Public submissions on proposed amendments to the *Poisons Standard*

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15), was made available on the TGA website on 22 December 2016 and 3 February 2017, closing on 10 February 2017 and 3 March 2017 respectively.

Public submissions received on or before these closing dates (10 February 2017 and 3 March 2017) are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulation 42ZCZL , the Secretary has removed information that the Secretary considers confidential.

Under regulation 42ZCZN of the Regulations, the Secretary, after considering the advice or recommendation of the expert advisory committee, must (subject to regulation 42ZCZO) make an interim decision in relation to the proposed amendment. If the interim decision is to amend the current *Poisons Standard*, the Secretary must, in doing so, take into account the matters mentioned in subsection 52E(1) of the Act (including, for example, the risks and benefits of the use of a substance, and the potential for abuse of a substance) and the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available on the TGA website.

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision).

Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must also invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the March 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #20), the Advisory Committee on Chemicals Scheduling (ACCS #19) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #15) was made available on the TGA website on 17 May 2017 and 15 September 2017, closing on 31 May 2017 and 3 October 2017 respectively. Public submissions received on or before these closing dates will be published on the TGA website in accordance with regulation 42ZCZQ.

Privacy statement

The Therapeutic Goods Administration (TGA) will not publish information it considers confidential, including yours/other individuals' personal information (unless you/they have consented to publication) or commercially sensitive information. Also, the TGA will not publish information that could be considered advertising or marketing (e.g. logos or slogans associated with products), information about any alleged unlawful activity or that may be defamatory or offensive.

For general privacy information, go to https://www.tga.gov.au/privacy. The TGA is part of the Department of Health and the link includes a link to the Department's privacy policy and contact information if you have a query or concerns about a privacy matter.

The TGA may receive submissions from the public on a proposed amendment to the Poisons Standard where there has been an invitation to the public for submissions on the proposal in accordance with the Therapeutic Goods Regulations 1990. These submissions may contain personal information of the individual making the submissions and others.

The TGA collects this information as part of its regulatory functions and may use the information to contact the individual who made the submissions if the TGA has any queries.

As set out above, the TGA is required to publish these submissions unless they contain confidential information.

If you request for your submission to be published in full, including your name and any other information about you, then the TGA will publish your personal information on its website. However, if at any point in time, you change your mind and wish for your personal information to be redacted then please contact the Scheduling Secretariat at medicines.scheduling@health.gov.au so that the pubic submissions can be updated accordingly.

Please note that the TGA cannot guarantee that updating the submissions on the TGA website will result in the removal of your personal information from the internet.

Please note that the TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

[redacted]

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting March 2017

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. **Flurbiprofen – Schedule exemption**
2. **Ibuprofen – Schedule 3 and Appendix H listing**
3. **Penciclovir – Schedule exemption**
4. **Loratadine – Schedule exemption**
5. **Ulipristal – Appendix H listing**
6. **Dihydrocodeine – Scheduling Review**

Date February 2017
Contact [redacted]

[redacted]
National Secretariat
[redacted]

FLURBIPROFEN

Down-schedule flurbiprofen from Schedule 2 to unscheduled when containing 0.25 per cent or less of flurbiprofen or, containing 10 mg or less per dose of flurbiprofen in undivided dosage forms.

Overview

The Guild does not support this proposal as we believe flurbiprofen should remain Schedule 2 so consumers have access to professional advice that can assist in determining the nature and cause of the condition being treated (sore throat) and determine a more suitable treatment or referral to a doctor if required.

The risks and benefits of the use of a substance

Allowing unscheduled and unsupervised sale of these products in general retail could pose an unnecessary and preventable risk across the following demographic groups as a result of reduced likelihood of identifying contraindicated use.

Use in pregnancy
Flurbiprofen has a B2 classification in relation to pregnancy and the product information states that use in pregnancy should only occur on medical advice and is contraindicated for use in the 3rd trimester.[1]

A 2016 TGA review confirmed that there is a known association between use of non-aspirin NSAIDs and increased risk of miscarriage, particularly when the medicine is taken close to the time of conception. However, warnings about this risk in PIs and labelling were not consistent across these products.[2]

Use in children
Flurbiprofen is not recommended for children under 12 years of age.[3]

Precaution with pre-existing health conditions.
Precaution is advised with consumers suffering asthma, renal impairment, stomach ulcers and heart failure.[4]

Interaction with other medications
Flurbiprofen should not be used with aspirin (which is already unscheduled) and if a consumer is taking other medications such as warfarin.[5]

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

Underlying cause of symptoms
Although most sore throats are not serious, certain demographic groups are more at risk of developing complications from a sore throat and may need to see their doctor. These groups include [6]:

