[redacted]

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting March 2020

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. **Ranitidine**
2. **Selective serotonin reuptake inhibitors (SSRIs)**
3. **Fexofenadine**
4. **Flurbiprofen**
5. **Ondansetron**
6. **Rizatriptan**
7. **Melatonin**
8. **Adapalene**
9. **Nicotine**
10. **Pentobarbital**

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1. RANITIDINE

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4

RANITIDINE except:

a. when included in Schedule 2;

b. in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit when supplied in the manufacturer's original pack containing not more than ~~14~~ 32 dosage units;

c. in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than ~~7~~ 16 dosage units.

Schedule 2

RANITIDINE in preparations supplied in the manufacturer's original pack containing not more than 1442 days' supply except:

1. in divided preparations for oral use containing 150 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than ~~14~~ 32 dosage units; or

2. in divided preparations for oral use containing 300 mg or less of ranitidine per dosage unit in the manufacturer's original pack containing not more than ~~7~~ 16 dosage units.

Overview

We believe that although ranitidine is a safe and effective medicine, the condition for which it is used could be or become quite serious if not investigated by a health care professional. If consumers are able to continue treatment without the intervention and counselling of a health a health care profession it could mask a more serious condition. Left untreated peptic ulcers can result in internal bleeding which can lead to anaemia or severe blood loss that may require hospital treatment.

The risks and benefits of the use of a substance

Risks
The following risks of ranitidine are listed in the TGA-approved PI:

Use in renal impairment.
Ranitidine is excreted via the kidney and in the presence of renal impairment plasma levels of ranitidine are increased and prolonged. Accordingly in the presence of significant renal impairment, serum levels should be monitored and dosage adjustments made. The clearance of ranitidine is increased during haemodialysis.

Use in the elderly.
In patients such as the elderly, persons with chronic lung disease, diabetes or the immunocompromised, there may be an increased risk of developing community acquired pneumonia. A large epidemiological study showed an increased risk of developing community acquired pneumonia in current users of H_2-receptor antagonists versus those who had stopped treatment, with an observed adjusted relative risk of 1.63 (95% CI, 1.07-2.48).

Interactions with Other Medicines and Other Forms of Interactions Ranitidine has the potential to affect the absorption, metabolism or renal excretion of other drugs. The altered pharmacokinetics may necessitate dosage adjustment of the affected drug or discontinuation of treatment.
Interactions occur by several mechanisms including:

1) Inhibition of cytochrome P450 linked mixed function oxygenase system. Ranitidine at usual therapeutic doses does not potentiate the actions of drugs which are inactivated by this enzyme system such as diazepam, lidocaine, phenytoin, propranolol and theophylline.

There have been reports of altered prothrombin time with coumarin anticoagulants (e.g. warfarin). Due to the narrow therapeutic index, close monitoring of increased or decreased prothrombin time is recommended during concurrent treatment with ranitidine.

2) Competition for renal tubular secretion. Since ranitidine is partially eliminated by the cationic system, it may affect the clearance of other drugs eliminated by this route. High doses of ranitidine (e.g. such as those used in the treatment of Zollinger-Ellison syndrome) may reduce the excretion of procainamide and N-acetylprocainamide resulting in increased plasma levels of these drugs.

3) Alteration of gastric pH. The bioavailability of certain drugs may be affected. This can result in either an increase in absorption (e.g. triazolam, midazolam, glipizide) or a decrease in absorption (e.g. ketoconazole, atazanavir, delavirdine, gefitinib).

If high doses (2 g) of sucralfate are coadministered with ranitidine, the absorption of the latter may be reduced. This effect is not seen if sucralfate is taken after an interval of two hours.

Benefits
Ranitidine is an effective treatment for the symptomatic relief of heartburn, acid indigestion due to gastroesophageal reflux.

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

Ranitidine is used for symptomatic relief of heartburn, acid indigestion due to gastroesophageal reflux.

Increasing the quantities available without a health care professional's intervention will increase convenience but may well lead to consumers self-treating a condition that could be much worse than indigestion.

The toxicity of a substance

As noted in the TGA approved Product Information document *"Treatment with a histamine H_2-antagonist may mask symptoms associated with carcinoma of the stomach and, therefore, may delay diagnosis of the condition. Accordingly, where gastric ulcer is suspected, the possibility of malignancy should be excluded before therapy with* [redacted] *oral liquid, tablets or injection is instituted*."

The Therapeutic Guidelines recommends the following indications for upper gastrointestinal endoscopy in patients with symptoms suspected to be due to gastro-oesophageal reflux[1]

[1] https://tgldcdp.tg.org.au/viewTopic?topicfile=disorders-oesophagus&guidelineName=Gastrointestinal#toc_d1e47

- alarm symptoms
    - anaemia
    - dysphagia (difficulty swallowing) or odynophagia (painful swallowing)
    - haematemesis and/or melaena
    - vomiting
    - weight loss
- new symptoms in an older person
- changing symptoms
- severe or frequent symptoms
- inadequate response to treatment
- diagnostic clarification of symptoms

Consumers who are able to purchase larger quantities of ranitidine may never be counselled as to the need to have further investigation of their symptoms.

We note that in the SUSMP under *Appendix F Warning Statements and General Safety Directions for Poisons* ranitidine when included in Schedule 2 it requires warning label number 96 which states:

> ***CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. If symptoms persist or recur within two weeks, consult a doctor***

As such we believe that the maximum quantity of ranitidine in Schedule 2 should not be more than 14 days' supply.

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

The dosage, formulation, labelling, packaging and presentation of the substance will presumably be similar to that already on the market only with increased pack sizes.

