

PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD

Regulation 42ZCZL, Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary of the Department of Health and Ageing publishes herein all valid public submissions made in response to the invitation for public submission on the proposed amendments to the Poisons Standard. These submissions were considered by and the joint ACCS-ACMS #2 and the Advisory Committee on Medicines Scheduling (ACMS) #6 (June 2012 meetings).

In accordance with the requirements of subsection 42ZCZL of the Regulations these submissions have had the confidential information removed.

Material claimed to be commercial-in-confidence was considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Discrete submissions have been grouped by substance. A number of applicants provided submissions that related to multiple substances. These submissions on multiple items have been separately grouped.

LIST OF SUBMISSIONS

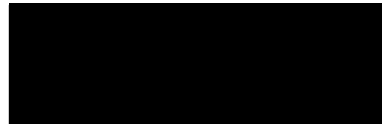
Substance	Total number of public submissions
Tylosin	2* submissions (1 submission under 'Submissions on multiple substances')
Tranexamic acid	1 submission
Ibuprofen and phenylephrine combination	4 submissions (2 submissions under 'Submissions on multiple substances')
Cetirizine	4 submissions (2 submissions under 'Submissions on multiple substances')
Omeprazole	3 submissions (2 submissions under 'Submissions on multiple substances')
Vibrio cholera/E. coli vaccine	4 submissions (2 submissions under 'Submissions on multiple substances')

Submissions on multiple substances

Substance	Total number of public submissions
Submissions on multiple substances	2 submissions: 1 submission on ibuprofen and phenylephrine, omeprazole, Vibrio cholera/E. coli vaccine and cetirizine. 1 submission on ibuprofen and phenylephrine, omeprazole, Vibrio cholera/E. coli vaccine, cetirizine and tylosin.

* One submission not published due to the commercial-in-confidence nature of the submission.

ACCS/ACMS
Tranexamic acid



■ May 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Dear Sir/Madam

**Public Comment Submission to the June 2012 joint-meeting of the
Advisory Committee on Chemicals Scheduling (ACCS) and the
Advisory Committee on Medicines Scheduling (ACMS)**

We refer to the notice published on 26 April 2012 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989*.



■ wishes to provide information on the following items for consideration at the June 2012 joint-meeting of the ACCS and ACMS:

- ■
- Tranexamic acid

Please see attached submission for details.



We look forward to further advice from the ACCS and ACMS. ■



Yours faithfully



ACCS/ACMS Joint-meeting: June 2012

Tranexamic acid

██████ supports the proposal to exclude tranexamic acid and its derivatives for non-therapeutic use from the current Schedule 4 entry.

Currently the Schedule 4 entry applies to all uses of tranexamic acid including cosmetic uses. ██████ believes that this is an inappropriate schedule entry for cosmetic uses. Substances used in cosmetics, if they are to be scheduled, should ideally be included in Schedule 5, 6 or 7, or Appendix C.

Tranexamic acid and its derivative cetyl tranexamate hydrochloride are used internationally in skin care products as skin conditioning and astringent agents. We are also aware that another tranexamic acid derivative, tocopheral tranexamate hydrochloride is used in oral care products (internationally). We are aware that some of our member companies have products on their international range containing cetyl tranexamic acid hydrochloride that they are not currently marketing in Australia due to the scheduling restriction.

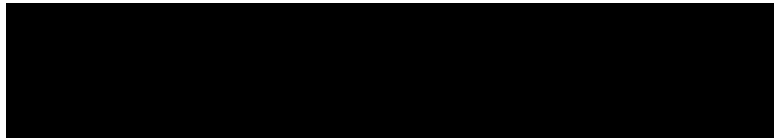
It is our understanding that toxicity information available for cetyl tranexamate hydrochloride indicates that the substance has low toxicity and low irritation potential.

Considering the low inherent toxicity of these derivatives of tranexamic acid and the fact that these products are readily available without prescription and without limitations in other economies such as the European Union and the USA for cosmetic use, we support exempting tranexamic acid and its derivatives from the Schedule 4 entry.

██████ suggests the following wording:

Schedule 4

TRANEXAMIC ACID **except** in cosmetic preparations



25th May 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

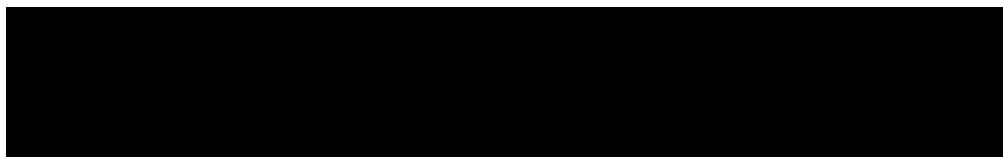
Dear Sir,

Re: Public Submission – under Reg. 42ZCZK of the Therapeutic Goods Regulations 1990. ACMS meeting, June 2012.

■ refers to the pre-June 2012 Scheduling meeting notice and we wish to comment specifically on the application to reschedule ibuprofen and phenylephrine from Schedule 2 to unscheduled when in divided preparations each containing 200 mg (or less) of Ibuprofen in fixed dose combination with 5 mg (or less) of Phenylephrine, in packs containing not more than 25 tablets. This consideration includes, but it is not limited to, restricting the entry for the treatment of adults and children aged 12 years of age and over. The comments below address a matter mentioned in section 52E of the Therapeutic Goods Act.

■ supports this rescheduling application, as it is logical. Each of the individual active ingredients at the proposed levels is already unscheduled in Australia and has been for at least seven years. The safety and efficacy of the proposed combination has already been assessed and approved by the Therapeutic Goods Administration (TGA) and deemed appropriate. The indication associated with this combination is 'Cold and Flu relief,' that are common illnesses and easily recognised by consumers. They are self-limiting, with symptoms generally present for three to four days for colds and six to eight days for influenza. They are illnesses which are suitable for self diagnosis and self-treatment by the consumer and they are not associated with protracted use. Therefore unlike pain management where treatment is either acute or chronic, colds and flu is short term, thus any abuse potential for this combination would not be any different to products that are currently available with the individual unscheduled active ingredients, such as ibuprofen, which is used for short term pain management.