[1] MIMS online - Strepfen Intensive ®
[2] https://www.tga.gov.au/alert/non-steroidal-anti-inflammatory-drugs-nsaids-review
[3] IBID
[4] IBID
[5] Choi, K. H., Kim, A. J., Son, I. J., Kim, K. H., Kim, K. B., Ahn, H., & Lee, E. B. (2010). Risk factors of drug interaction between warfarin and nonsteroidal anti-inflammatory drugs in practical setting. Journal of Korean medical science, 25(3), 337-341.
[6] NPS Medicines Wise- What are the symptoms of a throat infection? LINK

- 2–25 years old living in Aboriginal and Torres Strait Islander communities who are at high risk of rheumatic fever (e.g. in central and northern Australia)
- with heart problems caused by rheumatic fever
- with scarlet fever
- with a weakened immune system due to an illness such as HIV or leukaemia
- who are taking medicines that suppress the immune system (e.g. after an organ transplant, chemotherapy for cancer, or for rheumatoid arthritis)
- who have no spleen or whose spleen doesn't work properly
- with anaemia
- people who are taking anti-thyroid medicines for an overactive thyroid gland (e.g. carbimazole). Carbimazole can decrease the number of white blood cells (leucopenia), which reduces the body's ability to fight infection.

In the more general population, it is important to determine whether sore throat symptoms are caused by a bacterial infection (such as Streptococcus pyogenes) or by a virus such as the common cold or influenza.[7] Other symptoms associated with a bacterial infection may include fever, swollen glands and tonsillitis and could be indicative of a more serious infection which warrants further medical attention.

Having these products available in general retail with no access to professional advice increases the likelihood that treatment and assessment for more serious underlying conditions will be delayed.

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

While many of the risks outlined above are addressed through the Medicines Advisory Statements Specification for flurbiprofen, the Guild has consistently argued that warning and advisory labels cannot replace the professional advice provided by trained pharmacy staff.

Additionally, the sheer number of advisory statements that are required for flurbiprofen may also cause "warning label fatigue" and lead to consumers overlooking critical advice.

This risk is compounded by the fact that some of these products are throat lozenges and consumers may consequently perceive them to be "harmless", particularly if they are available in general retail.

Summary

The Guild does not support this proposal and believes the current scheduling to be appropriate.

IBUPROFEN- SCHEDULING

Amend the Schedule 3 entry for ibuprofen to include a modified release oral dose form of 600 mg of ibuprofen per dosage unit in packs of 32 or less dosage units when labelled:

- *with a recommended daily dose of 1200 mg or less of ibuprofen and*
- *not for the treatment of children under 12 years of age*

Overview

The Guild supports this proposal. Ibuprofen has an established safety profile and the risk and precautions associated with this medicine can be mitigated via the intervention of the pharmacist. The classification

[7] NPS Medicines Wise- What are the symptoms of a throat infection? LINK

would be consistent with the recent scheduling of other NSAIDs in a modified release dose oral form such as naproxen.

The risks and benefits of the use of a substance

Pharmacists are well placed to advise consumers regarding the modified dosage formulation and ensure patients use the lowest effective dose for the shortest period of time.

The advice of the pharmacist would also enhance the quality use of this medicine such that inappropriate use of ibuprofen for more transient pain is less likely to occur, where there may be more appropriate shorter acting alternatives.

The above statements were cited as part of the ACMS advice to the delegate regarding the scheduling of naproxen in the same dosage and form.[8]

Summary

The Guild supports this proposal.

IBUPROFEN- APPENDIX H LISTING

Include ibuprofen 600 mg in modified release dosage form in Appendix H.

Overview

In relation to listing of ibuprofen on Appendix H, the Guild has no objection to the listing providing that all advertisements for these medicines highlight the mandatory role of the pharmacist in determining the suitability of the product.

The Guild notes that other NSAIDs (diclofenac and naproxen) are currently listed on Appendix H and we do not consider these listings have had an adverse impact on public health.

Increase consumer awareness

The Guild believes listing ibuprofen on Appendix H would increase consumer awareness of a specific therapeutic product that may be more suitable, simpler to take, available without a prescription and encourages consumers to seek advice from a pharmacist. We believe this proposal if adopted will lead to consumers being better informed about products that are available without a prescription and the role of the pharmacist in determining whether those products are appropriate.

As part of the final decision in 2016 on listing naproxen on Appendix H, the primary reasons given for this decision were there was a public health benefit to advertising and there will not be appropriate use.[9]

The Guild believes this reasoning is relevant to the current proposal.

Summary

The Guild has no objection to the listing providing that all advertisements for these medicines highlight the mandatory role of the pharmacist in determining the suitability of the product for consumers.

[8] Scheduling delegate's final decisions: ACMS, July 2014- Naproxen LINK
[9] Delegate's final decision – Naproxen Appendix H – March 2016 LINK

PENCICLOVIR

Down-schedule penciclovir from Schedule 2 to unscheduled in preparations containing 1 per cent or less of penciclovir for the treatment of Herpes labialis in packs containing 10 g or less.

