The Pharmacy Guild of Australia

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS and Joint ACMS/ACCS Meeting June 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 (ACMS) and the Joint ACMS/ACCS

1. **Oxymetazoline**
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9. **Isothiazolinones**

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OXYMETAZOLINE

Proposal

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

Schedule 2

OXYMETAZOLINE **except** in nasal preparations containing 0.05% per cent or less of oxymetazoline.

Overview

The Guild does not support the proposed change to the schedule, as we do not believe that the proposed exemption is in the interest of public safety. We do not believe that product labeling alone is sufficient to ensure safe and effective use of the substance, and there is significant potential for harm if the opportunity for the health consumer to access health professional input is removed. This harm can result from the potential confusion arising from the indications, which often present with similar symptoms but have different aetiologies and therefore require different management. Some symptoms may persist longer than three days, such as rhinitis caused by seasonal hay fever, there is a greater risk that without health professional input, the consumer may use the product beyond the recommended limit, resulting in rhinitis medicamentosa. As well as the well-documented risk of cardiovascular side-effects of oxymetazoline, there is also potential for abuse of the substance[1] owing to the stimulant effects of oxymetazoline if ingested or injected.

[1] Shukla PC 1995, Acute ischemia of the hand following intro-arterial oxymetazoline injection. *J Emerg Med* < https://www.ncbi.nlm.nih.gov/pubmed/7782628> Last accessed 5 May 2020

The risks and benefits of the use of a substance

Risks

The Product Information lists a number of precautions and known side-effects of oxymetazoline, which increase its potential for harm, if there is no opportunity for a consumer to interact with a health professional. Precautions listed in the Product Information of one nasal spray formulation containing 0.05% oxymetazoline states that the product should be used in caution in patients with the following medical conditions:

- cardiovascular disease
- patients who are concurrently using of monoamine oxidase inhibitors (MAOI) or tricyclic antidepressant therapy due to the potential to cause a hypotensive crisis
- diabetes mellitus
- hypertension
- prostatic enlargement
- thyroid disease

This product should not be used with other cough and cold medicines, unless directed by a doctor.

Adverse Reactions

- **Neurologic disorder.** Headache, insomnia, dizziness.
- **Psychiatric disorder.** Nervousness, tremors.
- **Respiratory.** Nasal congestion, rebound congestion, dryness of the mouth and throat, local mucosal irritation, nasal stinging/ burning, sneezing.
- **Gastrointestinal disorder.** Nausea.
- **Cardiac disorder.** Hypertension, palpitation, reflex bradycardia

Post-marketing surveillance has reported numerous side- effects of oxymetazoline which are listed in the TGA-approved Product Information for the substance. These include cardiovascular side effects of hypertension, palpitations and reflex bradycardia in both adults and in children.

The unintentional misuse may result from a lack of consumer knowledge of when to select the product, confusion created by the availability of numerous nasal sprays with very similar marketing claims in terms of symptom relief, but with very different therapeutic indications and particularly different recommendations for dosage and administration. Rhinitis medicamentosa, or rebound congestion, arising from use of the substance extending beyond the recommended three day limit is not uncommon[2]. This occurs despite the warnings on the label, where a consumer continually uses a nasal decongestant spray, believing that this is the product that will relieve their symptoms, rather than recognising that it is in fact causing their ongoing congestion. Without pharmacist oversight in the selection of nasal decongestant sprays, there is not only the risk of this rebound congestion occurring, but for it to become an ongoing cycle, causing more serious damage over time. Pharmacists and pharmacy staff are trained to identify and be alert for this improper use of nasal decongestant sprays. Unlike in non-health retail environments, pharmacists and pharmacy staff are be able to immediately offer an appropriate alternative treatment, such as a nasal corticosteroid if the cause of congestion is atopic, or refer the consumer to their GP.

Similarly, the reduced input from a pharmacist may result in inappropriate selection for use of the oxymetazoline nasal spray in children.

