road: The Journey Taken by Headache Sufferers in Search of Help'. *Primary Health Care Research & Development* 20 (31 May 2018). https://doi.org/10.1017/S1463423618000324.

- The Guild could develop pharmacist education and guidance tools to support the rescheduling to highlight the risks of medication overuse headache, to proactively enquire about frequency of migraines and triptan and analgesic use. Furthermore, that best practice expects that pharmacists will proactively refer consumers at risk of MOH to their GP – highlighting the need for medical assessment of their headache and consideration of prophylactic treatment to reduce migraine frequency.

- Recording the supply of zolmitriptan in pharmacy software and uploading as an activity to the patient's My Health Record will provide a record of zolmitriptan use accessible to the internal pharmacy team, and with the shared care team respectively. The record of supply will provide a more accurate representation of patient use than might be obtained through the pharmacist consultation, and support awareness and clinical decision making for medical practitioners.

- Risk of developing MOH and chronic migraine expected to be lower with increased access to triptans rescheduled to Schedule 3, due to more rapid and effective treatment, and reduced duration and severity of migraine.

- Patients who require higher strengths and larger quantities can still visit a medical practitioner for a prescription.

- The availability of the 2.5mg in a pack size of 2 will address the issue of supply in situations where a person with diagnosed migraines requires treatment and cannot get to a doctor e.g. in after hours or rural/remote areas.

B. Accidental Ingestion

Considering the toxicological data described below (See: C. Intentional Overdose), accidental ingestion from even childhood ages, presents relatively low risk in the absence of pre-existing contraindicating conditions such as untreated high cardiovascular risk.

Risk Mitigation

- Accurate patient assessment to identify and screen-out patients where pharmacist supply of zolmitriptan is contraindicated, and/or where a medical assessment is required.
- Patient counselling to reinforce the need to keep medicines out of the reach of children.
- Counselling to stress the importance of not sharing medications with others due to the potential risk of harm if not appropriately assessed by a health professional.

C. Intentional Overdose

With respect to evidence of toxicological data following overdose of zolmitriptan, Product Information notes:

Volunteers receiving single oral doses of 50 mg commonly experienced sedation.

This lack of overt risk of harm is supported by toxicological information and guidance publicly available online through the respected US National Library of Medicine Toxnet database (on toxicological data for related sumatriptan) [25] and the New Zealand National Poisons Centre TOXINZ database.[26] TOXINZ notes that "*No toxic dose for zolmitriptan has been established. The highest single dose used in clinical trials was 50 mg in healthy subjects producing sedation in some cases.*"

Risk Mitigation:

- Acknowledging the low risk of harm from intentional overdose, limiting the pack-size available for supply by pharmacists to only two tablets of 2.5mg minimises the risk of both unintentional and intentional overdose through the restricted quantity of supply.

D. Worsened Outcome Due to Self-Management

Adverse Drug Effects

The history of use of zolmitriptan in clinical practice leads to a comprehensive understanding of its adverse effect profile, and compared to other 5HT-1 agonists in general. The potential adverse effects of greatest significance are well recognised and described in detail within the contraindication and precaution guidance, and adverse effect profile of product information. These effects are well studied and reviewed, and inform the evolution of therapeutic guidelines for health professionals.

Of greatest concern has been the potential for adverse cardiovascular events (detailed further below), however with extensive clinical trial experience and over 25 years of use in clinical practice, the incidence of these is considered rare when triptans are used appropriately and according to prescribing guidelines.[27]

We note that zolmitriptan has been available as a pharmacist-only medicine in New Zealand since 2009. Acknowledging the limitations of spontaneous adverse reaction reporting, particularly any attribution of causality considering the numerous known and unknown confounding factors, MedSafe's 'Suspected Medicine Adverse Reaction Search' (SMARS) database records list only 1 report on zolmitriptan with 2 reactions since 1 January 2000. [28] Compared with Australian reporting under prescription status, the TGA's Database of Adverse Event Notifications (DAEN)[29] has recorded 11 total reports since 1 Jan 2000.

The absence of a 'spike' in adverse event reporting that could (theoretically) signal an increase in inappropriate use and/or risk in patient safety resulting in harms, provides strong reassurance that S3 supply of triptans by pharmacists is safe and reasonable.

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[25] 'Sumatriptan - National Library of Medicine HSDB Database'. Available via: http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@DOCNO+7742

[26] 'Zolmitriptan TOXINZ - Poisons Information'. Available via: https://www.toxinz.com/Spec/1918366.

[27] Dodick, David W. 'Migraine'. *The Lancet* 391, no. 10127 (31 March 2018): 1315–30. https://doi.org/10.1016/S0140-6736(18)30478-1.

[28] https://www.medsafe.govt.nz/Projects/B1/ADRSearch.asp

[29] https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx

Risk mitigation

- The adverse effect profile of zolmitriptan is well described, even in conservative and publicly available sources of information such as product information sheets. This information, alongside factors that contraindicate or caution use of zolmitriptan understandably form a key focus of the pharmacists' assessment of the patient. This will be reinforced through professional guidance and tools such as the assessment questionnaires/aide memoires utilised internationally.

Risk of Cardiovascular / Cerebrovascular Events

All triptans are generally considered safe, with a very low potential risk of clinically significant serious adverse events.[30] Contraindications to triptan use are widely described in clinical guidelines and peer-reviewed literature, and clearly highlighted in product information.