Overview

The Guild does not support this proposal and believes the current scheduling to be appropriate. Best practice demands there is a level of professional intervention in the differential diagnosis and assessment of the appropriate, efficacious, judicious and safe use of penciclovir in herpes labialis to prevent inappropriate use and to promote appropriate referral to a medical practitioner. Broader access particularly by immunocompromised people has the potential to contribute to the prevalence of drug resistance.

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

Herpes Simplex virus type 1 (HSV-1) causes recurrent herpes labialis (cold sores), a common disease afflicting up to 40% of adults worldwide[10]. In addition to cold sores, the virus is also associated with ophthalmic infections, and herpes encephalitis. Five to thirty per cent of genital infections are caused by HSV-1 acquired through orogenital contact.[11]

Primary herpes simplex can be an extremely unpleasant and disabling infection. The lesions may appear anywhere on the skin or mucosa but are most frequent around the mouth, on the lips, on the conjunctiva and cornea, and on the genitalia. When oral ulceration is sufficiently severe to prevent eating or drinking, some patients, particularly children, have required admission to hospital.

Mild recurrent herpes simplex, particularly orofacial where the diagnosis is known, can be well managed with the over-the-counter anti-viral preparations. However, as detailed below, the self-diagnosis of the condition by an individual is not straightforward and in general, the population does not have the self-assessment capability to differentiate herpes labialis from other lesions. The experience in community pharmacy practice is that may often be mis(self)diagnosed. The differential diagnosis includes:

- in the primary infection a condition known as erythema multiforme, or occasionally a severe drug eruption.
- in secondary or recurrent herpes simplex bacterial infection such as impetigo or folliculitis, infected eczema or other inflammatory lesions including an insect bite, or allergic contact dermatitis.
- infected eczema can be recurrent and occur in the same areas affected by herpes simplex. This needs to be excluded, particularly on the face in children.
- an unusual presentation of a common infection is tinea of the face (tinea faceii). This can occasionally present as an acute pustular eruption in the moustache or beard area and needs to be considered.

The differential diagnosis for recurrent mucosal infections also includes aphthous ulcers in the mouth. Ulceration on the mucosal surface of the lower lip can be caused by squamous cell carcinoma. This needs to be excluded for any ulceration that has lasted more than one week.

[10]Lipsiitch M; Bacon T H; Leary J J; Anita R: Levin B R; *Effect of antiviral usage on transmission dynamics of herpes simplex type 1 and on antiviral resistance: predictions of mathematical models* Antimicrobial Agents Chemother 2000 Oct: 44 (10): 2824-35

[11] DeSimone E M. *Deramtologic side effects of medication* US Pharmacist 24:1 April 1997

Cold sore preparations are not recommended for application to mucous membranes, such as in the mouth, eye or vagina, as they may be irritant.

Summary

The Guild does not support his proposal and believes the current scheduling to be appropriate.

LORATADINE

Exempt from scheduling loratadine 10 mg or less in divided preparations for oral use in packs containing not more than 5 dosage units when used in children 6 -12 years of age for the treatment of seasonal allergic rhinitis.

Overview

The Guild does not support this proposal. The Guild does not believe it is in the public interest for loratadine indicated for use in children, to be available in general retail where there is no access to health professional advice.

The risks and benefits of the use of a substance

Sedating effect

Although loratadine is classified as a 'non-sedating' antihistamine, some studies have indicated that loratadine can have a negative effect on simple and choice reaction times, the respiratory muscle strength (RMS) and peak power amplitude of postural tremor, as well as autonomic cardiac regulation at 10mg doses. [12] [13] These studies suggest that taking non-sedating antihistamines to avoid the adverse reaction of drowsiness may not avoid unwanted motor control side-effects.[14]

The risk of cognitive impairment is also more likely when people take the medicine sporadically, as tolerance to these effects usually develop with regular use. There may be a greater risk that parents buying small packs of antihistamines from non-pharmacy outlets for their children are treating an acute condition and they may be unfamiliar with how the medicine affects their child and hence may be more susceptible to its adverse effects. Furthermore, other studies note that consecutive daily doses of loratadine cause an increase in tremor amplitude.[15]

In addition, when medicines are available for sale in general retail there are generally no controls or limits on the number of packs a consumer can purchase. This increases the risk of medicine misadventure. When loratadine is used at higher than recommended doses, there is an increased risk of impaired acuity and drowsiness.[16] These risks may be higher for young children.

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

Allowing loratadine medicines to be indicated for use in children's dosage in general retail, may lead to parents using loratadine products to treat their children for conditions other than allergic rhinitis such as

[12] Kavanagh, J. J., Grant, G. D., & Anoopkumar-Dukie, S. (2012). Low dosage promethazine and loratadine negatively affect neuromotor function. *Clinical Neurophysiology*, *123*(4), 780-786.

[13] Baumann-Birkbeck, L., Grant, G. D., Anoopkumar-Dukie, S., & Kavanagh, J. J. (2014). Drowsiness and motor responses to consecutive daily doses of promethazine and loratadine. *Clinical Neurophysiology*, *125*(12), 2390-2396.