As stated above the Appendix F warning label would be inconsistent with the quantity and as such we believe that the current scheduling remains appropriate.

The potential for abuse of a substance

There is little potential for "abuse" as such as this is not a substance with addictive properties. However we would argue that consumers may become complacent about their condition and rely on continued treatment with this product when they should have the condition investigated by a health care professional to rule out any sinister pathology.

Summary

We believe that the current scheduling for ranitidine remains appropriate.

2. SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRI)

Proposal

To include a new class entry as follows

Schedule 4
SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRI) except when separately specified in these Schedules.

Summary

We believe that it would be reasonable for a group entry for SSRIs to be included in the Poison Standard as this would capture emerging SSRIs that are not derivatives of specifically schedule SSRIs.

3. FEXOFENADINE

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4 -

FEXOFENADINE except:

a) when included in Schedule 2; or
b) ~~in divided preparations for oral use~~ 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
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.

Schedule 2

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

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
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.

Overview

The proposal would allow an exemption for small pack sizes of fexofenadine in packs with 5 dosage unites or less in a dose not exceeding 180 mg of fexofenadine and for children over 6 years of age in a pack with 20 dosages unit.

This is similar to a submission the ACMS considered in July 2016[2]. The Guild did not support that proposal and is not supportive of fexofenadine being exempt from scheduling. Irrespective of fexofenadine's safety profile, there are still public risks associated with its use.

The Guild does not believe it is in the public interest to further increase the scheduling exemption to allow increased quantities and strengths of fexofenadine to be available in general retail where there is no access to health professional advice. There is a particular issue with this substance with regards to the number of different doses which can cause confusion.

In addition we would caution the increased access for children aged 6 years and over without consultation with a health professional as there is a risk of misdiagnosis.

The risk and benefits of the use of the substance

Use in pregnancy

Fexofenadine has a pregnancy category rating of B2[2] and fexofenadine in medicines for oral use must be accompanied by the following advisory statement: "*If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine."* Other studies recommend the use of second generation antihistamines should be avoided during pregnancy and they should never be administered to nursing mothers.[3]

The Guild argues adherence to these advisory guidelines is less likely to occur if fexofenadine is purchased in general retail where there is no ready access to professional advice. While labelling may provide useful guidance for woman who are pregnant or breastfeeding, studies suggest not all consumers read information provided with the medicine. A survey of 1000 people conducted in Northern Ireland identified only 80% of participants always or often read the instructions on non-prescription medicine packages and that 3.4% rarely or never read the information. Combined with participants that only sometimes read the manufacturer's information, 10% of people could be at risk of misusing these medicines.[4]

Given this proposal would increase the quantity of tablets that could be sold in general retail, this exacerbates the current risk on non-adherence to important advisory statements.

Pro-arrhythmic potential

A study conducted in Europe investigated the pro-arrhythmic potential of antihistamines by combining safety reports of the FDA Adverse Event Reporting System (FAERS) with drug utilisation data from 13 European Countries. The study found five agents, which included fexofenadine had strong signals for torsadogenicity and recommends regulators and clinicians should consider risk-minimisation activities.[5]

The Guild believes that a further relaxing of the scheduling exemption for fexofenadine would increase the risk of medicine misadventure for consumers that have a pre-existing heart condition.

[2] https://www.tga.gov.au/book-page/12-fexofenadine

[3] Horak, F., & Stübner, U. P. (1999). Comparative tolerability of second generation antihistamines. *Drug safety*, *20*(5), 385-401.

[4] M Wazaify, E Shields, CM Hughes et al; Societal perspectives on OTC medicines; Family Practice 2005 22:170-176

[5] Poluzzi, E., Raschi, E., Godman, B., Koci, A., Moretti, U., Kalaba, M., ... & De Ponti, F. (2015). Pro-arrhythmic potential of oral antihistamines (H1): combining adverse event reports with drug utilization data across Europe. *PloS one*, *10*(3), e0119551

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

Increasing the amount of fexofenadine available in general retail may lead to consumers using fexofenadine products for conditions other than allergic rhinitis such as dermatitis, soap allergies or severe reactions to substances or insect bites. When medicines are sold outside pharmacy, there is no access to health professional advice regarding diagnosis nor the appropriateness of particular treatments.

This could result in a greater number of consumers self-medicating for undiagnosed conditions other than the product indications (allergic rhinitis) over a longer period without contact with a health professional. This risk is exacerbated by the lack of restrictions on the number of packs that can be purchased in a single transaction in general retail.

Co-morbidity with other conditions

Allergic rhinitis often coexists with asthma and atopic dermatitis.[6] Up to 80 per cent of patients with allergic asthma have comorbid rhinitis.[7] Guidelines indicate it is important to recognise and treat allergic rhinitis as part of ongoing management of asthma as the condition contributes to frequent symptoms and is associated with worse asthma control in children and adults.[8] This is less likely to occur if consumers are purchasing these products from general retail where there is no access to health professional advice.

Consumer Health literacy

Previous research conducted by the Australian Bureau of Statistics, identified that almost 60 per cent of adult Australians have low health literacy. This means that they may not be able to effectively exercise their choice when making healthcare decisions.[9] It has been estimated that people with low individual health literacy are between one-and-a-half and three times more likely to experience an adverse medicine outcome. More specifically, low individual health literacy has found to be associated with a lesser ability to demonstrate taking medicines appropriately and interpret labels and health messages.