Noting concerns expressed about the cardiovascular safety of triptans limiting their use, the American Headache Society convened a multidisciplinary expert group to review the cardiovascular safety of triptans and provide recommendations for their use in clinical practice. [31]

The expert panel considered extensive information from a range of sources including:

1) epidemiologic data on cardiovascular disease and migraine,
2) clinical trials data on cardiovascular adverse events with triptans,
3) post-marketing surveillance data on spontaneous reports of cardiovascular adverse events with triptans,
4) pharmacologic and pharmacodynamic studies relevant to cardiovascular safety of triptans, and
5) methods of evidence-based clinical assessment of cardiovascular risk

The comprehensive evidence considered, it's review and outcomes were published in the Consensus Statement: Cardiovascular Safety Profile of Triptans (5-HT1B/1D Agonists) in the Acute Treatment of Migraine.[31]

Of relevance to this proposal, the consensus statement from the specialist panel notes:

- There is insufficient evidence about the determinants of triptan-associated cardiovascular adverse events to support a definitive algorithmic approach to prescribing (or not prescribing) them.
- The panel unanimously agreed that the risk of triptan-associated cardiovascular adverse events appears to be extremely low among patients meeting the typical inclusion and exclusion criteria for triptan clinical trials or given triptans in a manner consistent with the US Prescribing Information – that is, in patients without known coronary artery disease.
- The panel cited a lack of compelling evidence that serious cardiovascular adverse events with triptans are more likely to occur in patients with coronary artery disease than in those without known coronary artery disease. Isolated, serious, cardiovascular adverse events have occurred in both groups of patients.
- The majority of data reviewed applied to patients without coronary artery disease – and shows the safety profile of triptans is well defined and appears to reflect a very low risk of serious cardiovascular adverse events in this patient population.

[30] Johnston, Mollie M., and Alan M. Rapoport. 'Triptans for the Management of Migraine'. *Drugs* 70, no. 12 (1 August 2010): 1505–18. https://doi.org/10.2165/11537990-000000000-00000.

[31] Dodick, David, Richard B. Lipton, Vincent Martin, Vasilios Papademetriou, Wayne Rosamond, Antoinette MaassenVanDenBrink, Hassan Loutfi, et al. 'Consensus Statement: Cardiovascular Safety Profile of Triptans (5-HT1B/1D Agonists) in the Acute Treatment of Migraine'. *Headache: The Journal of Head and Face Pain* 44, no. 5 (2004): 414–25. https://doi.org/10.1111/j.1526-4610.2004.04078.x.

The Consensus Statement concluded:

> *Considering the pharmacologic, epidemiologic, and clinical evidence in aggregate, the panel arrived at the following conclusions:*
> 1) *Chest symptoms occurring during use of triptans are usually nonserious and usually not attributed to ischemia.*
> 2) *While serious cardiovascular adverse events have occurred after use of triptans, their incidence in both clinical trials and clinical practice appears to be extremely low.*
> 3) *The cardiovascular risk-benefit profile of triptans favors their use in the absence of contraindications.*
> 4) *Most clinical trials and clinical practice data on triptans are derived from patients without known coronary artery disease.*
>
> ***These data support the conclusion that, in patients at low risk of coronary artery disease, triptans can be prescribed confidently without the need for prior cardiac status evaluation.***

Concerns about cardiovascular safety from the *use* of triptans must also be considered alongside evidence that migraine headache itself is associated with an increased risk of *long-term* cardiovascular and cerebrovascular events.[32]

Risk Mitigation

- Acknowledging current clinical evidence and guidance which describe a more limited level of risk, assessment questions from pharmacists will specifically identify relevant medical history details that would contraindicate use of zolmitriptan including: history of MI, peripheral vascular disease (or signs/symptoms of), angina, uncontrolled hypertension, stroke or transient ischaemic attacks.
- To support obtaining a full and accurate history of the patient, relevant clinical history may be obtained from shared care records (such as My Health Record) and patient dispensing history.

Medication Interactions

Post-marketing surveillance and international pharmacovigilance evidence demonstrates that clinically significant medication interactions with zolmitriptan occur in practice relatively rarely.

As a 5HT1 agonist, a commonly raised interaction of zolmitriptan is the combined use with other serotonergic agents, particularly the antidepressants, and the risk of serotonin syndrome. However, a recent population-based study of nearly 50,000 patients with more than 30,000 person-years being co-prescribed antidepressants and triptans, found no cases of life-threatening serotonin syndrome, and no cases where a triptan was unequivocally implicated as a cause.[33]

Whilst being a rarely seen reaction in general, pharmacists are very aware of the risk of serotonin syndrome as demonstrated in an Australian 'mystery shopper' study which found that pharmacists appropriately identified the potential signs of serotonin toxicity from the clinical history presented, and either took direct action to minimise harm to the patient by advising to cease the causative agent, or referred the patient to a doctor for assessment.[34]

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[32] Mahmoud, Ahmed N., Amgad Mentias, Akram Y. Elgendy, Abdul Qazi, Amr F. Barakat, Marwan Saad, Ala Mohsen, et al. 'Migraine and the Risk of Cardiovascular and Cerebrovascular Events: A Meta-Analysis of 16 Cohort Studies Including 1 152 407 Subjects'. *BMJ Open* 8, no. 3 (1 March 2018): e020498. https://doi.org/10.1136/bmjopen-2017-020498.