[14] Kavanagh et al (2012).). Low dosage promethazine and loratadine negatively affect neuromotor function. *Clinical Neurophysiology*

[15] Baumann-Birkbecket al (2014). Drowsiness and motor responses to consecutive daily doses of promethazine and loratadine.

[16] DL Spangler & S Brunton; Efficacy and central nervous system impairment of newer-generation prescription antihistamines in seasonal allergic rhinitis; 2006 www.medscape.com/viewacticle/540559

dermatitis, soap allergies, insect bites or more severe undiagnosed allergies. As mentioned, when medicines are sold outside pharmacy, there is no access to health professional advice regarding diagnosis nor the appropriateness of particular treatments.

The extended period of use that would be enabled under this scheduling proposal, could result in a greater number of consumers self-medicating for undiagnosed conditions other than the product indications (allergic rhinitis).

The proposal may also result in confusion for consumers as there will be different pack sizes of loratadine based on the age of indication. Loratadine is currently exempt from scheduling in pack sizes up to 10 dosage units when indicated for ages 12 and up.

Summary

The Guild does not support this proposal.

ULIPRISTAL

Allow advertising of ulipristal by inclusion in Appendix H for emergency post-coital contraception.

Overview

The Guild does not support this proposal. The Guild has concerns that advertising would not be in the public interest.

Likelihood of inappropriate use

Allowing advertising may lead to an increase in the number of requests for this medicine from third parties (e.g. partners, relatives).

While pharmacists can make a professional judgement on whether an emergency contraceptive should be supplied to third parties, the professional guidelines state that face to face contact with consumers should be encouraged.[17]

The Guild notes that levongestrel, which has been available as an over the counter emergency contraception for more than 10 years is not listed on Appendix H. The Guild did not support listing of levonorgestrel on Appendix H at the time that it was made Schedule 3.

Summary

The Guild does not support this proposal.

[17] PSA guidelines – Standard 6 Indirect Pharmacy Services https://www.psa.org.au/downloads/standards/professional-practice-standards-v4.pdf

DIHYDROCODEINE

To reconsider whether the Schedule 2 and Schedule 3 entries for dihydrocodeine should be amended or deleted, in view of the recent reconsideration of codeine scheduling.

Consideration may be given as to whether all current Schedule 2 and Schedule 3 entries for dihydrocodeine should be rescheduled to Schedule 4, or other scheduling options. Other scheduling options include amending or deleting the Schedule 2 entry and amending or deleting the Schedule 3 entry, reducing the pack size, and the inclusion of a label warning that dihydrocodeine can cause addiction.

Overview

The Guild considers that Schedule 3 is the appropriate schedule for dihydrocodeine in low doses for the treatment of unproductive coughs.

The Guild's position is that the decision to upschedule medicines containing codeine to Schedule 4 will simply add to overall healthcare costs, restrict access to patients who use these medicines safely and effectively and will not address the misuse of these products by some patients.

The Guild believes upscheduling dihydrocodeine to Schedule 4 will simply exacerbate the issues raised above.

The risks and benefits of the use of a substance

In the TGA's codeine rescheduling Regulation Impact Statement, the following statements were made regarding over-the-counter (OTC) cough and cold medicines.

> *Between the years of 2009-2012, the TGA carried out a comprehensive review of the medical literature relating to the safety and efficacy of OTC medicines containing various substances for the symptomatic treatment of cough and cold in children aged less than 12 years. As a result of this review, the TGA concluded that there was a lack of evidence to support the efficacy of OTC cough and cold medicines in children under 12 years of age,* ***although there was no immediate safety risk associated with their use in adults.*** [18]

In addition, the TGA's database of adverse events notifications indicates there have been no reported incidences of abuse or dependence relating to Rikodeine ® (the only dihydrocodeine over-the-counter product currently registered on the Australian Register of Therapeutic Goods) in the past 6 years.[19]

There are currently no Schedule 2 products registered on the ARTG so changing this schedule will not have a material impact on access to medicines.

In the absence of conclusive evidence regarding misuse/abuse of dihyrocodeine products, a Schedule 3 classification remains appropriate.

As an additional safety measure, the Guild supports the introduction of mandatory warning labels to complement the advice provided by the pharmacist when the medicines is supplied.

[18] Therapeutic Goods Administration – Codeine re-scheduling Regulation Impact Statement, 17
[19] Database of Adverse Event Notification- medicines, accessed 1/02/2017

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

In the Schedule 3 classification dihydrocodeine products are indicated for the relief of stubborn unproductive cough. Such symptoms are generally associated with self-limiting conditions such as a cold or flu and symptoms generally dissipate within a few days which greatly reduces the likelihood of prolonged use. The intervention of a pharmacist will assist in referral to a medical practitioner if the cough is being caused by an underlying chronic condition and ensure these medicines are not provided to children.