Consequently, it is the view of the Guild that consumers should receive advice on the correct and proper use of medicines and this is best achieved by consumers having access to professional advice form pharmacy staff. This is particularly important for the most vulnerable consumer groups, particularly children, the elderly, those from low socio-economic and/or culturally and linguistically diverse backgrounds as well as those with chronic or multiple disease conditions. Providing consumer access to information via hand-outs or labelling is not sufficient for such an important area such as health, especially given the low level of health literacy in Australia as outlined above. Facilitating access to professional advice for the prescribing and supply of medicines is the best way to maintain safe and cost-effective access to medicines.

The toxicity of a substance

The key feature of toxicity in overdose of less-sedating antihistamines is prolongation of the QT interval with associated risk of torsades de pointes. As mentioned previously given there are usually no restrictions on the number of packs that can be purchased by customers from general retail, this increases this risk of toxicity occurring.

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[6] Allergic rhinitis and conjunctivitis - Therapeutic Guidelines online

[7] Australian asthma handbook. Melbourne: National Asthma Council Australia, 2014. [Online] (accessed 4 March 2014. Accessed from NPSMediceinewise – Asthma and allergic rhinitis – accessed 2/05/2016

[8] National Asthma Council Australia. Allergic rhinitis and the patient with asthma. 2006. [Fulltext] (accessed 18 February 2014). Accessed from NPSMediceinewise – Asthma and allergic rhinitis – accessed 2/05/2016

[9] Australian Bureau of Statistics. *Health Literacy, Australia*. Canberra: Australian Bureau of Statistics, 2008

Summary

The Guild did not support the scheduling exemption for fexofenadine and consequently does not support any further scheduling exemptions.

Given the potential risk relating to use while pregnant or breastfeeding, pro-arrhythmic potential, the co-morbidity of allergic rhinitis with other conditions and concerns regarding consumer using fexofenadine for conditions other than allergic rhinitis, the Guild believes fexofenadine should be a scheduled substance so it is only available in pharmacy with ready access to pharmacy staff who can provide appropriate advice on quality use of medicines.

4. FLURBIPROFEN

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4

FLURBIPROFEN except when included or expressly excluded from Schedule 2.

Schedule 2

FLURBIPROFEN in preparations for topical oral use when:

a) in divided preparations containing 10 mg or less of flurbiprofen per dosage unit **except** when:
   1) not labelled for the treatment of children 12 years of age or less; and
   2) 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.

Overview

This proposal would allow the sale of flurbiprofen products as unscheduled items from any retail outlet so long as the package was labelled not for the treatment of children 12 years of age or less and not in packs with more than 16 dosage units.

We note that a similar submission was made to the ACMS in February 2010. We did not support the proposal to change the scheduling of flurbiprofen at that time and we still believe that the current scheduling remains appropriate.

Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID) with potent analgesic, antipyretic and anti-inflammatory properties. We have previously made submissions regarding the access to NSAIDs and the problems this can cause. This is especially a problem with this particular substance as it will be sold alongside other lozenges such as [redacted] which will possibly camouflage the risk. Consumers may think this is just another product like [redacted] or [redacted] and is without any risk of harm.

The risks and benefits of the use of a substance

Contraindications

As listed in the Prescribing Information (PI) for Stepfen lozenges, flurbiprofen is contraindicated where there is a hypersensitivity to, or history of asthma, bronchospasm, rhinitis and urticaria related to aspirin or other NSAIDs. Flurbiprofen is also contraindicated for people with a history of peptic ulceration and during the third trimester of pregnancy.

Interactions

The PI advises that although no clinical evidence exists for the interaction between OTC flurbiprofen and anti-hypertensives such as ACE Inhibitors and beta-blockers, it still advises caution when using this combination.

Also listed is interference with anticoagulant therapy and a recommendation to avoid concomitant use with methotrexate therapy.

The toxicity of a substance

Flurbiprofen is category B2 for pregnancy, with only limited evidence available to demonstrate whether it is harmful or not. The PI lists the third trimester of pregnancy as a contraindication due to the increased risk of premature closure of the fetal ductus arteriosus in utero and persistent pulmonary hypertension of the newborn infant.

The Guild also believes that it is inappropriate to rely on label warnings to caution against the use of topical oral preparations of flurbiprofen in pregnancy as it has been recognised that public health literacy is a significant issue and people do not always read and following the directions or warnings contained on or within the packet. From a range of 5 levels for health literacy, when examined by age, only 48% of females aged 15-44 years achieved a health literacy of Level 3 or above[10].

For a long time, the public have had access to unrestricted topical oral products such as [redacted] which can be consumed in large quantities without any significant safety concern. The Guild contends that the public generally regard preparations such as unrestricted lozenges as being without risk and may ignore pack warnings or dosage instructions.

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

Topical oral NSAIDs such as flurbiprofen are indicated for relief of pain, swelling and inflammation associated with sever sore throat. When a person has severe, sore throat, it is important that they at least have access to a health professional to assess whether it could be a more serious condition such as glandular fever or streptococcal infection. Although pharmacists are not able to diagnose such conditions, they are well placed to provide an effective triage and refer at-risk patients to the GP for diagnosis and appropriate treatment. If these products are exempted from scheduling, people with more serious conditions may be further delayed in having health professional intervention which could lead to greater complications or more time off school or work.

The Guild does not believe that there is a demonstrated need for increased access to topical oral flurbiprofen products. [redacted] is available without restriction from the same range of topical oral products and is indicated for minor mouth and throat infections and symptoms of inflammation[11]. This lozenge contains 10mg lignocaine to assist with throat pain and lignocaine has a Category A listing[12] for use in pregnancy. The Guild contends that a safer and effective product is already available without restriction and that topical oral flurbiprofen products should continue to be restricted to Schedule 2 to facilitate access to a pharmacist for advice.