Ibuprofen is a well established OTC Non Steroidal Anti-inflammatory medicine which has been available as unscheduled in Australia since January 2004. Ibuprofen was down scheduled to exempt status at the June 2003 NDPSC meeting when in divided preparations containing 200 mg or less of ibuprofen per dosage unit, in packs containing 25 or less dosage units, when ibuprofen is the only therapeutically active constituent other than an effervescent agent and when labelled with a maximum recommended daily dose of 1200 mg of ibuprofen.



Phenylephrine is a well established OTC sympathomimetic medicine with mainly direct effects on adrenergic receptors. Phenylephrine and its salts are most commonly used either topically or by mouth, for the symptomatic relief of nasal congestion. They are frequently included in preparations intended for the relief of cold and flu symptoms. The safety of Phenylephrine is well established, and has been available in scheduled as well as unscheduled Cold and Flu preparations both on its own, as well as in combination products for many years. In fact at the October 2005 NDPSC meeting, on the grounds of the safety profile of oral phenylephrine and on the basis of harmonisation with New Zealand, the NDPSC agreed to amend the current Schedule 2 entry for phenylephrine to increase the exemption for oral use to include preparations containing 50mg or less per recommended daily dose.

To further support that the proposed application is logical, it is important to note that at the June 2007 NDPSC meeting, the committee agreed to reschedule from Schedule 2 to exempt from Scheduling, Paracetamol (500mg or 1000mg) and Phenylephrine (10mg or 5mg) combinations based on the sound safety profile of these substances. Furthermore, it was noted that there was sufficient Australian market experience to support this down scheduling. The committee discussed that the two unscheduled substances should lead to the combination product also being unscheduled, unless there was a specific reason for this not to occur, especially given there was many years experience in the marketplace with this combination as a Schedule 2. In principle, this argument is no different to the proposed application. Like the re-scheduling application for Paracetamol (500mg or 1000mg) and Phenylephrine (10mg or 5mg), it is the current scheduling of ibuprofen that deems the proposed combination Schedule 2, as ibuprofen must be the only therapeutically active substance in order to be exempt, and this combination like the paracetamol and phenylephrine one, which also has had many years marketplace experience as a Schedule 2.

It is important to note that the scheduling framework in Australia is unlike the New Zealand requirements, which allows ibuprofen alone or in combination with another therapeutically active substance to be unscheduled. Thus the proposed combination in New Zealand is General sale, and this combination has been general sale since November 2004 Medicines Classification Committee meeting when the committee agreed to reclassify phenylephrine to general sale when containing not more than 50mg of phenylephrine per recommended daily dose. Therefore Trans Tasman harmonisation should also be a consideration for the ACMS when considering this application.

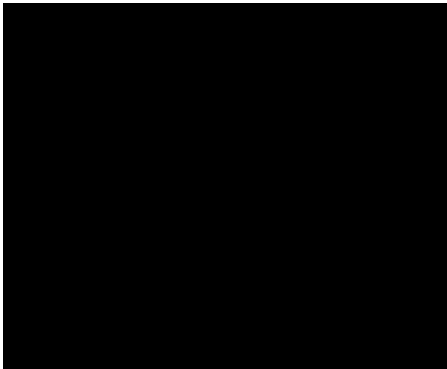
To further support the [REDACTED] established safety profile of the proposed combination, we wish to highlight that in June 2005, the NDPSC made a decision in the interest of Public health and safety to remove all pseudoephedrine-containing medicines from Schedule 2 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to S3 and above. The TGA adopted a modified approach to the registration of products that contain phenylephrine hydrochloride in place of pseudoephedrine. Although new combination products normally would require the safety and efficacy to be established first, the TGA were satisfied that ibuprofen and phenylephrine combinations at the levels proposed was not required to be submitted with specific safety and efficacy data.

In Conclusion, [REDACTED] supports the proposed application based on the following:

1. The safety and efficacy is well established and has had a few years experience as a Schedule 2 product
2. The individual active ingredients at the proposed levels are already exempt from scheduling
3. The indications associated with this combination is Cold and Flu which are self-limiting, suitable for self-treatment by the consumer and they are not associated with protracted use
4. The NDPSC decision that allowed paracetamol and phenylephrine combination to be exempt from scheduling in principle is no different to the proposed application.
5. Trans-Tasman harmonisation should be a consideration given the proposed combination is already General sale in New Zealand

The proposal to reschedule ibuprofen and phenylephrine from Schedule 2 to unscheduled is a logical application based on all of the above points. Please contact me if you have any further queries regarding the above.

Yours faithfully,

A large black rectangular redaction box covering the signature area.

[REDACTED]

Ibuprofen & phenylephrine.

24 May 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: SMP@health.gov.au

Invitation for public comment – ACMS meeting, June 2012

Ibuprofen and phenylephrine – Proposal to reschedule ibuprofen from Schedule 2 to unscheduled when in divided preparations each containing 200 mg (or less) of ibuprofen in fixed dose combination with 5 mg (or less) of phenylephrine, in packs containing not more than 25 tablets. This consideration includes, but is not limited to, restricting the entry for the treatment of adults and children aged 12 years of age and over.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] appreciates the opportunity to provide comment in relation to this issue. We wish to address relevant matters under section 52E of the Therapeutic Goods Act 1989 as these apply to the substances mentioned above: (a) risks and benefits; (c) toxicity; (d) labelling; (e) potential for abuse.

Introduction

Individually, Ibuprofen and Phenylephrine are both classified as Schedule 2 substances in the SUSMP, with scheduling exemptions for certain small pack sizes.

Relevantly, the current Ibuprofen Schedule 2 entry includes oral preparations when labelled with a recommended daily dose of 1200 mg or less, in divided preparations, each containing 200 mg or less of ibuprofen, in packs of not more than 100 dosage units. Smaller packs of up to 25 dosage units are unscheduled, in circumstances where Ibuprofen is the only therapeutically active constituent and prescribed labelling requirements are met.