Summary

In the absence of conclusive evidence regarding misuse/abuse of dihyrocodeine products, the Guild considers that Schedule 3 is the appropriate schedule for dihydrocodeine in low doses when indicated as a cough suppressant.

However as an additional safety measure, the Guild supports the introduction of mandatory warning labels to complement the advice provided by the pharmacist when the medicines is supplied.

[redacted]

Jared Brown
Manager
NSW Poisons Information Centre

[redacted]

10 February 2017
Advisory Committee on Medicines Scheduling
Therapeutic Goods Administration

Consultation: Invitation for public comment - ACMS meeting, March 2017
4. Delegate-initiated proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS) for scheduling advice.
To reconsider whether the Schedule 2 and Schedule 3 entries for dihydrocodeine should be amended or deleted, in view of the recent reconsideration of codeine scheduling. Consideration may be given as to whether all current Schedule 2 and Schedule 3 entries for dihydrocodeine should be rescheduled to Schedule 4, or other scheduling options. Other scheduling options include amending or deleting the Schedule 2 entry and amending or deleting the Schedule 3 entry, reducing the pack size, and the inclusion of a label warning that dihydrocodeine can cause addiction.

The NSW Poisons Information Centre (NSWPIC) provides a phone-based advice service on suspected poisonings to the public and health professionals calling from NSW, TAS and ACT on a near full-time basis and a shared after-hours service to the remainder of Australia. This results in approximately half of Australia's poisons-related calls being received by our Centre.

The NSWPIC supports further measures to decrease the potential for dihydrocodeine abuse and misuse. Cases of misuse/abuse of dihydrocodeine reported to NSWPIC have increased in recent years.

Table. Number of calls to NSWPIC relating to people who had misused or abused dihydrocodeine over the time period 1 January 2004 – 25 January 2017

Year	Misuse	Abuse	Misuse/abuse	Total
2004	0	0	0	0
2005	0	0	0	0
2006	0	0	0	0
2007	1	0	0	1
2008	0	0	0	0
2009	0	0	0	0
2010	0	0	0	0
2011	0	0	0	0
2012	2	1	0	3
2013	0	1	0	1
2014	0	2	0	2
2015	0	0	3	3
2016	1	2	2	5
2017*	0	0	0	0

Cases reported range from people using it for sleep, pain relief, abuse for opiate effects, to ensure they didn't have a cough. Doses range from 30-400ml. All but one case required hospitalisation.

If you required further analysis or information in relation to this data, please contact Jared Brown, NSW Poisons Information Centre on 02 9845 3969 or jared.brown@health.nsw.gov.au

Yours sincerely,

Jared Brown, FSHP MPH GradDipClinEpi(ClinTox) BPharm(Hons)

[redacted]

Consultation on proposed amendments to the Poisons Standard – for consideration by the Advisory Committee on Medicines Scheduling, March 2017

FEB
2017

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard referred to the March 2017 meeting of the Advisory Committee on Medicines Scheduling for scheduling advice.

PSA's comments relate to proposed amendments to loratadine, ulipristal and dihydrocodeine.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 29,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high quality continuing professional development, education and practice support to pharmacists;
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

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[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 July 2016 – 30 September 2016. At: **www.pharmacyboard.gov.au/documents/default.aspx?record=WD16%2f22249&dbid=AP&chksum=rnVoUMwwfTTCpKZCa53p7g%3d%3d**

[redacted]

Summary of PSA's position

Loratadine – *PSA does not support the proposal to extend the scheduling exemption for loratadine to include products to treat children 6–12 years of age.*

Ulipristal – *PSA does not support the inclusion of ulipristal in Appendix H due to the short period of experience of use as an S3 medicine.*

Dihydrocodeine – *PSA supports amending the scheduling of dihydrocodeine to: delete the S2 entry; amend the S3 and S4 entries to capture small and large pack sizes, respectively; and include a label warning on the potential to cause addiction.*

Comments on specific substances

Loratadine

Proposal to exempt from scheduling 10 mg or less in divided preparations for oral use in packs containing not more than 5 dosage units when used in children 6-12 years of age for the treatment of seasonal allergic rhinitis.

Seasonal allergic rhinitis is reported[2] to be one of the two most common respiratory conditions affecting an estimated 3.7 million Australians.

PSA understands this proposal is seeking to amend the current scheduling exemption for loratadine by extending it to include smaller pack sizes (no more than five dosage units) for use in children 6–12 years of age.

PSA's guidance[3] provided to pharmacists is that children aged less than 12 years with suspected first episode of hay fever should be referred to a medical practitioner. Further, parents may be unaware that medical advice should also be sought if symptoms are present indicating possible infection, or undiagnosed or uncontrolled asthma. Symptoms of seasonal allergic rhinitis in children can at times be confused with a pet allergy.[4]

PSA believes, therefore, that it is highly desirable that products for the treatment of seasonal allergic rhinitis in children 6–12 years of age are made available in a pharmacy environment where professional advice and intervention by pharmacists and trained staff are accessible.