[2]Mortuaire et al 2013, Rebound congestion and rhinitis medicamentosa: Nasal decongestants in clinical practice. Critical review of the literature by a medical panel. *European Annals of Otorhinolaryngology, Head and Neck Diseases*. Last accessed 21 April 2020. < https://www.sciencedirect.com/science/article/pii/S1879729612001378

Benefits

Oxymetazoline nasal sprays are indicated for symptomatic relief of nasal congestion associated with colds, hay fever, sinusitis and other respiratory allergies

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

TGA-approved Product Information lists the following indications for oxymetazoline:

- Temporary relief of nasal congestion due to colds, allergies and sinusitis

It is likely that while the general public can distinguish between some of the symptoms of colds and allergies, they are also more likely to experience the symptoms of allergies like seasonal hay fever, which is highly prevalent in Australia, for a longer period than, for example, the symptoms of a common cold. Without health professional input, the consumer is not likely to be aware why the duration of treatment with this substance should be limited, when the symptoms are the same and the condition is persistent. Without health professional input, the public is unlikely to be aware of what distinguishes one cause of nasal congestion from another.

The toxicity of a substance

While the applicant does present some toxicity data to argue for low toxicity of substance, the substance is not without harm. Oxymetazoline has been linked to one death as stated in the application. There is also documented harm resulting from abuse of the product via injection[3]. Therefore, the Guild argues that a health professional should be involved in therapeutic selection of the product, and that the existing schedule should be maintained.

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

The current packaging is inadequate to support safe and appropriate self-selection of the substance. If the proposed scheduling change was to proceed, there should be significant change to packaging, including greater and more prominent warning labels.

The potential for abuse of a substance

The reported low incidence of abuse is likely to be, at least in some part, attributed to the existing scheduling which requires the involvement of a health professional in the therapeutic selection and sale of products containing oxymetazoline. However, abuse has been documented[4] and there are anecdotal reports of pharmacists having to decline supply to people at risk of abusing or misusing the substance, including through oral ingestion of oxymetazoline solutions. Oxymetazoline is a non-selective alpha agonist and it can act on the central nervous system to cause euphoric effects[5]. The likelihood of abuse is likely to increase if controls on sale are lifted, as pharmacist was less involved in the selection of the product, as proposed by this change in scheduling.

[3] Shukla PC 1995, Acute ischemia of the hand following intro-arterial oxymetazoline injection. *J Emerg Med* < https://www.ncbi.nlm.nih.gov/pubmed/7782628> Last accessed 5 May 2020

[4] Shukla PC 1995, Acute ischemia of the hand following intro-arterial oxymetazoline injection. *J Emerg Med* < https://www.ncbi.nlm.nih.gov/pubmed/7782628> Last accessed 5 May 2020

[5] Giovannitti, JA Jr et al. Alpha-2 adrenergic receptor agonists: a review of current clinical applications. *Anesthesia progress* vol. 62,1 (2015): 31-9. < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389556/> Last accessed 8 May 2020.

Any other matters necessary to protect public health

The proposed schedule change does not have a clear benefit to the public. It does not increase access to the medication, as it will still be sold in pharmacies. Pharmacies are the easily accessible to the Australian public and the most frequented health locations; they are equitably distributed around the country and many trade extended hours including weekends. The proposed scheduling change may only affect the consumer adversely by potentially reducing their interaction with a health professional regarding their presenting symptoms and potential other health concerns.

Consumer Health literacy

Previous research conducted by the Australian Bureau of Statistics, has 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.[6] 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 outcome from using a medicine. Specifically, low individual health literacy has found to be associated with a lesser ability to demonstrate taking medicines appropriately and interpreting labels and health messages. This is particularly important with oxymetazoline, where use beyond the written recommended duration has a high probability in resulting in harm. Consequently, it is the view of the Guild that consumers should receive advice on the safe and effective use of medicines and this is best achieved by consumers having access to professional advice from pharmacy staff.

Summary

Based on the balance of risk to benefit from the proposed scheduling change to oxymetazoline, the Guild does not support the application for exemption of the substance from Schedule 2.

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

ELETRIPATN

Proposal

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

Schedule 4 – Amend entry

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

Schedule 3 – New Entry

ELETRIPTAN for oral use in tablets containing 40 mg or less per tablet and when in a pack containing not more than 2 dosage units.

Appendix H – New Entry

ELETRIPTAN

Overview

This scheduling change would allow pharmacists to supply eletriptan as a Schedule 3 medicine in packs of no greater than 2 tablets containing 40mg or less of the substance. The Guild is supportive of this proposal, as it would improve access to treatment for those people who have previously diagnosed with migraine, and who have previously been prescribed this medication to treat their condition.

Sumatriptan and zolmitriptan have both received final decisions for re-scheduling to Schedule 3. The Guild was supportive of this change and believes that scheduling of eletriptan should be consistent with that, as eletriptan has a similar safety profile and clinical indications.