Relevantly, the current Phenylephrine Schedule 2 entry excludes from scheduling oral preparations containing 50 mg or less of phenylephrine per recommended daily dose in packs containing 250 mg or less of phenylephrine.

[REDACTED]

Phenylephrine is also unscheduled when in combination with paracetamol and guaiphenesin when packed in blister or strip packaging or in a container with a child-resistant closure in packs of not more than 25 dosage units with the prescribed labelling requirements.

█ notes that the current policy in relation to the scheduling of products containing more than one poison is set out in the SUSMP under *Principles of Scheduling* as follows:

If a preparation contains two or more poisons, the provisions relating to each of the Schedules in which those poisons are included apply.

Where it is not possible to comply both with a provision relating to one of those Schedules and with a provision relating to another of those Schedules, the provision of the more restrictive Schedule applies, unless a contrary intention is indicated in the Schedules or relevant legislation.

Based on the above, and taking into account the scheduling exclusions, the combination of Ibuprofen and Phenylephrine ought to be exempted from scheduling when in compliance with the established restrictions for these ingredients.

This principle is the same as that applied in New Zealand. The 'Classification categories and criteria' page on the Medsafe website notes that "If the medicine has more than one active ingredient, the active with the most restrictive classification determines the classification of the product."

In New Zealand, Ibuprofen and Phenylephrine are individually available as general sale (unscheduled) medicines as follows:

Ibuprofen – for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack.

Phenylephrine - for nasal or ophthalmic use in medicines containing 1% or less; for oral use in medicines containing 50 milligrams or less per recommended daily dose and in packs containing 250 milligrams or less of phenylephrine per pack; except in medicines for the treatment of the symptoms of cough and cold in children aged 6-12 years

The combination of Ibuprofen and Phenylephrine as outlined in the scheduling proposal would therefore be available as an unscheduled medicine in New Zealand.

Overview

█ supports the rescheduling of and Ibuprofen/Phenylephrine combination consistent with current policy guidelines.

52E(1)(a) Risks and benefits – need to amend highlighted section

Ibuprofen and Phenylephrine both have a long history of safe use in Australia and both ingredients have well documented safety profiles.

The low risks associated with these ingredients are such that they are unscheduled in certain circumstances.

It is [REDACTED] position that the low risks individually associated with Ibuprofen and Phenylephrine will similarly be associated with a combination of the two.

In the absence of evidence demonstrating an increased risk associated with the combination, [REDACTED] therefore suggests that current policy in relation to scheduling of combination products be applied.

52E(1)(c) Toxicity

Ibuprofen and Phenylephrine both have well documented safety profiles and there is no evidence to show that combining the two actives will be associated with increased risk.

52E(1)(d) Labelling

[REDACTED] acknowledges that combination products may contribute to unintentional overdose (with consumers taking multiple products containing the same active). However, this is an issue that can adequately be dealt with through product labelling and would be best addressed by the regulator.

52E(1)(e) Potential for abuse

[REDACTED] is unaware of any evidence that Ibuprofen or Phenylephrine (either individually or in combination with each other) are associated with dependence, abuse or illicit use.

Summary

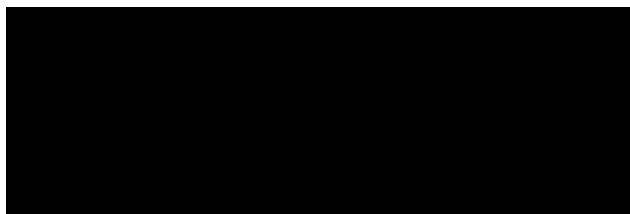
The current scheduling of Ibuprofen and Phenylephrine remains appropriate.

There is no evidence to suggest that a departure from scheduling policy is warranted for this particular combination.

We look forward to hearing the outcomes of the Committee's deliberations on this issue.

Yours faithfully,

[REDACTED]



25th May 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Dear Sir/Madam,

Re: Public Comment Submission under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 for the June 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS)

We refer to the pre-June 2012 scheduling meeting notice inviting public comment and [REDACTED] [REDACTED] wish to comment specifically on the application to reschedule cetirizine from Schedule 2 to exempt status.

[REDACTED] supports the proposal to reschedule cetirizine from Schedule 2 (Pharmacy Only) to exempt from scheduling status when in divided preparations of cetirizine for oral use containing 10 mg or less of cetirizine per dose in packs containing no more than 5 days supply for the short term treatment of seasonal allergic rhinitis (SAR).

The proposal to re-schedule cetirizine is logical given the recent exempt status for fexofenadine and loratadine, which are of the same class of second generation antihistamines and present low risk. The proposal in this application is aligned with the conditions allowed for exempt status for fexofenadine and loratadine, therefore it is important for the ACMS to consider the 'landscape' for second generation antihistamines when considering this application. Cetirizine is also exempt for scheduling in UK, Canada, US and New Zealand.

SUGGESTED SCHEDULING WORDING

Given this has come on the agenda due to trans-Tasman harmonisation we suggest the following scheduling wording for the SUSMP.

Schedule 2 – Proposed New entry/Amendment

CETIRIZINE in preparations for oral use **except** in preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when:

- (a) in a primary pack containing 5 dosage units or less; and
- (b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine



Schedule 4 – Proposed New entry/Amendment

CETIRIZINE in preparations for oral use **except:**

- (a) when included in or expressly excluded from Schedule 2

Cetirizine is a safe and effective treatment for adults and children over 12 years of age with SAR. This is a well known and acceptable OTC antihistamine and has been available in the Australian market place since 1993 with no significant safety issues. The rescheduling of cetirizine will allow for improved access for the treatment of SAR.

The recent exemption from scheduling of other second generation antihistamines from the same class (fexofenadine and loratadine) indicates the potential public need for ready access to treatment for their allergic conditions. Patients already have an awareness of their allergic conditions (particularly with SAR) and/or knowledge of how to manage these allergies with little help or counselling from a pharmacist or doctor, as recognised by the ACMS and the TGA delegate. The down scheduling of cetirizine will allow for a greater number of treatment options, especially for those consumers that may not find fexofenadine and loratadine appropriate for their needs.