[33] Orlova, Yulia, Paul Rizzoli, and Elizabeth Loder. 'Association of Coprescription of Triptan Antimigraine Drugs and Selective Serotonin Reuptake Inhibitor or Selective Norepinephrine Reuptake Inhibitor Antidepressants With Serotonin Syndrome'. *JAMA Neurology* 75, no. 5 (1 May 2018): 566–72. https://doi.org/10.1001/jamaneurol.2017.5144.

[34] Macfarlane., Brett, Jenny Bergin., and Gregory M. Peterson. 'Assessment and Management of Serotonin Syndrome in a Simulated Patient Study of Australian Community Pharmacies'. *Pharmacy Practice* 14, no. 2 (2016). https://doi.org/10.18549/PharmPract.2016.02.703.

The use of zolmitriptan with monoamine oxidase inhibitors (MAOIs) or within 24 hours of treatment with an ergotamine-containing or ergot-type medication (e.g. dihydroergotamine, methysergide) is explicitly contraindicated in product information. The potential for such medication interactions is already screened for by pharmacists when dispensing prescribed triptans. We note that that dihydroergotamine and ergotamine products ([redacted], [redacted] etc) are no longer marketed in Australia.

Risk Mitigation

- With a scope of practice that focuses on the use of medicines, a heightened awareness to identify concurrent medications when assessing suitability of over-the-counter treatments is considered a fundamental aspect of a pharmacist's role and professional practice. Awareness and understanding of pharmacodynamic and pharmacokinetic medication interactions features strongly within undergraduate and continuing professional education.

- While proactively reviewing medication combinations for the potential of interactions is considered a fundamental role of pharmacist practice, documenting supply of triptans by recording in the pharmacy dispensing software will provide electronic decision support through interaction checkers, and will also (along with the My Health Record) provide the opportunity to check medication history.

- The regulatory requirement to retain current clinical therapeutic references in pharmacies, including reference information on medication interactions, further supports the role of pharmacists in identifying and managing medication interactions – more so than any other health professional.

Inaccurate / Inappropriate Assessment by a Pharmacist

Consumers seeking assessment and advice for migraines and headaches are seen by pharmacists on a daily basis. Therefore, migraine is **not** a condition unfamiliar to pharmacists, and the considerable experience in assessment and over the counter management provides reassurance that assessment will be approached clinically and professionally appropriate. Also, there are already commercially available products in Schedule 3 that are only available without a prescription on the condition of being for the symptomatic relief of a migraine headache. There are precedents that require pharmacists to be familiar with migraine headaches.

ICHD-3 criteria clearly define the diagnostic criteria for episodic/acute migraine – based upon assessment of patient history taking.[22] In the absence of any warning signs of secondary headache, or history suggesting chronic migraine, obtaining a comprehensive history of the patient's symptoms and management thus far forms the basis for assessment of migraine. Patient assessment through an accurate history taking is fundamental to pharmacist education and scope of practice, therefore this application contends that is entirely appropriate to be conducted by pharmacists.

The risks of providing zolmitriptan to someone who fits a chronic migraine profile (as opposed to the proposed acute, episodic migraine frequency) would be less likely, considering available data of migraine frequency. Based on general practice presentation data from the BEACH study, the majority of Australians experience migraine at a frequency consistent with episodic rather than chronic migraine. With 74.2% of patients experiencing 1 or < 1 migraine per month, compared to 25.8% who experienced two or more migraines per month.[43]

We note that at previous meetings of the NDPSC the Committee had raised:

- **The Committee considered the possibility of patients over-using *sumatriptan* as well as the issue of chronic use and 'rebound' headaches.**

- **The possibility of serotonin syndrome precipitating due to concomitant use of *sumatriptan* and serotonergic antidepressants was also of concern.**

- **Cardiovascular risks were also highlighted, particularly rare but potentially life threatening coronary artery vasospasm in those with or without underlying cardiovascular disease**

- **The Committee ultimately agreed that, given concerns surrounding the lack of a real public health need for increased access given 'emergency supply' provisions already in place, the current Schedule 4 listing remained appropriate.**

We would argue that most, if not all, pharmacists would not use the "emergency supply" provisions to supply a patient with a triptan. For example, in Queensland the emergency supply provisions in the Poisons legislation[35] states:

> **194 Emergency sale of restricted drugs by pharmacist**
> (1) Despite section 193(1) (a), a pharmacist may sell a restricted drug to a person without prescription if the pharmacist reasonably believes—
> (a) an emergency exists; and
> (b) the person seeking the drug is under medical treatment requiring the use of the drug; and
> (c) it is essential to continue the treatment for the person's wellbeing.

Whilst some would argue that a triptan is essential to continue the treatment for a person's "wellbeing" this application argues that most pharmacists would consider continuing treatment with an anti-hypertensive is an "emergency" rather than the provision of an analgesic. This application does not accept the argument that "emergency supply" provisions negate the public health need for increased access.