The risks and benefits of the use of a substance

Risks

The safety profile of eletriptan is comparable to sumatriptan and zolmitriptan. The risks associated with eletriptan are not molecule specific but are rather associated with the therapeutic class i.e. “Triptans” or 5HT1 agonists. 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 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.

Benefits

Migraine has a considerable impact on the health and wellbeing of Australians, while also resulting in significant economic costs, through health system costs and lost productivity[7]. Clinical evidence and treatment recommendations for the management of acute, episodic migraine, highlights the importance of taking effective agents early in migraine onset and development to achieve the best outcomes. Clinical evidence shows that triptans are more therapeutically effective in reducing progression, severity and duration of migraine when taken within one hour of the onset of headache. Hence, making the medication more readily available without a prescription would assist in clinical practice.

[7] Deloitte Access Economics 2018, Migraine in Australia Whitepaper: Measuring the Impact’. < https://www2.deloitte.com/au/en/pages/economics/articles/migraine-australia-whitepaper.html> Last accessed 8 May 2020.

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

Eletriptan will be used by people who have previously been diagnosed with migraine and have previously been prescribed this medication by a medical practitioner.

The toxicity of a substance

The relatively long history of use of eletriptan and other 5HT-1 agonists in clinical practice leads to a comprehensive understanding of the adverse effect profile of the substance. 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.

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

The Guild does not anticipate any change to the dosage, formulation, labelling, packaging and presentation of the substance.

The potential for abuse of a substance

There is low potential of abuse of this substance.

Any other matters necessary to protect public health

The Guild is supportive of making all 5HT-1 agonists, including eletriptan, more accessible to people with a previous diagnosis of migraine, and who have been prescribed the medicine by a medical practitioner.

The Guild is supportive of Appendix H listing, but it should follow a period of familiarisation by the profession. This should also align with any approvals for the marketing of sumatriptan and zolmitriptan, to minimise confusion and ensure consistency across the therapeutic class.

Summary

The Guild is supportive of the proposed scheduling change, and believes that the same criteria should apply to eletriptan as to sumatriptan and zolmitriptan under Schedule 3.

CLOTRIMAZOLE

Proposal

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

Schedule 3

CLOTRIMAZOLE in preparations for vaginal use **except** when included in Schedule 2.

Schedule 2

CLOTRIMAZOLE for human use:
a) in preparations for vaginal use containing 1 per cent or less of clotrimazole; or
b) in dermal preparations; and
c) for application to the nails.

except in preparations for the treatment of tinea pedis. **Appendix F, Part 3**

Poison	Warning statements	Safety directions
CLOTRIMAZOLE in vaginal preparations when included in Schedule 2 or Schedule 3.		54,63,64,66

Overview

The Guild does not support the proposed scheduling changes because there is no clear benefit to the public. The Guild notes previous applications to down-schedule vaginal clotrimazole, most recently in 2017 [8]. This proposal does not offer any new or compelling evidence of patient benefit and we note that all the risks of potential patient harm that may arise from down-scheduling remain. While acknowledging that some consumers may feel embarrassed when seeking treatment for sensitive conditions, the risk of potential harm arising from self-diagnosis, including misdiagnosis and a delay in seeking appropriate and wholistic treatment, is likely to have far more negative health consequences for women, in the short and the longer term. An interaction with a pharmacist can help minimise the risk of misdiagnosis and is more likely to identify underlying pathologies, providing the consumer with a complete health solution, including a referral to their GP when required. The Guild is further opposed to this proposal, as it is misaligned with the key principles of antimicrobial stewardship (AMS) which calls for judicious use of antimicrobial and antifungal agents, in order to stem their overuse and potential for resistance.

The risks and benefits of the use of a substance

Benefits

Vaginal clotrimazole preparations in concentration of 1% provide effective treatment for vulvovaginitis in women.

Risks

The applicant has listed a high incidence of embarrassment and the high accuracy of self-diagnosis as the reasons for why these products should be able to be self-selected by consumers. The applicant quotes a study by Tenni (Tenni 2005) in which only 47% of first time sufferers could accurately self-diagnose vaginal thrush and 42% who would not require treatment, as an example of appropriateness for self-selection of the product.

[8] Therapeutic Goods Administration, Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, November 2017: 1.9 Clotrimazole. > https://www.tga.gov.au/book-page/19-clotrimazole> Last accessed 19 May 2020.