Summary

PSA does not support the proposal to extend the scheduling exemption for loratadine to include products to treat children 6–12 years of age.

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2 Australian Institute of Health and Welfare. Australia's health 2014. Australia's health series no. 14. Cat. No. AUS 178. Canberra: AIHW; 2014.

3 Sansom LN, ed. Hay fever. In: Australian pharmaceutical formulary and handbook. 23rd edn. Canberra: Pharmaceutical Society of Australia; 2015. pp. 538–41.

4 Becker JM. Pediatric allergic rhinitis. 4 May 2016. At: **http://emedicine.medscape.com/article/889259-overview**

Ulipristal

Proposal to allow advertising by inclusion in Appendix H for emergency post-coital contraception.

Schedule 3 listing

The Schedule 3 (S3) classification of ulipristal became effective on 1 February 2017 for the indication of emergency contraception within 120 hours (five days) of unprotected sexual intercourse or contraceptive failure.

The reclassification decision[5] was confirmed in 2016 and based on factors including:

- substantial benefit for women in providing another emergency contraception option with the ability to be used up to five days after unprotected sexual intercourse
- toxicity is minimal in recommended dose
- S3 emergency contraception has been established in Australia for over a decade; there is no evidence of use outside of the intended or increased extent of use as a result of an S3 listing
- overall, benefit outweighs risk for proposed use.

Suitability of advertising

PSA supported the original application to reschedule ulipristal to S3 based on the reported safety and efficacy profiles of the substance as well as the potential for increased therapeutic options and the need for timely access for the indication.

As flagged in our 2016 submission, PSA developed education materials and tools to support pharmacists meet new requirements according to the 1 February 2017 implementation date for S3 ulipristal.

In relation to a proposal to include ulipristal in Appendix H, PSA is aware that there is a public health benefit argument that advertising to consumers could help achieve a reduction in unplanned pregnancies by promoting greater awareness of access and availability of S3 ulipristal.

However, given health professionals (including prescribers) and consumers are transitioning to the new mode of S3 availability, PSA believes it would be desirable to gain further experience of ulipristal in the S3 environment and allow some time to monitor outcomes of the rescheduling. Accordingly, PSA does not believe it is the most appropriate time to support advertising to consumers.

Summary

PSA does not support the inclusion of ulipristal in Appendix H due to the short period of experience of use as an S3 medicine.

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[5] Therapeutic Goods Administration. Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health. 27 Oct 2016. At: **https://www.tga.gov.au/sites/default/files/scheduling-delegates-final-decisions-july-2016_for_web_upload.pdf**

Dihydrocodeine

Proposal to reconsider whether the Schedule 2 (S2) and Schedule 3 (S3) entries for dihydrocodeine should be amended or deleted, in view of the recent reconsideration of codeine scheduling.

Consideration may be given as to whether all current S2 and S3 entries for dihydrocodeine should be rescheduled to Schedule 4, or other scheduling options – which include amending or deleting the S2 and S3 entries, reducing the pack size, and the inclusion of a label warning that dihydrocodeine can cause addiction.

PSA notes that dihydrocodeine is currently included (with various limits and conditions) in:

- Schedule 2 (S2) – when compounded with aspirin and no other therapeutically active substance in divided preparations

- Schedule 3 (S3) – when compounded with one or more other therapeutically active substances in divided and undivided preparations.

A search for dihydrocodeine S2 or S3 products on the Australian Register of Therapeutic Goods shows a single entry – *Rikodeine* (9.5 mg / 5 ml) oral liquid (dihydrocodeine compounded with sorbitol, although the latter is not listed as an active ingredient in the ARTG public summary document[6]) with approved indication for the relief of stubborn, unproductive cough.

In Australia, PSA is aware that the scheduling of dihydrocodeine was considered in the context of reviews of cough and cold medicines for children.

Some overseas regulators (e.g. the UK Medicines and Healthcare products Regulatory Agency) have previously considered codeine-containing analgesics and dihydrocodeine-containing analgesics together in determining strategies to minimise the risk of harm. Measures have included strengthening warnings on labels, limiting or removing indications for non-prescription use, reducing pack size and providing more information to consumers about signs and symptoms of addiction. In the UK these measures were applied equally to codeine- and dihydrocodeine-containing analgesics.

As an antitussive, dihydrocodeine is one of the options (e.g. also pholcodine, dextromethorphan and codeine) that may be used in adults for short-term relief. Cough suppressants are regarded to have limited or no efficacy relative to placebo in treating chronic cough.[7] Pharmacists are cognisant that these substances can pose a number of adverse effects ranging from constipation and sedation, to risk of dependence through prolonged use. Concerns relating to the misuse of dihydrocodeine liquid preparation have been present for many decades and appropriately managed by pharmacists when abuse is suspected.