Overall, cetirizine 10 mg per day has a favorable benefit-to-risk profile as an exempt from scheduling medicine for treating symptoms of SAR. Extensive experience with cetirizine, encompassing more than 25 years of worldwide use both as a prescription medicine and as an OTC medicine (including General sale) supports the safety of cetirizine. General sale status has been allowed in Canada since 1995, UK since 2002, US since 2007 and NZ since 2012 with no significant issues relating to safety, and the benefits outweigh any risks. Cetirizine has been available as a Schedule 2 medicine in Australia for approximately 13 years. This OTC experience includes dosages equal to those proposed in this application and in patients with significant medical conditions. A review of the post-marketing experience in Australia, as well as in countries where cetirizine is available both as OTC as well as General sale confirms the safety of this drug and its appropriateness as a candidate for exempt from scheduling. A number of clinical trials demonstrate cetirizine to be effective in treating SAR, an approved indication. The safety risk of inadvertent or intentional overdose appears to be minimal.

The excellent safety profile of cetirizine has been established through many clinical trials and more than 25 years of post marketing experience by adults and children in 132 countries as both a Prescription Only and OTC drug product (including General sale). The safety profile generated from both clinical trials and in post-marketing surveillance since 1986 indicate that the drug is suitable for General sale use. Overall, the adverse event profile of cetirizine demonstrates that it is a well tolerated drug. Most reported adverse events were mild to moderate in nature. The benefit of cetirizine available as an exempt for scheduling medicine significantly outweighs the risk.

CONCLUSION

■ supports the proposal to reschedule cetirizine from Schedule 2 (Pharmacy Only) to exempt from scheduling status when in divided preparations of cetirizine for oral use containing 10 mg or less of cetirizine per dose in packs containing no more than 5 days supply for the short term treatment of SAR.

The recent exemption from scheduling of other second generation antihistamines from the same class (fexofenadine and loratadine) indicates the potential public need for ready access to treatment for their allergic conditions. SAR can have a detrimental effect on a patients' quality of life. Despite severe symptoms, people with SAR tend not to seek medical advice regarding treatment. Patients already have an awareness of their allergic conditions (particularly with SAR) and/or knowledge of how to manage these allergies with little help or counselling from a pharmacist or doctor, as recognised by the ACMS and the TGA delegate.

The safety and efficacy of cetirizine is well established and the benefit of cetirizine available as an exempt from scheduling medicine significantly outweighs the risk. Re-scheduling cetirizine is logical given the recent exempt status for fexofenadine and loratadine, which are of the same class of second generation antihistamines and present low risk.

Cetirizine is available as a General Sale medicine in UK, Canada, US and New Zealand. In Canada and New Zealand all second generation antihistamines are aligned in terms of sedation, and in the UK cetirizine and loratadine are aligned.

Previous NDPSC have acknowledged that the available evidence indicates that 10 mg cetirizine showed minimal sedative effects which is comparable to 10 mg loratadine. Having demonstrated a comparable CNS impairment/sedating potential at the 10 mg dose, cetirizine in presentations up to 10 mg merits comparable scheduling requirements as loratadine 10 mg.

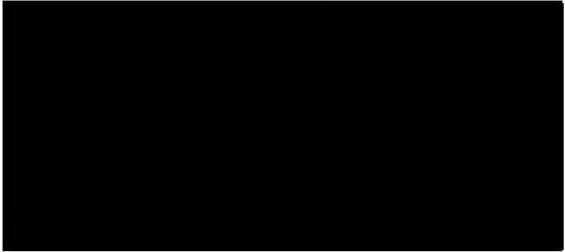

It is important for the ACMS to consider the 'landscape' for second generation antihistamines when considering this application.

Please contact me if you have any further queries regarding the above.

[REDACTED]

SUPPORTING DATA DETAILS

[REDACTED]

18th May, 2012

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: SMP@health.gov.au

Dear Sir,

Re: Public Submission – under Regulation 42ZCZK of the Therapeutics Goods Regulations 1990 – ACMS Meeting June 2012


In reference to the pre-June 2012 Scheduling Meeting notice inviting public comment, please find below commentary relating specifically to the scheduling proposal for cetirizine as outlined below:

Cetirizine – Proposal to re-schedule from Schedule 2 to unscheduled to harmonise with New Zealand. This consideration includes divided forms of cetirizine for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose in packs containing 5 days supply for the treatment of seasonal allergic rhinitis.

We note that the ACMS has recently rescheduled 2 non-sedating antihistamines (loratadine and fexofenadine) from Schedule 2 to unscheduled medicines. However, we would like to bring to the attention of the committee that these products differ from cetirizine. Unlike fexofenadine and loratadine, cetirizine is not categorized as a non-sedating antihistamine and is not excluded under Antihistamines in RASML from carrying a sedation warning statement.

According to RASML, cetirizine is required to include either of the following warnings:

This medication may cause drowsiness. Avoid alcohol. If affected do not drive a vehicle or operate machinery. OR This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.



We believe that these warning statements need to be taken into account when considering the benefit/risk of rescheduling cetirizine to be included as an unscheduled medicine.

[Redacted signature block]

Yours sincerely,

[Redacted signature block]

[Handwritten mark]

[REDACTED]

The Secretary,
Medicines and Poisons Scheduling Secretariat (MDP88)
GPO Box 9848
CANBERRA ACT 2601

25 May 2012

[REDACTED]

[REDACTED]

Dear Sir/Madam,

**Re: Invitation for public comment - ACMS and ACCS meetings, June 2012
Proposed amendments referred by the delegate for scheduling advice for
consideration by the Advisory Committee on Medicines Scheduling (ACMS)
Omeprazole - Proposal to amend the current Schedule 3 omeprazole entry to increase
the maximum allowed pack size from 14 to 28 dosage unit.**

[REDACTED] refers to the notice inviting public submissions under Regulation 42ZCZK of the Therapeutic Goods Regulations 1990 in relation to the June 2012 meeting of the Advisory Committee on Medicines Scheduling (ACMS). [REDACTED] would like to provide comment in relation to the proposed amendment to the current Schedule 3 omeprazole entry to increase the maximum allowed pack size from 14 to 28 dosage units referred by the delegate for scheduling advice.