The application argues that the 'do no harm' scenario, combining accurate diagnosis and no treatment required groups, is acceptable. The Guild disagrees with this interpretation and highlights that 42% of participants in this study used a medicine that they did not require and that less than half, only 47%, could accurately self-diagnose. Contrary to the argument put forward by the applicant, the authors were not supportive of self-selection and were concerned about the potential harm[9].

Some of the reasons why self-selection is not supported by the Guild are outlined below.

a) Misdiagnosis

Symptoms of vaginal thrush caused by *Candida sp* infections may be mistaken for other pathologies, such as urinary tract infections, bacterial vaginosis, dermatitis or sexually transmitted infections (STIs), which often present with symptoms similar to thrush. Therefore, by removing the interaction between a consumer and a pharmacist, these women are at a higher risk of harm through potential misdiagnosis and delay in treatment, as well as inadequate detection or management of other underlying conditions contributing to the opportunistic infection.

b) Delay in treatment of underlying conditions

With less than half of the study participants being able to accurately self-diagnose their condition, enabling them to self-select inappropriate or unnecessary treatment risks delaying access to appropriate treatment which will lead to prolonged symptoms and discomfort. Furthermore, vaginal *Candida Albicans* infection, may be indicative of a number of pathologies in females, including undiagnosed or undertreated diabetes, hormonal imbalances in post-menopausal women[10].

c) Antifungal resistance, antimicrobial stewardship and judicious use of medicines

Candida albicans is the most commonly implicated agent in vulvovaginal candidiasis or thrush. Increasing resistance of *Candida* spp to azole antifungals, including clotrimazole is well documented[11][12] In line with the principles of antimicrobial stewardship, judicious use of antifungal agents is required to reduce the risk of resistance to these medicines. In a study by Teni (Teni 2005) quoted by the applicant, 42% of women who self-diagnosed with thrush had normal vaginal flora. That represents a large number of women who might self-select unnecessary treatment. This is contrary to judicious, safe and effective use of medicines, one of the pillars of the National Medicines Policy, and to the principles of antimicrobial stewardship developed by the Australian Commission on Safety and Quality in Health Care and aimed at reducing antimicrobial resistance[13]. Interaction with a health professional in pharmacy is pivotal to prevent this misuse of the medicine and to contribute to optimal treatment for the consumer's presenting symptoms, including GP referral when required.

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[9] Hilmi, McCloskey, Tenni and Hughes (2007) Vulvovaginal Candidiasis in Australia: Let's take a look 'Down Under'. *Sexual Health* **4**, 298-298. < https://www.publish.csiro.au/sh/shv4n4ab36> Last accessed 8 May 2020

[10] eTG Complete June 2019. Dermatology: Candidal vulvovaginitis in women. *Therapeutic Guidelines Ltd*. Online accessed 6 May 2020.

[11] El-Houssaini et al 2019, Correlation between antifungal resistance and virulence factors in Candida albicans recovered from vaginal specimes. *Microbial Pathogensis*. < https://www-sciencedirect-com.ezproxy-f.deakin.edu.au/science/article/pii/S0882401018318035> Last accessed 5 May 2020.

[12] Centers for Disease Control & Prevention (CDC). Antifungal resistance. https://www.cdc.gov/fungal/antifungal-resistance.html last accessed 6 May 2020.

[13] Australian Commission on Safety and Quality in Healthcare 2018. Antimicrobial Stewardship in Australian Healthcare 2018. < https://www.safetyandquality.gov.au/sites/default/files/migrated/AMSAH-Book-WEB-COMPLETE.pdf>. Last accessed 6 May 2020

As explained above, reducing the interaction between a consumer and a pharmacist as a result of the proposed scheduling changes would not lead to better health outcomes for consumers. While it is not uncommon for people to feel a sense of embarrassment in relation to experiencing many acute and chronic health conditions, accurate diagnosis and appropriate, timely and effective treatment are likely to be regarded as more important. An interaction with a pharmacist is key to providing women presenting with symptoms with a complete health solution, including referral to their GP when required, and any scheduling change that would minimise the likelihood of this interaction should not be implemented in the Poisons Standard.

Precaution for use is also advised in pregnant women.

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

Clotrimazole formulations are commonly used to treat vaginal thrush, which is a common condition, experienced by approximately 75% of adult women at least once in their lifetime [14].