- **A Member noted that, at present, no zolmitriptan nasal delivery product was available in the Australian market. The Member asserted that it would be premature to downschedule without Australian marketing experience. Another Member therefore suggested that perhaps the Committee should instead be considering down-scheduling a tablet formulation of zolmitriptan.**

As suggested by the NDPSC member the Committee should be considering down scheduling a tablet formulation of zolmitriptan and we would agree. We would also not that if would be confusing to patients if sumatriptan was recommended for downschedule but zolmitriptan not on the basis of other formulations available given their similar other profile of pharmacology, precautions and indication for use.

[35] https://www.legislation.qld.gov.au/view/pdf/2014-10-01/sl-1996-0414

Risk Mitigation

- Recognising that pharmacists already assess the signs and symptoms of migraine and migraine frequency through taking a patient history, when considering the appropriateness for providing treatment with a triptan, pharmacists will have access to product information and guidance tools as aide memoires; as has been demonstrated in other jurisdictions where triptans are available from the pharmacist without prescription.. The [redacted]-endorsed migraine screening assessment for pharmacist supply of zolmitriptan could be modified for use in Australia.
- As described above, the evidence of safety of zolmitriptan use supports pharmacist supply, therefore any clinical consequences of inadvertent erroneous supply are not expected to be overly problematic. However, documentation in pharmacy software and uploading the activity to the My Health Record, will provide a record of accountability, as well as further safety mechanism through the assessment of migraine and choice of treatment being shared with the patient's wider team of care.

Concluding Remarks on Risk

In their paper on 'Improving the Decision-Making Process for Nonprescription Drugs: A Framework for Benefit-Risk Assessment'[20], Brass, Lofstedt and Renn note:

> *"All drugs are associated with risks of adverse events, ranging from the rare idiosyncratic effects to predictable ones that reflect the drug's pharmacodynamics. Obviously, these risks are not eliminated when a drug moves from prescription-only to non-prescription status, and therefore they must be reflected in benefit–risk analyses…*
>
> *…However, these risks are not necessarily higher with non-prescription use if the consumer makes an appropriate selection of the drug and uses it in compliance with all label directions...*
>
> *…There is much evidence to suggest that compliance and adherence to prescription directions on the part of consumers are far from perfect, making the comparator for risks in the non-prescription setting less obvious"*

We believe that the broad and lengthy experience of pharmacist supply of triptans internationally, combined with extensive experience with the clinical use of triptans should provide the Committee and the Delegate the confidence to approve the downscheduling of both of the triptans.

Benefits

A. Improved Access and Improved Clinical Outcomes

All triptans are generally considered to be effective, safe and well tolerated.[30] Compared to each other, no one triptan is considered better tolerated or more efficacious than another in all clinical endpoints – largely due to pharmacokinetic heterogeneity. It is accepted that the response to a specific triptan is unable to be predicted, and that failure to one agent doesn't predict failure to respond with an alternate triptan.[41] In practice, patients often trial alternative triptans, different doses, or alternative routes of administration to find what works best for them.[30]

Rescheduling zolmitriptan to Schedule 3 will permit consumers to access effective treatment rapidly, and without the delay of needing to schedule an appointment to see a GP, waiting in the practice rooms to be seen, only to receive a prescription that must be taken to a pharmacy for dispensing.

It is widely recognised through both peer-reviewed literature and clinical guidelines that early initiation of treatment is a significant predictor of enhanced therapeutic outcomes. Furthermore, early treatment can prevent migraine pain from worsening, and lessen the risk of central sensitisation.[36, 37]

The TEMPO study found that early triptan intake **(i.e. within one hour of headache onset)** was more effective than late dosing (≥ 1 hour after headache onset) at producing freedom from pain at 2 hours; as well as being more efficacious in other clinical endpoints of sustained pain-free state, recurrence rate, and rate of redosing.[38]

As pharmacists are considered to be one of the most accessible health professionals, through their physical location, longer opening hours (particularly over weekends), and the ability to speak with a pharmacist without an appointment, people who experience episodic migraines and meet the assessment criteria process, will be able to access treatment more rapidly. In doing so, they will be able to take it within the evidence-demonstrated timeframe for it to be most effective.

The clinical benefits of triptans for the management of migraine are well known, and described in treatment guidelines and systematic reviews of evidence including Guidelines of the International Headache Society for Controlled Trials of Acute Treatment of Migraine Attacks in Adults,[39] and The American Headache Society Evidence Assessment of Migraine Pharmacotherapies.[40]

Two reports from authors from specialist headache and neuroscience clinics in the United Kingdom have described high levels of unmet therapeutic need from primary headaches including episodic migraine.[24, 41]

Ong and Felice's paper discussed the three basic approaches to choosing acute treatment:[41]

- 'the stratified': where choice of medication is based on attack severity and disability – and the medication perceived to be most useful is administered first. Patients experiencing more severe attacks are treated first-line with a triptan, whereas those whose migraines are comparatively more mild are more likely to go to an NSAID first (escalating to a triptan if not effective);
- 'step-care-across-attacks' approach generally begins with an NSAID or other nonspecific analgesic, which is then escalated to a triptan for subsequent attacks if this was not beneficial.
- 'step-care-within-attack' approach is where the patient takes a simple analgesic at the onset of attack, and escalates to another medication class within the attack if the initial treatment is ineffective.