[REDACTED] wishes to take this opportunity to indicate that it opposes the proposed amendment to the current scheduling of omeprazole to increase the maximum number of dosage units available under Schedule 3 and considers the current schedule to be appropriate i.e. omeprazole 20 mg or less, in packs containing no more than 14 dosage units (equivalent to 14 day's supply) in Schedule 3.

Omeprazole is approved for the relief of heartburn and other symptoms of Gastro-oesophageal reflux disease (GORD) as short-term use in the over-the-counter (OTC) setting when recommended by a pharmacist. [REDACTED] considers OTC therapy with a Proton Pump Inhibitor (PPI) should be limited to those patients with mild symptoms likely to respond to the lowest effective dose. Patients with an unsatisfactory response to short term OTC PPI therapy should be referred to a physician for further assessment to eliminate the possibility of more serious underlying disease. GORD is a chronic relapsing disease as a result of the inappropriate relaxation of the lower oesophageal sphincter. If left untreated it can develop into erosive oesophagitis and other complications such as oesophageal strictures, oesophageal ulcers, Barrett's oesophagus and oesophageal carcinoma. Patients with GORD presenting with typical reflux symptoms may have either symptomatic non-erosive reflux disease (without mucosal damage) or erosive oesophagitis (with mucosal breaks). As the symptom severity of GORD does not correlate with the disease severity, proper evaluation and management by a healthcare professional is considered necessary to ensure the best health outcomes for patients.

There are readily available alternative treatments for the relief of the symptoms of heartburn which can be used by patients for the self management of their condition. However, should a

The currently approved Product information for LOSEC states 'oral dosing with omeprazole 20 mg once daily provides rapid and effective reduction of gastric acid secretion. After a single dose the onset of antisecretory effect occurs within one hour and is maximal within 2 hours. With repeated once daily dosing the maximum effect is usually achieved within 4 days of commencing treatment.' In consideration of this it would seem that 14 days therapy would appear to be sufficient to provide relief of simple heartburn or other symptoms of gastro-oesophageal reflux disease. A patient requiring treatment with a PPI in excess of 14 days should be investigated to eliminate the possibility of a more serious underlying disease state.

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████████████████████

Vibrio cholera and E.coli.



11/05/2012 01:26 PM

To <SMP@health.gov.au>

cc

bcc

Subject re proposal to down schedule cholera vaccine [SEC=No Protective Marking]

DOCUMENT NOT YET CLASSIFIED

To whom it may concern

We are very concerned regarding the following proposal:

Vibrio cholera and
enterotoxigenic Escherichia
coli vaccine

Proposal to down-schedule cholera vaccine from Schedule 4 to Schedule 3 to harm
Zealand. This consideration includes a new specific entry for both vibrio cholera v
enterotoxigenic Escherichia coli vaccine in Schedule 3.

[REDACTED] I strongly recommend against implementing this down-schedule for
the following reasons:

- 1) The risks and benefits of any vaccine, regardless of route of administration, need to be discussed with a medical practitioner well-versed in this area. Pharmacists and/or their assistants are neither trained nor placed, to offer appropriate pre-travel health advice to intending travellers.
- 2) The reasons to use this vaccine need to be appropriate to the destination, rather than utilised on self-perception whether this be over the internet or well-meaning but often inaccurate and inappropriate advice of friends. Pharmacists or their assistants are neither trained nor placed, to offer appropriate pre-travel health advice.
- 3) There are a number of precautions, contraindications and interactions with this particular vaccine which require medical input, based on the individual's medical history and needs. For example, antibiotics may inactivate this vaccine. Certain other medicines cannot be used at the same time or within a given time period. The children's dose is complex to formulate and dispense.
- 4) [REDACTED] with this vaccine, the formulation and dosage can easily be mistakenly performed by the patient without appropriate medical or nursing supervision.
- 5) It is important to note that the vaccine is not 100% effective for both cholera and E Coli. Without appropriate discussion, travellers would be under the false assumption they would be fully covered.
- 6) WHO no longer recommend cholera vaccination for any traveller (other than rare high risk situations). A vaccine offering partial cover for both cholera and E Coli would result in confusion to the average individual.
- 7) If this medication were to become schedule 3, ie 'over the counter', there is no doubt that

inappropriate or inaccurate use would ensue, with consequent harm to the individuals and leave the dispensing pharmacy open to legal action. Appropriate informed consent for use of any vaccine, whether parental or oral, can only take place in a medical setting.

Based on the potential for both increased risk and harm associated with this vaccine, as well as the great complexities associated with dispensing this vaccine, we therefore strongly recommend against alteration of the schedule of this medication. Vaccination should only occur associated with an appropriate medical consultation.

I am available should you wish to discuss this further.

Sincerely

[REDACTED]

DOCUMENT NOT YET CLASSIFIED



10/05/2012 10:38 AM

To "'SMP@health.gov.au'" <SMP@health.gov.au>

cc

bcc

Subject Comment on proposal to reschedule [REDACTED] vaccine [SEC=No Protective I

DOCUMENT NOT YET CLASSIFIED

Thankyou for the opportunity to comment on the proposal to reschedule [REDACTED] vaccine, in order to harmonise with a change of scheduling in New Zealand.

[REDACTED] working in the field for more than 20 years, [REDACTED]
[REDACTED] I think this would be an inappropriate rescheduling, and should not be implemented.

Firstly, the principle of changing just to harmonise with New Zealand is obviously fundamentally flawed, as the context in which NZ made their decision is completely different to the Australian setting. They have a major manpower and distribution problem of GPs, a very influential pharmacy lobby, they have a listed indication for traveller's diarrhoea (TD) and have not considered the public health aspects in relation to their decision.

More importantly, the use of an important vaccine to be divested to pharmacists is a significant policy shift with deep implications.