The toxicity of a substance

Generally well tolerated, with infrequent reports of mild symptoms of topical irritation in users and rare reports of irritation or burning in the sexual partner.

The potential for abuse of a substance

There is low potential for abuse of the substance.

Summary

Based on the estimate of consumer risk to benefit, the Guild does not support the proposed scheduling change.

[14] El-Houssaini et al 2019, Correlation between antifungal resistance and virulence factors in Candida a bicans recovered from vaginal specimens. *Microbial Pathogenesis*. < https://www-sciencedirect-com.ezproxy-f.deakin.edu.au/science/article/pii/S0882401018318035> Last accessed 5 May 2020.

SILDENAFIL

Proposal

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

Schedule 4

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

Schedule 3 – New Entry

SILDENAFIL in divided preparations for oral use containing 50 mg of sildenafil per dosage unit in packs of not more than 4 dosage units in accordance with the requirements of Appendix M.

Appendix M – New Entry

Appendix M

SILDENAFIL where the pharmacist providing professional advice:

• Has demonstrated achievement of competency through completion of an accredited training course that meets the requirements set out in the Pharmaceutical Society of Australia competency-based education framework for supply of sildenafil as a Pharmacist Only medicine; and
• Complies in all respects with the relevant professional practice standards, and the Pharmaceutical Society of Australia professional practice guidance for supply of sildenafil as a Pharmacist Only medicine; and
• Confirms a PDE5 inhibitor has previously been prescribed by a medical practitioner for the patient for treatment of erectile dysfunction; and
• Documents the supply of sildenafil in a clinical information system in accordance with professional practice guidance.

Overview

The applicant has proposed a new entry for sildenafil as a Schedule 3 medicine, that would see it more readily available to Australian health consumers. As a Schedule 3 medicine, sildenafil would be available for patients who have previously been prescribed the medicine by their doctor. It is proposed that up to four tablets of 50mg would be made available under Schedule 3. The applicant has proposed a list of Appendix M criteria for pharmacists undertaking accredited training before supplying the medication.
The Guild supports a change in the schedule that would lead to increased access to sildenafil for patients who have previously used the medication under the advice of their doctor. However, the professional practice guidance should not be limited to training developed by the Pharmaceutical Society of Australia (PSA) or written in a way that would disadvantage other training providers to develop accredited training for pharmacists and therefore the Guild is not supportive of the wording of Appendix M.

The risks and benefits of the use of a substance

Risks

Priapism

Prolonged erections lasting more than four hours and priapism (painful erections greater than 6 hours) have been reported infrequently with sildenafil. It is vital that pharmacists warn patients about this rare but potentially serious side-effect and how to seek treatment.

Use in men with cardiovascular disease

Sildenafil has vasodilator properties, resulting in mild and transient decreases in blood pressure and, as such, potentiates the hypotensive effect of nitrates. Furthermore, there is a degree of cardiovascular risk associated with sexual intercourse and although a patient's cardiovascular health would have been assessed by their doctor prior to initiating treatment with sildenafil, there is similarly a role for the pharmacist in assessing risk prior to the supply of the medication.

CONTRAINDICATIONS

TGA approved PI for Viagra® brand of sildenafil warns against use of nitrates

> *Nitrates and VIAGRA must not be used concomitantly. VIAGRA was shown to potentiate the hypotensive effects of both acute and chronic nitrate administration and therefore, its co-administration with NO donors, organic nitrates or organic nitrites in any form, either regularly or intermittently is contraindicated. Drugs which must not be used concomitantly include glyceryl trinitrate (injection, tablets, sprays or patches), isosorbide salts, sodium nitroprusside, amyl nitrite, nicorandil or organic nitrates in any form.*

Benefits

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

Sildenafil is indicated for the treatment of erectile dysfunction in adult males.

The toxicity of a substance

Post marketing surveillance has shown a number of rare side-effects, including effects on the cardiovascular system, headaches and visual disturbances. These are listed in the TGA approved Product Information for the Viagra® brand of sildenafil.

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

We note that only the 50mg tablets in quantities of up to four tablets have been proposed for this scheduling change. Sildenafil is commercially available in 25mg and 100mg strengths and in packs of up to 12 tablets of the 100mg strength. It is unclear why the applicant has not considered listing the other strengths or pack sizes. This is likely to be disadvantageous to patients being treated with the higher strength formulations.