[36] Tepper, Stewart J., David W. Dodick, Peter C. Schmidt, and Donald J. Kellerman. 'Efficacy of ADAM Zolmitriptan for the Acute Treatment of Difficult-to-Treat Migraine Headaches'. *Headache: The Journal of Head and Face Pain* 59, no. 4 (2019): 509–17. https://doi.org/10.1111/head.13482.

[37] Charles, Andrew. 'The Pathophysiology of Migraine: Implications for Clinical Management'. *The Lancet Neurology* 17, no. 2 (1 February 2018): 174–82. https://doi.org/10.1016/S1474-4422(17)30435-0.

[38] Lantéri-Minet, M, G Mick, and B Allaf. 'Early Dosing and Efficacy of Triptans in Acute Migraine Treatment: The TEMPO Study'. *Cephalalgia* 32, no. 3 (1 February 2012): 226–35. https://doi.org/10.1177/0333102411433042.

[39] Diener, Hans-Christoph, Cristina Tassorelli, David W Dodick, Stephen D Silberstein, Richard B Lipton, Messoud Ashina, Werner J Becker, et al. 'Guidelines of the International Headache Society for Controlled Trials of Acute Treatment of Migraine Attacks in Adults: Fourth Edition'. *Cephalalgia* 39, no. 6 (1 May 2019): 687–710. https://doi.org/10.1177/0333102419828967.

[40] Marmura, Michael J., Stephen D. Silberstein, and Todd J. Schwedt. 'The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies'. *Headache: The Journal of Head and Face Pain* 55, no. 1 (2015): 3–20. https://doi.org/10.1111/head.12499.

[41] Ong, Jonathan Jia Yuan, and Milena De Felice. 'Migraine Treatment: Current Acute Medications and Their Potential Mechanisms of Action'. *Neurotherapeutics* 15, no. 2 (1 April 2018): 274–90. https://doi.org/10.1007/s13311-017-0592-1.

Of the three approaches, 'stratified' was considered more effective and associated with lower healthcare costs.[41] The level of disability and severity guides treatment choice, with NSAIDs being appropriate for mild attacks but the more effective triptans are being recommended as first choice for more severe migraine attacks.[24, 41, 42]

Increasing the availability of zolmitriptan by rescheduling to Schedule 3 will permit consumers who experience moderate-severe migraine to treat earlier in onset, providing more rapid and effective relief, while:

- reducing over-reliance on simple analgesics (and thus reduce risk of MOH),
- reducing severity of migraine and risk of headache escalation,
- reducing risk of headache recurrence
- reducing the duration of migraine

B. Improved public health

The Public Health Burden of Migraine

The whitepaper 'Migraine in Australia', prepared by Deloitte Access Economics in 2018 presents a sombre insight into the magnitude and considerable impact migraine has on Australians.[43]

Key findings of the whitepaper describe:

- 4.9 million people in Australia suffer from migraine. 71% of migraine sufferers are women and 86% are of working age,
- 7.6% of migraine sufferers experience chronic migraine (≥15 migraine days per month),
- The total economic cost of migraine in Australia is $35.7 billion, consisting of:
    - $14.3 billion of health system costs;
    - $16.3 billion of productivity costs; and
    - $5.1 billion of other costs.
- In addition to migraine imposing significant wellbeing costs on sufferers.

The findings of the Deloitte whitepaper are supported by The Global Burden of Diseases, Injuries, and Risk Factors Studies (GBD), which assess the prevalence, incidence, and years lived with disability (YLDs) for a comprehensive range of diseases and injuries across all countries. A systematic analysis of data from the GBD 2016 study showed that headache, and in particular migraine, is "a large public health problem" and one of the main causes of disability for both sexes and all age groups worldwide – but particularly in young adult and middle-aged women.[44] The review noted a limited global impact from the improvement in efficacy of headache treatments (including triptans) "*perhaps partly a reflection of how poorly available they are*".

[42] Pringsheim, Tamara, William Jeptha Davenport, Michael J. Marmura, Todd J. Schwedt, and Stephen Silberstein. 'How to Apply the AHS Evidence Assessment of the Acute Treatment of Migraine in Adults to Your Patient with Migraine'. *Headache: The Journal of Head and Face Pain* 56, no. 7 (2016): 1194–1200. https://doi.org/10.1111/head.12870.

[43] 'Migraine in Australia Whitepaper | Deloitte Australia | Deloitte Access Economics Report, Health'. Deloitte Australia. https://www2.deloitte.com/au/en/pages/economics/articles/migraine-australia-whitepaper.html.

[44] Stovner, Lars Jacob, Emma Nichols, Timothy J. Steiner, Foad Abd-Allah, Ahmed Abdelalim, Rajaa M. Al-Raddadi, Mustafa Geleto Ansha, et al. 'Global, Regional, and National Burden of Migraine and Tension-Type Headache, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016'. *The Lancet Neurology* 17, no. 11 (1 November 2018): 954–76. https://doi.org/10.1016/S1474-4422(18)30322-3.

There are considerable productivity costs associated with migraine. Almost all migraine sufferers experience reductions in work capacity and social activity, and approximately half require bedrest to manage their pain[45]. Loss of productivity from employees results from a combination of absenteeism and presenteeism, and while migraine leads to significant absenteeism from work, the majority of productivity time loss occurs through presenteeism.[43] Absenteeism rates range from an estimated 2.9 days to 10.7 days per year, while presenteeism is estimated at 24.7 days and 8.2 days per year for chronic and episodic migraine respectively[46].