Summary

The Guild believes that there is neither a public need for increased access to topical oral preparations containing flurbiprofen or that unrestricted access to such products is in the public interest. Of particular concern is the contraindication for these products during the third trimester of pregnancy and possible

[10] ABS Health Literacy Australia 4233.0 2006 (updated June 2008): http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/73ED158C6B14BB5ECA2574720011AB83/$File/42330_2006.pdf

[11] MIMS Online Abbreviated Product Listing – Strepsils Plus; www.mimsonline.com.au

[12] http://www.tga.gov.au/docs/pdf/medpreg.pdf

interactions with commonly used medicines. In light of this, the Guild cannot support the proposed exemption to scheduling.

5. ONDANSETRON

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4

ONDANSETRON except when included in Schedule 3

Schedule 3

ONDANSETRON for human therapeutic use in divided preparations containing 4 mg or less in packs containing not more than 4 dosages units.

Appendix H

ONDANSETRON

Overview

This proposal would allow for the sale of ondansetron 4 mg in packs not more than 4 dosage units as a Schedule 3 medicine.

The Guild does not oppose the intent of this proposal and advice from our members is that this product is currently prescribed widely for nausea from a variety of causes not just chemotherapy and post-surgical nausea. However, we note that the substance is not indicated for "general use" but only for nausea from chemotherapy and post-surgical nausea.

The risks and benefits of the use of a substance

Risks

The PI notes the following special warnings and precautions:

> Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective $5HT_3$-receptor antagonists.
>
> Ondansetron prolongs the QT interval in a dose dependent manner. In addition, postmarketing cases of torsades de pointes have been reported in patients using ondansetron.
>
> Avoid ondansetron in patients with congenital long QT syndrome. Ondansetron should be administered with caution to patients who have or may develop prolongation of QTc, including patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias or patients taking other medicinal products that lead to QT prolongation or electrolyte abnormalities.
>
> Hypokalemia and hypomagnesemia should be corrected prior to ondansetron administration.
>
> Serotonin syndrome has been described following the concomitant use of ondansetron and other serotonergic drugs. If concomitant treatment with ondansetron and other serotonergic drugs is clinically warranted, appropriate observation of the patient is advised.

As ondansetron is known to increase large bowel transit time, patients with signs of subacute intestinal obstruction should be monitored following administration.

We believe that the risks associated with ondansetron could be adequately managed by the pharmacist during counselling but the TGA-indication would restrict sales to patients undergoing treatment with chemotherapy and post-surgical nausea. We believe that these patients would be unlikely to present to a community pharmacy as they would have been provided with sufficient supplies at the clinic or hospital where they were undergoing treatment.

Interactions with other drugs

There is no evidence that ondansetron either induces or inhibits the metabolism of other drugs commonly coadministered with it. Specific studies have shown that there are no pharmacokinetic interactions when ondansetron is administered with alcohol, temazepam, alfentanil, furosemide, tramadol or propofol.

Ondansetron is metabolised by multiple hepatic cytochrome P-450 enzymes: CYP3A4, CYP2D6 and CYP1A2. Due to the multiplicity of metabolic enzymes capable of metabolising ondansetron, enzyme inhibition or reduced activity of one enzyme (e.g. CYP2D6 genetic deficiency) is normally compensated by other enzymes and should result in little or no significant change in overall ondansetron clearance or dose requirement.

Caution should be exercised when ondansetron is co-administered with drugs that prolong the QT interval and/or cause electrolyte abnormalities.

Based on reports of profound hypotension and loss of consciousness when ondansetron was administered with apomorphine hydrochloride, concomitant use with apomorphine is contraindicated.
In patients treated with potent inducers of CYP3A4 (i.e. phenytoin, carbamazepine and rifampicin), the oral clearance of ondansetron was increased and ondansetron blood concentrations were decreased.

Following a single 8 mg tablet dose of ondansetron, a threefold to fourfold decrease in the systemic exposure has been seen in adult epileptic subjects maintained on chronic doses of carbamazepine (n = 8) or phenytoin (n = 8) and not receiving chemotherapy. The effect of these enzyme inducing agents on intravenous ondansetron has not been assessed, but the absence of any first pass effects would be expected to result in a smaller change in exposure than seen following oral dosing. Due to the limited efficacy data in subjects on antiepileptics and the many variables that may influence exposure and response, the clinical significance of this drug interaction in cancer patients receiving chemotherapy is not known.

Serotonergic drugs (e.g. SSRIs and SNRIs). Serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) has been described following the concomitant use of ondansetron and other serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs).

Data from small studies indicate that ondansetron may reduce the analgesic effect of tramadol.

Pharmacists could, when counselling the patient regarding their nausea and vomiting, verify that the patient was not on any other medicine(s) that may interact with ondansetron. However, as mentioned above the TGA-indication restricts use to patients with nausea from chemotherapy or post-surgery.

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

The TGA-approved indication for ondansetron is for the prevention and treatment of nausea and vomiting induced by cytotoxic therapy and radiotherapy.

We note that the Therapeutic Guidelines[13] states that:

> *A number of neural pathways are implicated in nausea and vomiting, including dopaminergic, serotonergic, histaminergic, cholinergic, neurokinin and cannabinoid receptor-mediated pathways. Different causes of nausea and vomiting have varying effects on these pathways. Currently, no available antiemetic acts on all receptor sites involved in the emetic response, so no antiemetic is universally effective. Additionally, nausea and vomiting are caused by different neural pathways and transmitters, so antiemetic drugs can have varying effects on these symptoms (eg vomiting may be reduced with little effect on nausea). Therefore, the choice of antiemetic is determined by the clinical situation, including the patient's comorbidities, and previous response to antiemetics.*

The Therapeutic Guidelines "Practitioner Information Sheet"[14] states the following for ondansetron:

Drug	Indication	Usual daily dosage	Precautions
Ondansetron (5-HT3–receptor antagonist)	General use	Orally or intravenously: 4 to 8 mg 8 to 12-hourly	rapid intravenous administration can cause visual disturbance can cause headache, constipation and prolongation of the QT interval (dose-dependent effect); rarely associated with dystonic reactions

We note that the Therapeutic Guidelines suggests that ondansetron can be used for "general use" and does not limit use to nausea associated with cytotoxic therapy and radiotherapy. This may explain why ondansetron is quite commonly prescribed as a non-PBS item by medical practitioners for nausea and vomiting from causes other than chemotherapy.