Recording in clinical information system

The Guild is supportive of the proposal to stipulate the recording of sildenafil supply in clinical software. Furthermore, we believe that labelling the product with the patient's name and directions would be best practice, contributing to both patient safety and to the consistency of clinical practice and pharmacy workflows. There is the added benefit of recording, as the medication would be visible in the patient's My Health Record.

The potential for abuse of a substance

Although abuse of sildenafil is unlikely, there may be some potential for misuse of the medication if the patient is not given appropriate counselling by the pharmacist.

Any other matters necessary to protect public health

Appendix H listing of sildenafil

The Guild does not support Appendix H listing at this time.

The Guild is supportive of a staged approach to consumer marketing of sildenafil, following a period of implementation and review. This would enable pharmacists to undertake training, develop, embed and review professional practice and workflow processes associated with the supply of sildenafil, and ensure safe, effective and quality use of medicines. It would not be in the interest of consumers to advertise the Schedule 3 availability of sildenafil until the profession has had the opportunity to undertake training and implement associated best practice.

Summary

The Guild is supportive of making sildenafil more accessible to people with a diagnosis of erectile function and who have been treated with sildenafil. The wording of the proposed appendix M criteria should be amended to make it explicit that training is not to be limited to that developed or provided by the PSA, and it should encourage all pharmacist training providers to support the supply of sildenafil. This would ensure that more pharmacists have access to training and will be able to supply the substance.

The Guild is not supportive of Appendix H listing at this time. A staged approach to consumer marketing should be taken, following a period of familiarisation post the scheduling change.

IBUPROFEN

Proposal

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

Schedule 2

IBUPROFEN in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen:

a) in liquid preparations when sold in the manufacturer's original pack containing 8 g or less of ibuprofen; or
b) in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units **except** when:
    i. as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent);
    ii. packed in blister or strip packaging or in a container with a child-resistant closure;
    iii. in a primary pack containing not more than 25 dosage units;
    iv. compliant with the requirements of the Required Advisory Statements for Medicine Labels;
    v. not labelled for the treatment of children 6 years of age or less; and
    vi. not labelled for the treatment of children under 12 years of age when combined with phenylephrine.
c) in divided preparations, each containing 400 mg or less of ibuprofen in a primary pack containing not more than 12 dosage units, when labelled:
    i. not for the treatment of children under 12 years of age.

Overview

The Guild does not support the proposed scheduling change. The reasons for the proposed change do not warrant the increased risk associated with the potential for confusion and misuse created by an additional strength of ibuprofen being more readily available. Furthermore, the current range of commercially available ibuprofen formulations adequately serves the needs of people with swallowing difficulty or for those seeking the convenience of a small preparation. This includes liquid preparations, gel capsules, small, coated tablets in a range of brands.

There is no evidence in practice, or in the proposal put forward by the applicant, of a public benefit of making available up to 12 tablets of 400mg ibuprofen. As all other ibuprofen containing products, these medicines have a large potential for harm and should be sold under direct supervision of a pharmacist.

The risks and benefits of the use of a substance

Risks

As a product that is readily available in pharmacies and grocery stores, consumers are likely to be familiar with ibuprofen in its current strength of 200mg per tablet. They are less likely to be familiar with the 400mg tablets that have traditionally been available by prescription and only more recently as a Schedule 3 medicine. Making the higher strength tablets more readily available is likely to add to confusion and lead to potential overdose, where people who would on occasion take two tablets of 200mg may take two tablets of the 400mg ibuprofen. This has a potential to cause adverse effects.

Drug interactions and precautions

TGA approved Product Information lists many interactions and precautions for people considering using ibuprofen. These include chronic conditions that are relatively prevalent in the Australian community such as asthma, cardiovascular disease including hypertension, diabetes, gastrointestinal disorders, depression and medicines that are used to treat these conditions. The potential drug interactions with ibuprofen are well documented and occur via a number of pathways, including through hepatic metabolism mediated through the cytochrome P450 (CYP450) pathways, the effects on renal function through the renin-angiotensin system including the risk of renal impairment, the anti-platelet effects and many others. Ibuprofen should be used with caution and by consulting with of a health professional, such as in the community pharmacy setting.

Benefits

Ibuprofen is indicated for the relief of acute and/or chronic pain states in which there is an inflammatory component.