The Migraine in Australia whitepaper translates this productivity cost into economic terms by applying time lost to the Australian general population employment rates and average weekly earnings by age and gender. The productivity costs of migraine in Australia totals $16.3 billion in 2018. Of particular relevance to this application - $12.2 billion (75%) is attributed to episodic migraine.

Productivity costs by chronic and episodic migraine, total ($ million)

Productivity Component	Chronic migraine	Episodic migraine	Total
Reduced workforce participation	2,784	4,772	7,556
Absenteeism	542	3,666	4,208
Presenteeism	803	3,750	4,553
Total	**4,129**	**12,188**	**16,317**

(Source: Deloitte Access Economics[43])

Impact of Migraine and Headache on ED and Hospitals

Rescheduling of triptans to Schedule 3 may also reduce the number of emergency (ED) department presentations and hospital admissions for migraine management. Two recent Australian studies have reported how migraines are a common presenting complaint to the ED and is increasing. [47, 48] Noting further that management of patients presenting to EDs is more challenging as their symptoms are more prolonged, severe and refractory to usual first-line treatment.[47] While an earlier study Queensland study found the majority of over 800 nontraumatic headache presentations to Queensland EDs were of a "benign diagnosis" of benign primary headache.[49]

The Migraine in Australia whitepaper also reports on the impact of migraine on emergency department presentations and hospital admissions with 'headache' being the 20th most common principal diagnosis according to AIHW data (2,376,774 presentations in 2016-17)[50].

[45] 'Migraine in Australia Whitepaper | Deloitte Australia | Deloitte Access Economics Report, Health'. Deloitte Australia. https://www2.deloitte.com/au/en/pages/economics/articles/migraine-australia-whitepaper.html.

[46] 'Migraine in Australia Whitepaper | Deloitte Australia | Deloitte Access Economics Report, Health'. Deloitte Australia. https://www2.deloitte.com/au/en/pages/economics/articles/migraine-australia-whitepaper.html.

[47] Cheng, Chris-Tin, Gemma Therese Wen Min Law, Cristina Roman, Gim Tan, and Biswadev Mitra. 'Evaluation of the Assessment and Management of Acute Migraines in Two Australian Metropolitan Emergency Departments'. *Journal of Emergency Medicine, Trauma and Acute Care* 2016, no. 3 (14 November 2016): 10. https://doi.org/10.5339/jemtac.2016.10.

[48] Shao, Emily, James Hughes, and Rob Eley. 'The Presenting and Prescribing Patterns of Migraine in an Australian Emergency Department: A Descriptive Exploratory Study'. *World Journal of Emergency Medicine* 8, no. 3 (2017): 170–76. https://doi.org/10.5847/wjem.j.1920-8642.2017.03.002.

[49] Chu, Kevin H., Tegwen E. Howell, Gerben Keijzers, Jeremy S. Furyk, Robert M. Eley, Frances B. Kinnear, Ogilvie Thom, Ibrahim Mahmoud, and Anthony F. T. Brown. 'Acute Headache Presentations to the Emergency Department: A Statewide Cross-Sectional Study'. *Academic Emergency Medicine* 24, no. 1 (2017): 53–62. https://doi.org/10.1111/acem.13062.

[50]

The studies mentioned above examined the patient characteristics and choice of treatment in managing migraine within the ED. What is not apparent from the data is the treatment history of the presenting patients other than if prophylaxis treatment was prescribed in one. There is no picture of the patient history in reaching the point of presenting to ED, what acute treatments had been tried (if any), how long the migraine had progressed, whether they sought advice or management from their GP, or if they perceived barriers in doing so such as cost, access or availability of a suitable appointment time.

As with the experience with many other more common ailments, it could be argued that a sizable proportion of patients presenting to ED for migraine did so as they did not have ready access to effective treatment, their migraine had progressed – and to the level of severity that required immediate assessment and treatment, or they could not afford or have the time available to see a GP. Had these patients been able to rapidly access triptan treatment in the early stages of their migraine, hospital presentations may be avoided.

We believe that a significant burden of migraine on public health in Australia is irrefutable, and that a considerable contributing cause of this are the multiple barriers in timely access to effective treatment. This results in a considerable impact on health system costs, productivity and wellbeing. Rescheduling triptans to permit the appropriate supply by pharmacists for episodic migraine will provide one mechanism to help address this significant health need.

C. Enhanced consumer involvement

Evidence from a range of studies has demonstrated that consumers are active decision makers in managing their migraines and headache.[51, 52] Their decision to treat their migraine considers a range of factors, and in many cases they will delay treatment to determine if it is a migraine developing, or waiting until the severity warrants treatment.[52]

However, current evidence is showing there is an unmet need in managing acute, episodic migraine with consumers seeking advice and management from emergency departments, chiropractors, and osteopaths.[24] In their study of 'Patients' decision-making for migraine and chronic daily headache management', Peters et al describe in detail how the knowledge, self-awareness and experience of migraineurs themselves informs their behaviour and management [51] The patients studied integrated their knowledge, experiences and perceptions to make decisions about their management that suited their individual expectations and preferences. The authors also note how many initiatives to improve the care of migraine overlook the migraineur as an essential resource of migraine management.[51]