However, if the substance was to be Schedule 3 pharmacists would only be able to supply for the TGA-approved indication and not for "general use" as recommended in the Therapeutic Guidelines. As consumers would most likely be requesting a product for "general use" it would put community pharmacists in an invidious position of having to refuse a product for which the consumer may well have previously been prescribed by a medical practitioner "off-label".

The toxicity of a substance

According to the TGA approved PI the safety of ondansetron for use in human pregnancy has not been established. Evaluation of experimental animal studies does not indicate direct or indirect harmful effects with respect to the development of the embryo or foetus, the course of gestation, and perinatal and postnatal development. However, as animal studies are not always predictive of human response, the use of ondansetron in pregnancy is not recommended.

A study by Parker et al[15] titled *"Ondansetron for Treatment of Nausea and Vomiting of Pregnancy and the Risk of Specific Birth Defects"* concluded that for the majority of specific birth defects investigated, there was no increased risk associated with first-trimester use of ondansetron for treatment of nausea and

[13] https://tgldcdp.tg.org.au/viewTopic?topicfile=nausea-vomiting#toc_d1e76
[14] https://tgldcdp.tg.org.au/fulltext/quicklinks/nausea-and-vomiting_table6-4.pdf
[15] https://journals.lww.com/greenjournal/Fulltext/2018/08000/Ondansetron_for_Treatment_of_Nausea_and_Vomiting.16.aspx

vomiting of pregnancy compared with no treatment, although modest associations with cleft palate and renal agenesis–dysgenesis warrant further study.

Another study by Krista et al "*Association of Maternal First-Trimester Ondansetron Use With Cardiac Malformations and Oral Clefts in Offspring"* concluded that among offspring of mothers enrolled in Medicaid, first-trimester exposure to ondansetron was not associated with cardiac malformations or congenital malformations overall after accounting for measured confounders but was associated with a small increased risk of oral clefts.

The Therapeutic Guidelines states that for nausea and vomiting during pregnancy the following[16]:

Trial nondrug therapies for 1 week; if ineffective, and after discussion of the risks and benefits of antiemetic therapy with the patient, consider starting:

pyridoxine 12.5 mg orally, in the morning and at midday, and 25 mg at night (uncategorised by the Therapeutic Goods Administration [TGA])

PLUS

doxylamine 25 mg orally, at night. Increase as tolerated to 12.5 mg in the morning and at midday, and 25 mg at night (TGA category A) [Note 3].

If nausea and vomiting persists and the woman can tolerate oral therapy, **add** to the above regimen either:

1 metoclopramide 10 mg orally, 3 times daily (TGA category A) [Note 4]

OR

1 ondansetron 4 to 8 mg orally, 2 to 3 times daily (TGA category B1) [Note 5]

OR

1 prochlorperazine 5 to 10 mg orally, 3 to 4 times daily (TGA category C)

OR

1 promethazine 10 to 25 mg orally, 3 to 4 times daily (TGA category C).

The Note 5 for ondansetron states *"Safety data in humans about ondansetron in pregnancy are conflicting; a small increase in cardiovascular malformations has been reported."*

Whilst the safety data for the use of ondansetron in pregnancy are conflicting there is no brand of ondansetron that is TGA-indicated for use in pregnancy so pharmacists would be restricted to providing ondansetron for patients with nausea from chemotherapy as this is the only TGA-approved indication. Until the TGA-indication for ondansetron includes nausea from causes other than chemotherapy we do not believe it's appropriate for this substance to be downscheduled.

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

The proposal is for 4 mg tablets in a pack size of not more than 4 tablets. This would be sufficient for an episode of nausea and vomiting.

[16] https://tgldcdp.tg.org.au/viewTopic?topicfile=nausea-vomiting#toc_d1e251

The potential for abuse of a substance

Ondansetron is not an opioid and the potential for abuse would be very low.

Summary

We believe that ondansetron would be an appropriate substance for downsheduling, however until the TGA indication includes nausea for reasons other than chemotherapy then it would not be appropriate to downschedule this substance.

6. RIZATRIPTAN

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4

RIZATRIPTAN except when included in Schedule 3

Schedule 3

RIZATRIPTAN for oral use in medicines for the acute relief of migraine attacks with or without aura in patients who have a stable, well-established pattern of symptoms when in tablets containing 5 milligrams or less per tablet and when sold in a pack containing not more than 2 tablets.

Appendix H

RIZATRIPTAN

Appendix M - New Entry

RIZATRIPTAN - to be dispensed by a registered pharmacist who has assessed a patient's symptoms to be consistent with an acute, episodic migraine attack; and that assessment and supply is consistent with expected professional standards of practice and specifically related clinical tools and resources; and that a history of migraine or acute migraine treatment has ideally been verified e.g. via the patient's My Health Record, or through previous prescribing/dispensing.

The pharmacist will record the supply of this medicine in their dispensing software, and include the patient's name, address and directions for use and date of supply. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will upload a record of supply to the patient's My Health Record.