Anecdotally, some pharmacists have observed and reported that dihydrocodeine provides a better therapeutic outcome for consumers with a dry stubborn cough, when compared to pholcodine or dextromethorphan use. In considering the potential outcome of dihydrocodeine

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[6] Therapeutic Goods Administration. Public Summary for ARTG Entry 10587. 2016;Nov. At: **www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=71A4B2E34451D145CA258064003CB276&agid=(PrintDetailsPublic)&actionid=1**

[7] Sansom LN, ed. Cough. In: Australian pharmaceutical formulary and handbook. 23rd edn. Canberra: Pharmaceutical Society of Australia; 2015. pp. 524–7.

being rescheduled to Schedule 4, PSA believes one of the likely negative outcomes will be the limited availability of alternative over-the-counter antitussive products. This would present a different outcome to the codeine rescheduling scenario where it was regarded that alternative non-prescription analgesics would continue to be readily available and therefore the impact on consumers would not be significant.

With an overall similar characteristic and safety profile, PSA accepts the reason for dihydrocodeine scheduling to be reassessed in light of the recent codeine rescheduling decision. Indeed, PSA has been unable to locate any information or evidence to warrant the application of different scheduling conditions to dihydrocodeine compared to codeine.

However, for the reasons outlined above, PSA suggests the other proposed scheduling options for dihydrocodeine have merit and would support the following:

- delete the S2 entry
- amend the S3 entry to include smaller pack sizes
- include a label warning on the potential to cause addiction
- amend the S4 entry to capture the larger pack sizes.

Summary

PSA supports amending the scheduling of dihydrocodeine to: delete the S2 entry; amend the S3 and S4 entries to capture small and large pack sizes, respectively; and include a label warning on the potential to cause addiction.

Submitted by:

Pharmaceutical Society of Australia
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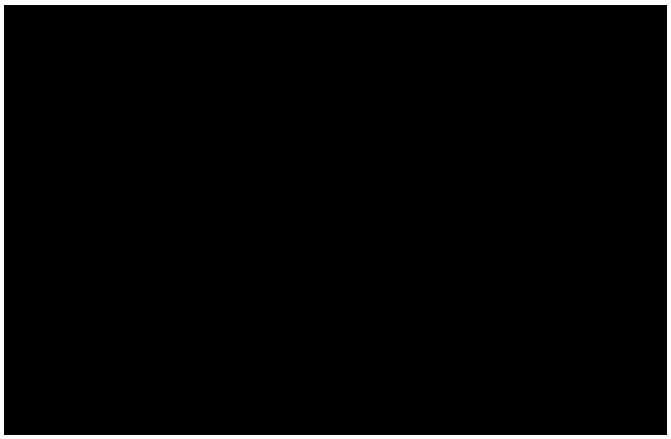
10 February 2017



Public Health Association of Australia submission on scheduling of Ulipristal Acetate

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Introduction

The Public Health Association of Australia

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups.

The PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

Vision for a healthy population

The PHAA has a vision for a healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and healthy environment, improving and promoting health for all.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Priorities for 2017 and beyond

Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. The aims of the PHAA include a commitment to:

- Advancing a caring, generous and equitable Australian society with particular respect for Aboriginal and Torres Strait Islanders as the first peoples of the nation;
- Promote and strengthen public health research, knowledge, training and practice;
- [redacted] ecologically sustaini[redacted]Australia, including tackling global warming, environmental change and a sustainable population;
- Promote universally accessible people centered and health promoting primary health care and hospital services that are complemented by health and community workforce training and development;
- Promote universal health literacy as part of comprehensive health care;
- Support health promoting settings, including the home, as the norm;
- Assist other countries in our region to protect the health of their populations, and to advocate for trade policies that enable them to do so;
- Promote the PHAA as a vibrant living model of its vision and aims.

Preamble

PHAA welcomes the opportunity to provide input to the Therapeutic Goods Administration (TGA) on the issue of advertising ulipristal acetate (or [redacted]) as an emergency contraception as part of the Appendix H – Schedule 3 poisons permitted to be advertised.

The PHAA advocates for the reduction of social and health inequities as an over-arching goal of national policy and as a key measure of our progress as a society. All public health activities and related government policy such as access to and awareness of emergency contraception options should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Health Equity

As outlined in the Public Health Association of Australia's objectives:

> *Health is a human right, a vital resource for everyday life, and a key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions of society that underpin people's health. The health status of all people is impacted by the social, political, and environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease.*

The PHAA notes that:

- Health inequity differs from health inequality. A health inequality arises when two or more groups are compared on some aspect of health and found to differ. Whether this inequality (disparity) is inequitable, however, requires a judgement (based on a concept of social justice) that the inequality is unfair and/or unjust and/or avoidable. Inequity is a political concept while inequality refers to measurable differences between (or among, or within) groups.[1]
- Health inequity occurs as a result of unfair, unjust social treatment – by governments, organisations and people,[2] resulting in macro politico-economic structures and policies that create living and working conditions that are harmful to health, distribute essential health and other public services unequally and unfairly, preventing some communities and people from participating fully in the cultural, social or community life of society.