The considerable impact of migraine on wellbeing, both for the person experiencing migraine as well as the family and carers, also plays a vital factor in the level of consumer engagement to effectively manage their condition.[43]

The proposal to reschedule zolmitriptan to Schedule 3 would permit people who experience migraines to have the choice to engage with their pharmacist about management, as they see this highly effective treatment can be accessed more timely and cost-effectively. Pharmacists will carefully assess migraine and management history, and will continue to refer people with signs of chronic migraine, or more serious

[51] Peters, M, H Hu jer Abu-Saad, V Vydelingum, A Dowson, and M Murphy. 'Patients' Decision-Making for Migraine and Chronic Daily Headache Management. A Qualitative Study'. *Cephalalgia* 23, no. 8 (1 October 2003): 833–41. https://doi.org/10.1046/j.1468-2982.2003.00590.x.

[52] Foley, Kathleen A., Roger Cady, Vincent Martin, James Adelman, Merle Diamond, Christopher F. Bell, Jeffrey M. Dayno, and X. Henry Hu. 'Treating Early Versus Treating Mild: Timing of Migraine Prescription Medications Among Patients With Diagnosed Migraine'. *Headache: The Journal of Head and Face Pain* 45, no. 5 (2005): 538–45. https://doi.org/10.1111/j.1526-4610.2005.05107.x.

symptoms to their medical practitioner for medical investigation and management. However, those people without contraindications who can be identified as experiencing an acute, episodic migraine could be provided with zolmitriptan safely and appropriately.

D. Economic benefits

In addition to the analysis of the economic impact on productivity loss from migraine described above, the Migraine in Australia whitepaper evaluated costs on the Australian health system due to migraine.[43] Key findings of their analysis of health system costs were:

- In 2018, the total cost of migraine on the health system is estimated to be $14.3 billion, with $11.5 billion attributed to episodic migraine.
- Majority of costs incurred within hospitals for emergency department presentations and hospital admissions ($6.8 billion).
- Federal and State Governments bear approximately 76% of the health system costs, while individuals and families bear 16%.
- Total cost of migraine GP consultations was estimated to be $63.5 million (chronic and episodic migraine) – which combines the cost of the MBS rebate and average patient contribution.

The Australian study by Shao et al also noted the significant cost involved with migraine patients attending the ED, with over a third (36%) of their patient cohort arriving by ambulance, and the average length of stay for patients was 322 minutes[48].

We believe that increasing access to effective treatment of migraine through the rescheduling of zolmitriptan to Schedule 3 would lead to more effective management of episodic migraine in the Australian population. With more effective management of episodic migraine, this would lead to a reduction on health system costs, particularly through:

- Reduction in costs from emergency department presentations and hospital admissions.
- Reduction in Medicare Benefits Schedule (MBS) cost for management of episodic migraine (potentially balanced by an increase in management of chronic migraine through better identification).
- Reduced Pharmaceutical Benefits Schedule costs for prescribed triptans, due to a shift in cost to privately purchased treatment over-the-counter.

The purposes for which a substance is to be used and the extent of use of a substance

Zolmitriptan as a Schedule 3 substance will be used by consumers who have previously been diagnosed with migraine and have previously been prescribed it by a medical practitioner.

Zolmitriptan has been on the Australian market for many years and is a safe and effective substance.

The dosage, formulation, labelling, packaging and presentation of a substance

The maximum quantity would be 2 tablets of 2.5 mg which should be sufficient for at least one episode of a migraine.

Obligations through the Appendix M statement will require the pharmacist to label the product with the patient's name and directions for use and the date of supply to ensure that the patient has it recorded within the pharmacy software and in their My Health Record, and that they are made aware of the maximum dose and other necessary information.

Appendix M criteria[53]

1. Specific pharmacist training on the provision of the medicine

The Guild Learning and Development team would be happy to develop an Assessment and Management of Migraine course that would cover the nature and use of the zolmitriptan for migraine, alternative treatments where relevant, risk factors and guidance on when to refer for medical assessment. The course would also provide guidance on the use of supporting materials such as a modified [redacted] questionnaire as provided by [redacted] and the [redacted]. See Appendix 1.

The Guild Learning and Development arm, [redacted] already has developed a CPD-accredited module titled "Pharmacy Health Solutions: Migraine". This course discusses the treatment of migraine, including contraindications and adverse effects.

The Learning Objectives are:

- Recognise the impact of migraine
- Identify the pathophysiology of migraine, including symptomatic presentation
- Recognise the differences between migraine and other headache presentations
- Discuss the treatment of migraine, including contraindications and adverse effects
- Outline the best practice treatment of migraine
- Recognise the role of the pharmacist in managing symptoms of migraine

There is also a unit titled "[redacted] (erenumab) for the prevention of migraine: A guide for community pharmacists. This course examines the symptoms, pathophysiology, and role of pharmacists in the treatment of migraine, and introduces erenumab – a monoclonal antibody for the prevention of migraine.