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

The application purports that there is a greater need to improve availability of 'stronger' OTC analgesics since codeine-containing OTC products became up scheduled. However, ibuprofen is already readily available, from pharmacies and from supermarkets. It is also indicated for short-term use and not for the management of 'strong pain'.

The toxicity of a substance

There are many significant drug interactions and physiological adverse effects associated with ibuprofen use, that make it potentially a very toxic substance if not used with caution and as directed by a health professional.

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

The Guild does not support the assertion that labelling is adequate to prevent the potential confusion and harms associated with the proposed scheduling change.

The potential for abuse of a substance

There is low potential for abuse of ibuprofen.

Summary

The Guild believes that there is neither a public need for the increased access to oral preparations containing 400mg of ibuprofen or that greater access to such products is in the public interest. Of particular concern are the many possible interactions with commonly used medicines and precautions for use in people with commonly occurring conditions. The Guild therefore does not support the proposed scheduling change.

CUMYL-PEGACLONE

Proposal

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

Schedule 9 – New Entry
2,5-DIHYDRO-2-(1-METHYL-1-PHENYLETHYL)-5-PENTYL-1H-PYRIDO[4,3-B]INDOL-1-ONE (CUMYL-PEGACLONE)

Summary

The Guild has no objection to the proposed scheduling change.

NICOTINE

Proposal

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

Schedule 7

NICOTINE **except**:
a) ~~when included in Schedule 6~~;
a) when included in Schedule 4 ~~in preparations for human therapeutic use; or~~
b) in tobacco prepared and packed for smoking; or
c) for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.

Schedule 6

~~NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.~~

Schedule 4
NICOTINE in preparations for human ~~therapeutic~~ use **except**:
a) when for human therapeutic use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use; or
b) in tobacco prepared and packed for smoking.

Appendix D, Item 5- New Entry
Nicotine when included in Schedule 4.

Summary

The Guild has no objection to the proposed scheduling change. The Guild supports World Health Organisation Framework Convention on Tobacco Control.

METHYLISOTHIAZOLINONE AND METHYLCHLOROISOTHIAZOLINONE

Proposal

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

Schedule 6

METHYLISOTHIAZOLINONE **except**:

a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or

b) in other preparations that are not intended for direct application to the skin containing ~~0.1~~ 0.05 per cent or less of ~~methylisothiazolinone~~ isothiazolinones in total when labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Appendix F, Part 3 – Amend Entry

Poison	Warning statements	Safety direction
METHYLISOTHIAZOLINONE.	28 X	.
28: (Over) (Repeated) exposure may cause sensitisation. X: CONTAINS ISOTHIAZOLINONES REPEATED EXPOSURE MAY CAUSE SENSITISATION (written in letters not less than 1.5 mm in height)		

Schedule 6 – Amend Entry

METHYLCHLOROISOTHIAZOLINONE **except**:

a) in rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylchloroisothiazolinone and methylisothiazolinone in total; or

b) in other preparations that are not intended for direct application to the skin containing ~~0.1~~ 0.05 per cent or less of ~~methylchloroisothiazolinone and methylisothiazolinone in total~~. isothiazolinones in total when labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION

(written in letters not less than 1.5 mm in height)

Appendix F, Part 3 – Amend Entry

Poison	Warning statements	Safety direction
METHYLISOTHIAZOLINONE.	28 X	.
28: (Over) (Repeated) exposure may cause sensitisation. X: CONTAINS ISOTHIAZOLINONES REPEATED EXPOSURE MAY CAUSE SENSITISATION (written in letters not less than 1.5 mm in height)		

Summary

The Guild has no objection to the proposed scheduling change.

ISOTHIAZOLINONES

Proposal

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

Schedule 6- New Entry

ISOTHIAZOLINONES not elsewhere specified in these Schedules, **except** in preparations that are not intended for direct application to the skin containing 0.05 per cent or less of isothiazolinones in total and labelled with the statements:

CONTAINS ISOTHIAZOLINONES

REPEATED EXPOSURE MAY CAUSE SENSITISATION (written in letters not less than 1.5 mm in height)

Schedule 6 – Delete Entry
~~OCTHILINONE **except** in paints, jointing compounds and sealants containing 1 per cent or less of octhilinone calculated on the non-volatile content~~.

Schedule 6 – Delete Entry
~~4,5-DICHLORO-2-N-OCTYL-3(2*H*)-ISOTHIAZOLONE.~~

Summary

The Guild has no objection to the proposed scheduling change.