The Dukoral vaccine is a cholera vaccine, specifically indicated for the prevention of cholera. The at-risk populations for cholera are however very specific, and this has a very limited and specific application. This application is not widely understood by many GPs, let alone pharmacists. In general, it should be prescribed after a formal risk-assessment, as would be expected as part of a travel medicine consultation. Inappropriate prescribing of cholera vaccine remains widespread globally, as many prescribers do not understand the actual epidemiology or risk to humans.

This principle applies to all travel-related vaccines, that is their recommendation should be only made after a detailed assessment of an individual's health and immune status, detailed review of risk of exposure accounting for activity, location and time, as well as their understanding of behavioural change for risk-mitigation. Pharmacists are not trained to do this level of assessment.

To suggest that the vaccine should be made available because it has a role to play in reducing traveller's diarrhoea is even more complex. The fact that ETEC and cholera share a toxin is fortuitous, not deliberate. The overall rate of TD reduction is only of the order of 20%, quite short-lived in effect, and it varies based on the rates of ETEC as a cause of TD in various locations. This means that the indication for this purpose is highly selective, as only those people where significant co-factors increasing risk will gain potential benefit from the vaccine.

The opportunity for inappropriate use of prescribing is obvious. This is quite likely in the setting of pharmacy prescribing, as the detailed risk-benefit assessment will not be done.

The rescheduling of this travel and public health vaccine to a pharmacy product is entirely inappropriate and irresponsible.

[REDACTED]

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DOCUMENT NOT YET CLASSIFIED

MAY
2012

Purpose

Recommendations

1. **Ibuprofen and phenylephrine.** [REDACTED] is firmly opposed to the proposal to reschedule ibuprofen from Schedule 2 to unscheduled when in divided preparations each containing 200 mg (or less) of ibuprofen in fixed dose combination with 5 mg (or less) of phenylephrine, in packs containing not more than 25 tablets regardless of any proposed restrictions on use by age.
2. **Omeprazole.** [REDACTED] does not support the proposal to amend the current Schedule 3 entry to increase the maximum allowed pack size from 14 to 28 dosage units.
3. **Vibrio cholera and enterotoxigenic *Escherichia coli* vaccine.** [REDACTED] supports the proposal to reschedule cholera vaccine from Schedule 4 to Schedule 3.
4. **Cetirizine.** [REDACTED] does not support the proposal to reschedule from Schedule 2 to unscheduled including divided forms for oral use containing 10 mg (or less) of cetirizine hydrochloride per dose in packs containing five days supply for the treatment of seasonal allergic rhinitis.

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[REDACTED]

Ibuprofen and phenylephrine

Australian consumers have access to many ibuprofen-containing products, both single active ingredient preparations and combination products, for short term analgesia and cough and cold treatment. With a plethora of available products the risk of inappropriate use of ibuprofen is increased for example through duplication of ibuprofen-containing doses from the use of multiple medicines.

While some risk might be minimised with appropriate labels on the pack, from a quality use of medicines perspective, [REDACTED] believes pharmacists and trained pharmacy staff have an important role in assisting consumers with appropriate use and optimal outcomes.

[REDACTED] therefore firmly opposes any proposal to reschedule ibuprofen from Schedule 2 to unscheduled in fixed dose combination with phenylephrine.

Omeprazole

Non-prescription medicines for the treatment of heartburn and symptoms of gastro-oesophageal reflux disease (GORD) are widely available to Australian consumers with proton pump inhibitors (PPIs) being regarded as first line therapy and considered to be more effective than histamine-2 receptor antagonists. Omeprazole is currently included in Schedule 3 (S3) for this purpose.

█ provides professional practice guidance to pharmacists on a number of S3 products. The guidance documents are based on available evidence and specific for the approved indication for S3. For omeprazole, guidance statements provided to pharmacists include the following:¹

- For initial therapy, a two week course of PPI is recommended at the following dose: omeprazole 20 mg once daily.
- Referral is recommended if long term use or a higher dose is required.
- Referral for further investigation is recommended if two weeks of continuous therapy with a PPI has failed to adequately control symptoms, or symptoms recur following an initial course of therapy.
- The patient should be advised to see their doctor if they start to exhibit any alarm symptoms or if symptoms persist or recur after completing a two week course of a PPI.

Generally for GORD presentations in the community pharmacy setting, the recommended treatment with omeprazole is 20 mg once a day for seven to 14 days. If symptoms persist or if relapse occurs after 14 days, further investigation is recommended.² Therefore the usual circumstances for S3 supply by pharmacists would not warrant the provision of a 28 dosage unit pack.

PPIs are generally well tolerated, however there have been reports of increased rate of community-acquired pneumonia and a two- to three-fold increase in risk of *Clostridium difficile* infection.³ While these possible adverse effects are likely to be more pertinent for the use of PPIs at higher doses and/or long term, the risk of *C. difficile* infection may be a noteworthy caution given reports of an increase in rate overseas and evidence of a new strain of *C. difficile* in Australia.⁴

In summary, █ does not support the proposal to amend the maximum allowable pack size for S3 omeprazole to 28 dosage units.

¹ Pharmaceutical Society of Australia. Guidance for provision of a *Pharmacist Only* medicine: proton pump inhibitors. November 2011.

² Biscopoulos D (Managing Ed.). AusDI Advanced. Phoenix Medical Publishing Pty Ltd. May 2012.

³ National Prescribing Service. Pharmacy practice review: a counselling and action resource. Quality use of prescription PPIs. April 2009.

⁴ Stuart RL, Marshall C. *Clostridium difficile* infection: a new threat on our doorstep. MJA, 194: 331–2 (2011).

Vibrio cholera and enterotoxigenic *Escherichia coli* vaccine

Intestinal infection with *Vibrio cholerae* leads to cholera, an acutely dehydrating, watery diarrhoeal disease. Cholera remains a global public health problem. Enterotoxigenic *Escherichia coli* is reportedly the most common cause of bacterial diarrhoea in developing countries. Both are spread via contaminated water or foods.