Overview

This proposal would allow for the supply of rizatriptan as a Schedule 3 medicine in tablets containing 5 mg or less in packs not greater than 2 tablets. We believe that this a reasonable proposal and would allow diagnosed migraineurs who have previously used this medicine to access supplies of this medicine to treat their condition without needing to consult with their GP for a prescription.

This proposal is similar to previous submissions to the ACMS for sumatriptan and zolmitriptan which we supported.

Rescheduling would permit consumers who fit the criteria for safe and appropriate supply, to access highly effective treatment in a timelier manner that would be more therapeutically effective. Rescheduling would also align the scheduling classification with New Zealand.

Migraine has a considerable impact on the health and wellbeing of Australians, while also resulting in a significant economic and productivity cost to the country. Clinical evidence and treatment recommendations for the management of acute, episodic migraine, highlights the importance of taking effective agents early in migraine development to achieve the best outcomes. The 5HT1 agonists or

‘triptans’ have a preeminent position in the management of migraine, but are currently only available in Australia with a prescription.

An abundance of clinical evidence demonstrates that triptans are more therapeutically effective in reducing progression, severity and duration of migraine when taken within one hour of the onset of headache. Studies also demonstrate how consumers have an active role in decision-making about the management of their migraine, and often wait to assess if the symptoms they’re experiencing will or do lead to a migraine attack.

The risks and benefits of the use of a substance

A long history of clinical use of triptans world-wide, including over-the-counter provision by pharmacists in many countries, has demonstrated their safety and tolerability. Pharmacists are already experienced in assessing headache and migraine on a daily basis in practice, and with guidance to reinforce a low-risk population of episodic migraine sufferers, can provide this effective treatment safely and appropriately.

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

Rizatriptan 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.

The toxicity of a substance

The relatively long history of use of rizatriptan in clinical practice leads to a comprehensive understanding of the adverse effect profile of rizatriptan and 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.

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

The dosage, formulation, labelling, packaging and presentation of the substance will presumably remain as it currently is. We note that the pharmacist will under the Appendix M criteria have to label the product with the patient name and dose as they would do if they are dispensing it on a prescription. There is the added benefit that a record will be made on the patient’s My Health Record.

The potential for abuse of a substance

There is little potential for abuse of this substance as it is not an opioid.

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 rizatriptan 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 or Sweden (2013).

7. MELATONIN

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 4

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

Schedule 3

MELATONIN in modified release formulations up to 2 mg for human use when supplied under the requirements of Appendix M.

Appendix M

MELATONIN - The pharmacist will record the supply of this medicine in their dispensary software, and include the patient's name, address, date of birth and gender. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will upload a record of supply to the patient's My Health Record

Overview

The proposal would allow for the supply of melatonin in modified release formulations up to 2 mg for use by patients if dispensed by the pharmacist and recorded on the patient's My Health Record. This would appear to be a reasonable proposal and we would support this change as it would provide access to a safer medicine for insomnia than the currently available Schedule 3 medicines. This will also harmonise with New Zealand where melatonin was recently downschedule to Prescription Only Except When.

The risks and benefits of the use of a substance

Risks

Melatonin is a naturally occurring hormone produced by the pineal gland and is structurally related to serotonin. Physiologically, melatonin secretion increases soon after the onset of darkness, peaks at 2-4 am and diminishes during the second half of the night. Melatonin is associated with the control of circadian rhythms and entrainment to the light-dark cycle. It is also associated with a hypnotic effect and increased propensity for sleep.

As stated in the TGA-approved PI melatonin is relatively non-toxic although some mild side-effects have been reported with higher doses and extended-release formulations, including:

- Drowsiness
- Daytime sleepiness
- Headaches
- Nausea

No evidence suggests that people develop tolerance to melatonin.

Benefits

The British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders notes the efficacy of melatonin in a wide-range of sleep disorders in an equally broad range of defined population groups from older people, the blind,

children, and people with 'neurodevelopmental' disorders such as autism and attention-deficit hyperactivity disorder (ADHD).[17]

The consensus statement makes a number of comparisons between available hypnotic agents (including melatonin and commonly used benzodiazepines), and specifically recommends melatonin prolonged release be offered as first line pharmacological therapy in patients aged over 55 years when medication treatment is indicated.[18]

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

The TGA-approved indication is for "Monotherapy for the short term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over."

It is difficult to estimate the extent of use of the substance without access to current sales data, however, it would be expected that many consumers who are currently using sedating antihistamines for insomnia would likely trial a course of melatonin given the safety benefits.

The toxicity of a substance

We note that at the 60th Meeting of the Medsafe Medicines Classification Committee stated that *"melatonin has a good safety profile … and was considered a safer option than alternative pharmacological treatments for insomnia, such as sedating antihistamines…"*.

We also note that in the USA melatonin is classified as a dietary supplement and is available OTC.

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

The dosage of the slow release formulation is 2 mg once daily 1-2 hours before bedtime and after food.

We presume that the labelling packaging and presentation of the substance would be identical to that already produced and that this would be labelled with the patient name and dose by the pharmacist as if it was being dispensed on a prescription. There would have the added benefit of a record being made on the patient's My Health Record to address issues of "fragmentation of care".

The potential for abuse of a substance

The potential for abuse of this medication is limited. It is not a drug of addiction and it has no euphoric effect. It cannot be converted into another more active substance for illicit use.

As noted in the Australian Medicines Handbook there do not appear to be any dependence or withdrawal effects, or rebound insomnia.

[17] Wilson S et al. British Association for Psychopharmacology Consensus Statement on Evidence-Based Treatment of Insomnia, Parasomnias and Circadian Rhythm Disorders: An Update. Journal of Psychopharmacology 2019;33(8): 923–47. https://doi.org/10.1177/0269881119855343.