[53] https://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard

The Learning Objectives are:

- Describe the symptoms of migraine and its possible causes
- Discuss the burden of migraine and its prevalence in Australia
- Describe the mechanism of action of erenumab in comparison to current prophylactic treatment options
- Discuss the key product information for erenumab
- Discuss the clinical findings of erenumab in the prevention of migraine
- Identify the safety consideration for patients prescribed erenumab including common adverse events
- List the key counselling points that should be provided to patients prescribed erenumab
- Discuss the role that pharmacists can play in providing lifestyle advice and support to patients with migraine

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

Clinical Decision

The application for zolmitriptan proposes a Schedule 3 entry that enables a registered pharmacist to supply these substances to patients who have had a history of use verified by the pharmacist using the patient's My Health Record or dispense software history. As with all Schedule 3 supply a pharmacist must determine a therapeutic need and by verifying previous prescribing and dispensing the pharmacist can be sure that the patient has been prescribed this substance previously. A pharmacist may use questionnaires such as a modified [redacted] questionnaire as an aide memoire much as they use the PSA's Emergency Hormonal Contraception questionnaire.

The Appendix M entry also states that the pharmacist must record this supply on their dispensary software and include the patient's name, address, date of birth and gender. All this information is necessary to upload on the patient's My Health Record.

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

Advice and education

As with all Schedule 3 medicines the pharmacist will determine therapeutic need for zolmitriptan in addition they will dispense and label the product with the dose. The pharmacist will provide any information that the patient requires bearing in mind that this will not be a new medicine for the patient because the pharmacist will have to verify that the patient has taken zolmitriptan previously prescribed by a medical practitioner.

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

We note that the suggested Schedule 3 entry for zolmitriptan is:

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.

The pack size is only 2 tablets of 2.5 mg which is sufficient for the treatment of an acute migraine attack. Patients requiring larger doses and increased quantities would still be able to consult with their medical practitioner for a prescription. The availability of a small pack size will accommodate those patients who cannot see their doctor for an acute attack e.g. on a weekend or after hours.

We agree that the supply of these substances should be recorded by the pharmacist on the patient's My Health Record to ensure there is no 'fragmentation of care". The pharmacist will note when verifying the patient's history if they are using too much and recommend that they consult their doctor.

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

The Appendix M requires that the pharmacist verify that the patient has been previously diagnosed with migraine and has been prescribed zolmitriptan. The pharmacist could do this by verifying the patient's My Health Record or their dispense software. If the patient was not obtaining benefit from the substance then the pharmacist would refer the patient to their medical practitioner for re-assessment. As the pharmacist must dispense the product and upload to the patient's My Health Record there will be no fragmentation of care because the patient's medical practitioner will have access to the patient's history. According to the Digital Health Agency[54] there is a National Participation Rate of 90.1% for the My Health Record. Those Australians who choose to opt out of the My Health Record are still able to access zolmitriptan by visiting their prescriber for a zolmitriptan prescription.

6. Record keeping and information sharing

As noted above a pharmacist will not initiate treatment with zolmitriptan and must verify previous prescribing and dispensing on the patient's My Health Record or their dispense software.

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. This will address the issue of "fragmentation of care".

[54] https://www.myhealthrecord.gov.au/sites/default/files/my_health_record_dashboard_-_30_june_2019.pdf

Summary

A fundamental requirement for the efficacy of triptans (5HT-1 agonists) in the acute treatment of migraine, is to administer within one hour of the onset of migraine headache. The current restrictions in accessing these medications via prescription only, and the time delay in seeking a GP appointment, attending and then obtaining the required prescription (in addition to economic and physical access barriers) prevents these patients from achieving proper therapeutic benefit.

Delay in treatment increases the risk of more severe and prolonged headache pain, increases risk of inappropriate simple analgesic use and risk of medication overuse headache, increases risk of progression to chronic migraine, and increases the economic and productivity costs to Australia.

Pharmacists have appropriate skill and knowledge to appropriately assess the migraine symptoms and history of patients/consumers. They already support people experiencing migraine with advice and the provision of simple analgesics, however also being able to provide sumatriptan or zolmitriptan to an appropriate selection of people would minimise delays in treatment and improve health outcomes.

The assessment and management of migraine, including treatment with triptans, is within the professional scope of practice – as is recognised through undergraduate education, post-registration professional development and practice, and the medication scheduling of triptans in comparable countries such as New Zealand, the United Kingdom (2006)[55], Sweden (2008), and Germany (2006)[56].

Increasing the access to sumatriptan and zolmitriptan for acute migraine through rescheduling to Schedule 3 does not eliminate the availability through prescription from a person's general practitioner. Nor will it lead to the frequently decried "fragmentation of care", with the obligations described in the proposed Appendix M statement.

Downscheduling will provide safe and timely access to sumatriptan and zolmitriptan for people suffering acute, episodic migraine.

[55] https://www.pharmaceutical-journal.com/learning/learning-article/practice-guidance-published-on-the-over-the-counter-supply-of-sumatriptan/10022365.article?firstPass=false

[56] http://www.pharmatimes.com/news/triptan_for_migraine_goes_otc_in_germany_995858

3. CAFFEINE

Given the recent fatality associated with inadvertent caffeine overdose we agree that the current availability of pure or highly-concentrated caffeine powder presents a risk of poisoning.

We note that the new Schedule 4 entry will not result in the scheduling of caffeine that occurs naturally in foods or items covered by a Food Standard Code nor will it include stimulant preparations such as [redacted] that are labelled with a maximum recommended daily dose of no more than 600 mg of total caffeine.

We do no object to the proposed amendment to the Poisons Standard.