In Australia, cholera vaccine is available for active immunisation for individuals who will be visiting areas epidemic or endemic for cholera and who are at high risk of infection. The Australian Immunisation Handbook⁵ does not recommend routine cholera vaccination for travellers but suggests immunisation should be considered for:

- people at increased risk of diarrhoeal disease (eg. those with achlorhydria); and
- people at increased risk of severe or complicated diarrhoeal disease (eg. those with poorly controlled or otherwise complicated diabetes, inflammatory bowel disease, HIV/AIDS or other conditions resulting in impaired immunity, significant cardiovascular disease); and

it could also be considered for humanitarian disaster workers.

The product is regarded to have a good safety profile with no significant side effects.

With good access for consumers, community pharmacies are an ideal site to provide travel health advice. Many consumers often do not seek pre-travel health advice and leave their vaccinations and planning until the last minute. Pharmacists would be equipped to provide cholera vaccines as well as other travel advice including prevention of venous thromboembolism, staying healthy while travelling and minimising health risks, travelling with medicines, and good hygiene and sanitation practices. The provision of additional travel health advice is important to ensure travellers do not rely on vaccination alone.

█ notes that the Medicines Classification Committee in New Zealand recently agreed to reschedule vibrio cholera and enterotoxigenic *E. coli* vaccine from prescription medicine to restricted medicine (equivalent to Pharmacist Only Medicine in Australia) on condition that appropriate educational material and campaign for pharmacists was established.⁶ █ recommends a similar arrangement be approved in this country and would seek to work with relevant product sponsors to deliver an appropriate education package.

█ supports the proposal to reschedule cholera vaccine to Schedule 3.

⁵ National Health and Medical Research Council. The Australian Immunisation Handbook, 9th ed. Canberra, ACT: Australian Government (2008). Available at: www.immunise.health.gov.au

⁶ Minutes of the November 2011 Medicines Classification Committee meeting. Available at: www.medsafe.govt.nz/profs/class/mccmin15nov2011.htm

Cetirizine

Seasonal allergic rhinitis (SAR) is a common presentation in community pharmacy with around 15 per cent of the Australian population (or about 3.1 million people) affected by the condition.⁷ The condition can usually be recognised by consumers and is suitable for short-term, self-treatment and there are many over-the-counter products available to effectively manage these symptoms. Allergic rhinitis (AR) can, however, be caused by other allergens such as chemicals or environmental allergens and individuals can display symptoms all year round. Allergic rhinitis is also one of the most prevalent allergic disorders and has links with conditions such as asthma.

The current Schedule 2 (S2) entry allows consumers to treat SAR by having timely access to cetirizine and from an environment where professional advice and intervention can be provided at the time of purchase of the product. To improve self management of SAR by consumers, pharmacists can also discuss strategies and tips on avoiding exposure to allergens which trigger symptoms.

Consumers can sometimes confuse symptoms of colds with SAR and also it is possible that some may continue to treat non-seasonal AR. These scenarios are common in the community pharmacy setting and supports this environment as being appropriate as it provides opportunities for follow-up and monitoring and, when necessary, referral to a medical practitioner. [REDACTED] does not believe an unregulated environment is in the best interests of consumers seeking optimal health outcomes. For example, long term AR if not treated appropriately can have an impact on performance and productivity in every day life and therefore quality of life.

An important consideration is that second generation antihistamines are usually marketed with an emphasis on the 'non-drowsy' profile when in fact, most should be regarded as 'less sedating' as sedation is experienced in approximately 10 per cent of patients.⁸ Of particular concern to [REDACTED] is that there are reports indicating:

- cetirizine, at therapeutic doses, causes an increase in sedation, decreased psychomotor function and worsening cognitive function;⁹ and
- cetirizine was three and a half times more likely to result in reports of sedation than loratadine.¹⁰

These reports are consistent with the inclusion of cetirizine in the current *Standard for the uniform scheduling of medicines and poisons* (Poisons Standard 2011)¹¹ at Appendix K which is a list of human medicines required to be labelled with a warning regarding their sedation potential.

The possibility of drowsiness and impact on cognition should be a key point emphasised to consumers through a pharmacy setting and not just through mandatory warning statements on the packaging.


⁷ Australian Institute of Health and Welfare. Allergic rhinitis ('hay fever') in Australia. Cat. no. ACM 23. Canberra: AIHW; November 2011.

⁸ Sansom LN, ed. Australian pharmaceutical formulary and handbook. 22nd edn. Canberra: Pharmaceutical Society of Australia, 2012.

⁹ Lehman JM, Blaiss MS. Selecting the optimal oral antihistamine for patients with allergic rhinitis. *Drugs*. 66: 2309–19 (2006).

¹⁰ Mann RD, Pearce GL, Dunn N, Shakir S. Sedation with "non-sedating" antihistamines: four prescription-event monitoring studies in general practice. *BMJ*, 320: 1184–7 (2000).

¹¹ Available at: www.comlaw.gov.au/Details/F2011L01612



Pharmacists will also have a role in reducing the risk of falls (as a consequence of sedation and drowsiness) particularly in the elderly, and advice broadly about avoiding alcohol. Access to non-prescription medicines from community pharmacies where professional intervention is available has been shown to help avoid adverse events and further costs to the health care system.¹²

██████ believes the current scheduling arrangements for cetirizine should be retained from a patient safety perspective. Further, pharmacists and trained pharmacy staff can provide advice to consumers to assist with optimal use of cetirizine and suggest other strategies to minimise exposure to allergens.

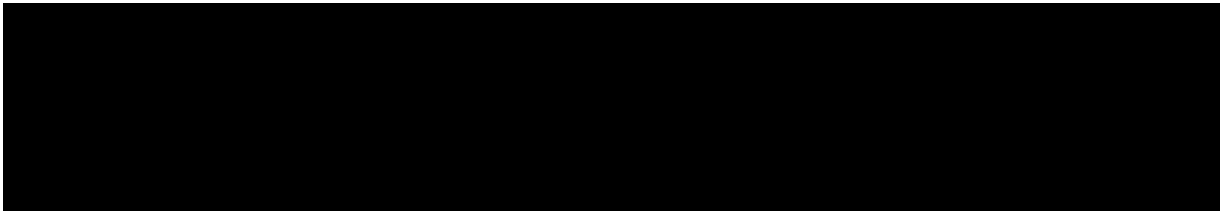
In summary, ██████ is firmly opposed to the proposal to reschedule cetirizine from S2 to unscheduled.

