The Pharmacy Guild of Australia

PROPOSED AMENDMENTS TO POISONS STANDARD

Comments by The Pharmacy Guild of Australia to the Notice of interim decisions made under Regulation 42ZCZN of the *Therapeutic Goods Regulations 1990*

10 June 2020

1. **Rizatriptan**
2. **Ondansentron**
3. **Melatonin**
4. **Adapalene**
5. **Selective serotonin reuptake inhibitors (SSRIs)**
6. **Ranitidine**
7. **Fexofenadine**
8. **Flubiprofen**

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Interim decision

RIZATRIPTAN **except** when included in Schedule 3.

Schedule 4 – Amend Entry

RIZATRIPTAN when in divided oral preparations containing 5 milligrams or less per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of migraine symptoms.

Index –Amend Entry

Schedule 3 – New Entry

RIZATRIPTAN

Appendix H – New Entry

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RIZATRIPTAN

Schedule 3 Appendix H

Proposed date of effect of the proposed amendment: **1 February 2021**

Overview

The Guild supports the interim decision to down-schedule rizatriptan to Schedule 3 medicine for the treatment of migraine in patients previously diagnosed with the condition. The scheduling change will result in timelier access to the medicine, which is critical in maximising its efficacy, while its safety profile is favourable to enable pharmacists in the community to handle patients requests with safety and efficacy.

Furthermore, the Guild supports the recommendation to align the scheduling for rizatriptan with the down-scheduling of sumatriptan and zolmitriptran.

Any other matters necessary to protect public health

The ‘triptans’ class of medicines

In line with our support for the scheduling changes for sumatriptan, zolmitriptan and rizatriptan, the Guild supported the application to down-schedule eletriptan presented to the June 2020 ACMS meeting. The Guild supported the submission based on the drug class effect of ‘triptans’ which show similar efficacy and risk profile across the drug class. While the decision of this proposal is pending, should it be successful, the Guild would urge the delegate to seek to implement the scheduling changes in alignment across the drug class. The commencement date, the changes to labelling and any advertising provisions should be aligned to improve patient access by minimising delays of Schedule 3 availability of one substance over another. Harmonisation would also minimise confusion and ensure consistency in workflows for the community pharmacy sector.

ONDANSETRON

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision not to amend the current Poisons Standard in relation ondansetron.

Overview

The Guild supports the interim decision of the delegate to maintain the existing scheduling standard. We agree with the delegate's assessment of the potential likelihood in increased off-label use of ondansetron and the potential for associated increased risks.

MELATONIN

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to down-schedule melatonin in modified release formulations from Schedule 4 to Schedule 3 by amending the current Poisons Standard as follows:

MELATONIN for human use, **except** when included in Schedule 3.

Schedule 4 – Amend Entry

MELATONIN in modified release tablets containing up to 2 mg of melatonin for the treatment of primary insomnia for adults aged 55 or over, in packs containing not more than 30 tablets.

Index – Amend Entry

Schedule 3 – New Entry

MELATONIN

APPENDIX H – New Entry

Schedule 4

MELATONIN

Schedule 3 Appendix H

The Committee recommended the following Required Advisory Statements for Medicine Labels (RASML) statement to the Over the Counter Evaluations Section at the Over-the-Counter Medicines Evaluation Section at the TGA:

1. Do not use this product if you have impaired liver function or autoimmune disease or taking other medications. Consult your doctor or pharmacist.
2. Do not use if you are pregnant or breastfeeding. Consult your doctor.
3. Do not use in children and adolescent under 18 years of age.
4. Do not use if you are allergic to melatonin. If you get an allergic reaction, stop taking and seek medical advice immediately.
5. Consumption with alcohol, other medications or natural health products with sedative properties is not recommended.
6. This product may cause drowsiness

Implementation date: **1 October 2020**.

Overview

The Guild supports the interim decision to down-schedule modified release melatonin preparations of 2mg strength, pack of 30. This is in support of the proposition that increased access to melatonin may reduce the use, and the associated side-effects, of other commonly used sleeping medicines, including over-the-counter sedating anti-histamines and benzodiazepines. There is minimal potential for the abuse of the substance.

Other issues to consider

The Scheduling change being applicable only to those aged 55 and over may be aligned to the TGA approved indication, but is not consistent with common prescribing practices. That is, melatonin is often prescribed to younger adults for the management of insomnia. Listing of the drug under Appendix H is likely to induce consumer use in all age groups, not just in those over the specified age of 55 and above, making it more difficult for pharmacists to manage. Furthermore, the Guild agrees that melatonin has a preferable side-effect and risk profile to other classes of sleeping agents, namely sedating agents such as benzodiazepines , hence improving access to melatonin across all age adult age groups should yield greater positive quality use of medicines outcomes for a more health consumers. The Guild urges consideration of a broader age listing, for those aged 18 years and over, which does not conflict with the current TGA listing but which more closely reflects contemporary use of sustained release melatonin.

ADAPALENE

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision to down-schedule adapalene in topical preparations by amending the current Poisons Standard as follows:

ADAPALENE **except** when included in Schedule 3.

Schedule 4 – Amend Entry

ADAPALENE in topical preparations containing 0.1 per cent or less of adapalene for the treatment of *acne vulgaris* in adults and in children over 12 years of age.