[18] ibid

In fact there is evidence that the use of melatonin would curtail the abuse of these substances[19]. The study by Cardinali et al concluded that *"A major advantage is that melatonin has a very safe profile, it is usually remarkably well tolerated and, in some studies, it has been administered to patients at very large doses and for long periods of time, without any potentiality of abuse".*

Summary

Melatonin is a safe medicine used for the treatment of insomnia. Patients with primary insomnia will benefit from access to a proven, ARTG-registered product with a better safety profile than alternative prescription-only products such as benzodiazepines, Z-rugs or other Schedule 3 products such as promethazine or doxylamine.

We believe that the proposal fits all the criteria for a Schedule 3 medicine. In addition it will harmonise with New Zealand where melatonin has recently been downscheduled.

[19] https://www.ncbi.nlm.nih.gov/pubmed/26438969

8. ADAPALENE

Proposal

The Applicant's proposed amendments to the Poisons Standard are:

Schedule 4

ADAPALANE except when included in Schedule 3.

Schedule 3

ADAPALANE in preparations for human external therapeutic use or human therapeutic or cosmetic use containing 0.1 per cent or less of adapalene.

Appendix H

ADAPALANE

Appendix M

ADAPALENE - The pharmacist will record the supply of this medicine in their dispensary software, and include the patient's name, address, date of birth and gender. The pharmacist will label product with patient's name and directions for use and date of supply. The pharmacist will verify that the patient is not intending to become pregnant, is pregnant or is breastfeeding. The pharmacist will upload a record of supply to the patient's My Health Record.

Overview

This proposal would allow for the supply of adapalene products following dispensing and recording on the Patient's My Health Record. This would appear to be a reasonable request and we support this proposal as it will provide an effective and safe treatment for patients suffering from acne. We note that when FDA decided to make this product "over the counter" it did not consider that teratogenicity was an issue.

The risks and benefits of the use of a substance

Risks

As noted in the TGA-approved PI, adapalene is pregnancy category D. Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result in low systemic exposure due to minimal dermal absorption.

However, we note that Minutes of the Nonprescription Drugs Advisory Committee Meeting[20] discussion on the use by females with reproductive potential stated that:

> *Committee Discussion: There was an overall consensus that use of adapalene gel 0.1% would be safe, in the over-the-counter (OTC) setting, by females with reproductive potential which could be at risk of fetal harm with exposure to potentially teratogenic drugs.*

[20] https://www.fda.gov/media/99323/download

One committee member noted that pregnant women will use the drug but, based on the reassuring animal data, he saw no signal for teratogenicity. Other members agreed, noting that the evidence demonstrating no teratogenicity risk is substantial.

One committee member raised the point that counseling about teratogenicity risk of retinoids as a class, and explaining why topical adapalene is different from other drugs in the class, might be useful in patient-provider discussions.

We also not the following in a paper by Tau et al[21]:

There are conflicting reports on the safety of topical retinoid medications in women who are pregnant or lactating. Isolated cases have been reported of congenital malformations that were temporally associated with the use of these agents (Autret et al., 1997, Lipson et al., 1993, Loureiro et al., 2005, Navarre-Belhassen et al., 1998, Panchaud et al., 2012, Selcen et al., 2000). However, a large observational prospective study of 235 women who were exposed to a topical retinoid during their first trimester were compared with 444 women in the control group and no statistically significant differences in the rates of spontaneous abortions and minor or major birth defects were detected (Panchaud et al., 2012). A formal consensus on the safety of topical retinoid medications during pregnancy is lacking (van Hoogdalem, 1998). Additionally, manufacturers advise that these agents should not be used during pregnancy. Tretinoin and adapalene are classified as FDA pregnancy category C but tazarotene is category X. Patients should be counseled on these pregnancy risks when initiating retinoid treatment if they desire pregnancy.

Furthermore a paper by Harris and Copper[22] stated the following:

The current Australian therapeutic guidelines warn that topical retinoids are teratogenic and state that they should be avoided in women who are planning to become pregnant, are pregnant or breastfeeding. The regulatory concern of the teratogenic potential of topical tretinoin is contrary to previous human percutaneous absorption studies. A human study that examined the percutaneous absorption of tretinoin in various formulations indicated that it was minimally absorbed and did not affect the endogenous levels of the drug or its metabolites in the subjects studied.

There has also been a study that examined the incidence of major congenital anomalies for 215 exposed women versus 430 non-exposed age-matched women, and concluded that topical tretinoin is not associated with increased risk for major congenital disorders.

It would appear that in theory adapalene would pose a risk of teratogenicity but that evidence demonstrating no teratogenicity risk is substantial.

Benefits

Adapalene is a naphthoic acid derivative. Adapalene is an active metabolite and therefore requires no metabolic conversion. As noted in the TGA-approved Product Information the efficacy of adapalene topical products have been assessed in 2 randomised, double blind, parallel comparison clinical trials. In the first trial, 350 subjects with acne vulgaris associated with at least 20 facial non-inflammatory comedones and 10 inflammatory lesions were enrolled for treatment with adapalene cream or the cream

[21] https://www.sciencedirect.com/science/article/pii/S2352647517300862?via%3Dihub

[22] Harris, Victoria Rebecca, and Alan J. Cooper. "Modern Management of Acne." *The Medical Journal of Australia* 206, no. 1 (January 16, 2017): 41–45. https://doi.org/10.5694/mja16.00516.

vehicle administered once daily. For adapalene and vehicle groups respectively after 12 weeks treatment, the mean % reductions from baseline in total lesions were 32% vs 15% ($p<0.05$), in non-inflammatory lesion counts were 37% vs 15% ($p<0.05$) and investigator's global assessment scores were 1.13 vs 1.26 ($p<0.05$). The difference between the treatment groups in % reduction in inflammatory lesions (15% vs 5%) was not statistically significant.