Social Determinants of Health

The social determinants of health are the conditions in which people are born, grow, live, work and age, including the health system. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels, which are themselves influenced by policy choices. The social determinants of health are mostly responsible for health inequities – the unfair and avoidable differences in health status seen within and between countries. This is particularly pertinent when considering issues such as women's health policies.

The determinants of health inequities are largely outside the health system and relate to the inequitable distribution of social, economic and cultural resources and opportunities. Health inequities are the result of the interaction of a range of factors including: macro politico-economic structures and policy; living and working conditions; cultural, social and community influences; and individual lifestyle factors.

Advertising of ulipristal acetate for emergency contraception under Appendix H – Schedule 3 poisons permitted to be advertised

PHAA strongly encourages the TGA to allow advertising of ulipristal acetate within Appendix H – Schedule 3 poisons permitted to be advertised. This can ensure that women are more aware of their fertility control options following unprotected sexual intercourse. Increase awareness of such options remains in line with the right to access safe and appropriate health care[3] and supports the reduction of social and health inequities which should be an overarching goal of national policy. This is particularly pertinent when considering issues such as access to emergency contraception.

Advertising of ulipristal acetate therefore ensures the ability for appropriate and safe emergency contraception management from pharmacies and provides a framework for how ulipristal acetate can be provided to women in Australia.

Context of emergency contraception

- Approximately 200,000 unplanned pregnancies in Australia every year[4]
- Approximately 80,000 abortions are performed in Australia every year.[5]
- European research indicates that 30% of women will have unprotected sex over the course of a year with emergency contraception (EC) having been used by one in four (24%) of these women.[6]
- Given that no contraceptive method is 100% effective, greater awareness about EC options and fertility in Australia is required.

Increasing awareness about safe and accessible emergency contraception is an essential health service

In Australia, women currently have three EC options: Copper intrauterine device, levonorgestrel emergency contraceptive pill and the ulipristal acetate emergency contraceptive pill. However a majority of women in Australia have very little awareness, knowledge or access to these options.[7]

While a majority of women in Australia have heard of EC or the 'morning after pill' they have relatively poor understanding of where it can be obtained, how it works and its effects.[8]

Ovulation is unpredictable[9] and pregnancy risk varies markedly across the menstrual cycle,[10] – a risk factor which many women are unaware of.[11]

Contrary to myths about EC, international research demonstrates that awareness and access to EC does not make women more likely to engage in unprotected intercourse. Instead, awareness and access to EC an be a motivating factor for increasing women's knowledge about their fertility, and adoption of an on-going contraceptive method after using emergency contraception as well as increased or more consistent use of standard contraception.[12]

Further, women should be aware that no abortifacient effects amongst women have been reported following administration of emergency contraceptive pills at any dose.[13]

Increased awareness of emergency contraceptive options therefore helps to reduce the impact of unintended pregnancies on individuals and the broader health system[14] and the PHAA strongly advocates for increased awareness regarding access to safe and accessible emergency contraception.

Ulipristal acetate

PHAA also believe it is important that ulipristal acetate be permitted to advertise under Appendix H – Schedule 3 poisons permitted to be advertised as it has increased efficacy and a longer window of opportunity to prevent unintended pregnancy compared to other available EC options.

There is an extensive amount of evidence which evaluates the safety, efficacy and efficiency (in relation to a longer window of EC availability) of ulipristal internationally and within Australia.[15] Given ulipristal is appropriate to be used five days following unprotected sexual intercourse there is a significant benefit to women's health, and broader public health outcomes, in increased awareness of ulipristal acetate as an option through appropriate media.

Ulipristal acetate has been found to be more effective in preventing pregnancy in the first 24 hours than the other emergency contraceptive options currently available however, as a prescription is required for ulipristal acetate it is unlikely that many women will be able to access it within the recommended timeframe.

As ulipristal acetate being a Schedule 3 item, women are entitle to understand this option gives them a longer window of availability compared to levonorgestrel and therefore can prevent a greater number of unintended pregnancies.[16]

PHAA strongly advocates for health equity. Restrictions on the advertising of ulipristal acetate will impact some women disproportionately more than others. For example, women who are already at a disadvantage to accessing appropriate and timely health care due to living in rural areas, or from low socioeconomic backgrounds as well as women new to Australia who may be unaware and more hesitant in seeking a health professional for information about EC.

Conclusion

PHAA supports the inclusion of ulipristal within Appendix H. We are particularly keen that the following points are highlighted:

- Awareness of safe and accessible emergency contraception is an essential health service.
- Women should be able to access information about all forms of contraception (including emergency contraception) which should be affordable and accessible.
- Ulipristal acetate provides increased efficacy and a longer window of opportunity to prevent unwanted pregnancy compared to other available emergency contraception.

The PHAA appreciates the opportunity to make this submission. Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.

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