Schedule 3 – New Entry

ADAPALENE

Appendix H – New Entry

ADAPALENE

Index – Amend Entry

Schedule 4

Schedule 3 Appendix H

Proposed date of effect of the proposed amendment: **1 June 2021**

Overview

The Guild supports the proposed scheduling change as it will improve consumer access to the medicine. We note the demonstrated safety profile of low-dose topical preparations, while supporting labelling and packaging changes that will further enhance the safe use of aldapalene-containing products. The July 2021 commencement of the proposed amendment is supported by the Guild, as it should work to support the manufacturers to implement the labelling and packaging changes, and therefore help ensure safe use of the substance.

SELECTIVE SEROTIONIN REUPTAKE INHIBITORS (SSRIS)

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made an interim decision not to amend the current Poisons Standard in relation to include a Selective Serotonin Reuptake Inhibitors (SSRI) group entry.

Overview

The Guild supports the delegate's reasons not to amend the current Poisons Standard in relation to include a SSRI group entry.

RANITIDINE

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment to increase the pack sizes available for general sale and in pharmacies for ranitidine, made an interim decision not to amend the current Poisons Standard.

Overview

The Guild is supportive of the delegate's decision not to amend the existing scheduling of ranitidine.

FEXOFENADINE

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment to broaden the availability of fexofenadine, made an interim decision to amend the current Poisons Standard in relation to fexofenadine as follows:

Schedule 4 – Amend Entry FEXOFENADINE **except**:

a) when included in Schedule 2;

b) or in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and
ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine;

c) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

i) in a primary pack containing 5 dosage units or less and not more than 5 days' supply; and

ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or d) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

FEXOFENADINE in preparations for oral use **except** in divided preparations:

Schedule 2 – Amend Entry

a) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

ii) labelled with a recommended daily dose not exceeding 120 mg of fexofenadine;

b) for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

i) in a primary pack containing 5 dosage units or less and not more than 5 days'

supply; and

ii) labelled with a recommended daily dose not exceeding 180 mg of fexofenadine; or c) for the treatment of seasonal allergic rhinitis and children 6 years of age and over when:

i) in a primary pack containing 20 dosage units or less and not more than 10 days' supply; and

ii) labelled with a recommended daily dose not exceeding 60 mg of fexofenadine.

Proposed date of effect of the proposed amendment: **1 October 2020**

Summary

The Guild does not support the interim decision to down-schedule the highest strength od fexofenadine 180mg, in packets containing up to 10 days' supply.

The Guild is concerned with that will lead to reduced interaction with a health professional, to address underlying the causes and offer holistic treatment of allergic rhinitis. It may also lead to consumers self-selecting the product inappropriately, despite product labelling.

While the interim decision states that down-scheduling will lead to greater consumer access of this mediation, the Guild's view is there is adequate access to this medicine, through Australia's network of community pharmacy and that further down-scheduling is therefore not required. Community pharmacies are the most accessible health destinations in Australia and are equitably distributed across metropolitan, rural and regional areas to ensure Australians have timely and affordable access to medicines.
The geo-spatial analysis demonstrates that pharmacy accessibility is high throughout Australia. In capital cities, 97 per cent of consumers are no further than 2.5 km from a pharmacy. In regional areas, 65 per cent of people are within 2.5 km of a pharmacy.[1]

[1] Geospatial analysis MacroPlan Dimasi 2016

FLUBIPROFEN

Interim decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment to broaden the availability of flurbiprofen, made an interim decision to amend the current Poisons Standard as follows:

FLURBIPROFEN **except** when included in or expressly excluded from Schedule 2.

FLURBIPROFEN in preparations for topical oral use when:

Schedule 4 – Amend Entry

Schedule 2 – Amend Entry

a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit **except** when:

i) for the treatment of adults and children over 12 years of age; and ii) in a primary pack containing not more than 16 dosage units.

b) in undivided preparations containing 0.25 percent or less or 10 mg or less per dose of flurbiprofen.

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Schedule 4 Schedule 2

FLURBIPROFEN

Proposed date of effect of the proposed amendment: **1 October 2020**

Summary

The Guild does agree with the proposed scheduling change. While the delegate states that down-scheduling will lead to greater consumer access of this mediation, the Guild's view is there is adequate access to this medicine, through Australia's network of community pharmacy and that further down-scheduling is not therefore required. Community pharmacies are the most accessible health destinations in Australia and are equitably distributed across metropolitan, rural and regional areas to ensure Australians have timely and affordable access to medicines. The geo-spatial analysis demonstrates that pharmacy accessibility is high throughout Australia. In Australian capital cities, on average, a person is located under 1 km from the nearest pharmacy. Outside the capital cities, Australians are 6.4 km on average from their nearest pharmacy.[2]

Risk of misdiagnosis of COVID-19 symptoms

Sore throat is one of the cardinal symptoms of the SARS-CoV-2 virus responsible for the current COVID-19 pandemic. In line with public health messaging, anyone experiencing COVID-19 symptoms, including a sore throat should seek testing for the virus. The Guild is concerned that making flubiprofen- containing products accessible outside of the pharmacy setting may lead consumers to delay accessing testing and health professional advice. This may present a greater risk of spread of the virus. Down-scheduling any substance used to treat a sore throat, or other symptoms of COVID-19 infection may subvert the current public health messaging at this time and should be reconsidered.

[2] Geospatial analysis MacroPlan Dimasi 2016