In the second trial, 277 subjects with acne vulgaris were enrolled for treatment with adapalene cream or tretinoin cream 0.05% administered once daily. For adapalene and tretinoin treatment groups respectively after 12 weeks treatment, the mean % reductions from baseline in total lesions were 60% vs 67% ($p<0.05$), in non inflammatory lesions were 64% vs 72% ($p<0.05$), in inflammatory lesions were 43% vs 56% ($p<0.05$) and in the investigator's global assessment scores were 51% vs 57% ($p<0.05$). Adapalene, when applied topically, penetrates into the hair follicles due to its lipophilic nature. Follicular absorption occurs 5 minutes after topical application.

The medication binds the nuclear retinoic acid receptors (RAR), RAR-beta and RAR-gamma. This complex then binds DNA through retinoic acid response elements and induces gene transcription, leading to downstream keratinocyte proliferation and differentiation.

As a result, adapalene decreases microcomedone formations, exfoliates mature comedones and has anti-inflammatory effects.

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

Adapalene in topical preparations is TGA-indicated for topical treatment of comedo, papular and pustular acne (acne vulgaris) of the face, chest or back.

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

Presumably the adapalene products currently on the market can be labelled by the pharmacist with the patient's name and directions for use as if it was being dispensed on a prescription. The benefit of the Appendix M inclusion means that the patient will have the supplied recorded on their My Health Record.

The potential for abuse of a substance

There is no abuse or misuse of this substance as it is not an opiate or a drug of dependence. Adapalene cannot be modified into any addictive substance or any substance of abuse.

Summary

Adapalene is a safe and effective substance that fulfils the criteria for Schedule 3 and is available in the USA as an OTC product and in New Zealand without a prescription. It will provide a safer and less irritant alternative to tretinoin for acne sufferers. There is some contention over its teratogenicity with the FDA determining that this is not a valid reason why it should not be available as an OTC product in the USA. The suggested inclusion in Appendix M should address this issue and will be consistent with the New Zealand "prescription only except when" listing.

Acne is a condition that can be diagnosed by a consumer with advice from their pharmacist. By making adapalene available from a pharmacist as Schedule 3 Appendix M acne sufferers will have access to a safe and effective treatment

11. NICOTINE

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 7

NICOTINE except:

a) when included in Schedule 6;
b) in preparations for human therapeutic use; or
c) in tobacco prepared and packed for smoking; or
d) in tobacco prepared and packed for heating.

Overview

This proposal would allow the sale of heated tobacco products alongside other tobacco products for human use.

The Guild fully supports tobacco control in Australia and encourages its members to provide appropriate smoking-cessation treatments, which meet the varying needs of smokers in the Australian community.

The market for personal vaporisers, of which electronic cigarettes containing nicotine (e-cigarettes) are the most common type, has grown rapidly in recent years. The Guild is opposed to having these products in any schedule that would allow for sale in a pharmacy. The Guild does not support the sale of personal vaporisers in pharmacies, regardless of whether or not they contain nicotine, given the potential for harm as the risk profile for these products is not well established without any therapeutic benefit.

Personal vaporisers remain largely unregulated in Australia and those that contain nicotine cannot be sold legally. There are currently no restrictions on the sale of non-nicotine containing devices that do not make a therapeutic claim. The Therapeutic Goods Administration (TGA) has not approved the use of personal vaporisers as a tool to help smokers quit.

With respect to Heated Tobacco Products (HTPs) we do not believe that there is sufficient evidence that this product is safer than tobacco for smoking and does not appear to be a product to aid in the cessation of smoking. However, we note that one of the Recommendations from *the "Report on the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia*" was that the National Health and Medical Research Council fund an independent and comprehensive review of the evidence relating to the health impacts of electronic cigarettes (e-cigarettes). This review should be updated every two years to take into account the findings of new research into e-cigarettes. Topics covered by the review should include:

- The effectiveness of e-cigarettes as an aid to help people quit smoking tobacco cigarettes;
- The health effects of ingredients commonly used in E-cigarette liquids. Following the review, any ingredients found to have significant negative impacts on human health should be prohibited from use in e-cigarette liquids;
- The likelihood that e-cigarettes will increase the number of young people using nicotine and the number of young people smoking;
- The health impacts of long term e-cigarette use;

- The relative health impacts of e-cigarettes as compared to tobacco products.

We note that the National Centre for Epidemiology & Population Health is now undertaking the *"Public Health Assessment of electronic cigarette use in the Australian context"* [23] and this may provide more information on this topic. The Report is expected to be completed by December 2020.[24]

Summary

The Guild does not support this amendment and believes that the current scheduling remains appropriate.

[23] https://researchers.anu.edu.au/projects/25501

[24] https://athra.org.au/blog/2019/08/01/finally-information-about-the-scientific-inquiry-into-vaping-but-questions-remain/

11. PENTOBARBITAL

Proposal

It has been proposed to amend the Poisons Standard as follows:

Schedule 8

PENTOBARBITAL. ~~except when included in Schedule 4.~~

Schedule 4 - Delete entry

~~PENTOBARBITAL when packed and labelled for injection.~~

Summary

The Guild agrees with both of the Coroner's reports, referred to in the proposal, that injectable pentobarbital be moved from Schedule 4 to Schedule 8 thereby ensuring that all forms of the substance would be subject to restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.