¹² Williams KA et al. Non-prescription medicines and Australian community pharmacy interventions: rates and clinical significance. *Int J Pharm Pract* (2011). Doi: 10.1111/j.2042-7174.2010.00091.x

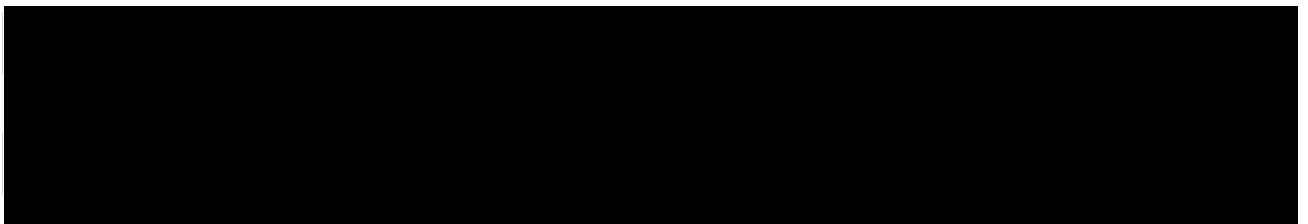
Submission on multiple substances.



Advisory Committee for Medicines Scheduling Meeting of 4-5 July 2012



Closing date for submission – 25 May 2012



Background

[REDACTED] welcomes the opportunity to comment on proposed amendments to the Standard for the Uniform Scheduling of Medicines and poisons (SUSMP) being considered by the Advisory Committee on Medicines Scheduling (ACMS) at its meeting of 4-5 July 2012.

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Comments on Proposed Amendments

[REDACTED] has considered the proposed amendments to the SUSMP of relevance to community pharmacy, with particular reference to Section 52E(1) of the Therapeutic Goods Act 1989 and the current Scheduling Policy Framework⁹. We provide comments for the following proposed amendments in line with the rationale for our position provided above:

1. Ibuprofen and phenylephrine
2. Omeprazole
3. Vibrio cholera and enterotoxigenic E-coli vaccine
4. Cetirizine
5. [REDACTED]
6. Tylosin

[REDACTED]

⁹ NCCTG Scheduling Policy Framework for Medicines and Chemicals – Effective date 1 July 2010

[REDACTED]

1. **Ibuprofen and phenylephrine – Proposal to reschedule ibuprofen from Schedule 2 to unscheduled when in divided preparations each containing 200 mg (or less) of ibuprofen in fixed dose combination with 5 mg (or less) of phenylephrine, in packs containing not more than 25 tablets. This consideration includes, but it is not limited to, restricting the entry for the treatment of adults and children aged 12 years of age and over.**

██████ does not support any scheduling exemption for medicines containing ibuprofen or phenylephrine, either as a single ingredient or in combination. Neither medicine can be regarded as innocuous, both having significant health risks which warrant facilitating access to pharmacist advice. These risks are accentuated in combination products.

Phenylephrine

Although the use of phenylephrine as a nasal decongestant has significantly increased over recent years due to greater restrictions on supplying the more effective decongestant pseudoephedrine, the use of phenylephrine is not risk free. It may interact with heart or blood pressure medicines, antidepressants, diabetes medicines, migraine headache medicines and other decongestants. It should be used with caution under medical advice in people with heart disease, heart rhythm disorder, high blood pressure, circulation problems, diabetes, glaucoma, thyroid disorders, kidney disease, enlarged prostate or urination problems, anxiety, sleep disorders, bipolar disorder or other mental illness.¹⁰

Ibuprofen

Analgesic nephropathy, which can result in permanent kidney damage, occurs in approximately four out of 100,000 people, primarily from self-medication.¹¹ The US National Kidney Foundation advises that non-steroidal anti-inflammatory drugs (NSAIDs), including ibuprofen, should be avoided in consumers with decreased kidney function, and only used under a doctor's care by people with kidney disease, heart disease, high blood pressure, liver disease, people who are over 65 years of age or who take diuretics.¹²

It has been estimated that as many as 1 in 7 Australians aged 25 years and over have some degree of chronic kidney disease, which in 2007-08, contributed to 15% (nearly 1.2 million) hospitalisations.¹³ Indigenous and older Australians appear to be at a greater risk of chronic kidney disease.

People who take ibuprofen in combination with certain blood-pressure medicines, ACE inhibitors (ACEI) or angiotensin II receptor antagonists (A2RA) and diuretics, are at risk of a 'triple whammy' effect, which may predispose vulnerable patients to renal failure. Risk factors for the triple whammy include advanced age, pre-existing renal impairment and dehydration. These blood-pressure medicines are some of the most commonly prescribed medicines in Australia, in particular for older Australians. An analysis of prescriptions for combination products (ACEI + diuretic or A2RA + diuretic) dispensed from June 2010 to July 2011 under the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) showed that there were nearly 6 million prescriptions dispensed for concessional and veteran patients – see Attachment 1. [NOTE – for ease of analysis, it has been assumed that concessional and veteran patients consist predominantly of older Australians]

Assuming this equates to 12 prescriptions per patient over the 12 month period, approximately 500,000 high-risk patients are at additional risk of impaired renal function from combining their blood pressure medicine with ibuprofen. This has not even taken account of high-risk patients who also take ACEIs or A2RAs and diuretics as separate medicines or those who also take prescription NSAIDs.

More and more evidence is being discovered regarding the link between NSAIDs and serious cardiovascular events. Various observational studies found that diclofenac, and possibly ibuprofen, were associated with an increased risk of myocardial infarction.¹⁴ Although this relationship is dose dependent, the risk is increased if used in combination with other prescription or non-prescription NSAIDs. While NSAIDs do not appear to cause new occurrence of heart failure, their use is strongly correlated with heart failure relapse and although the risk appears greatest with diclofenac, heart failure has been observed with all NSAIDs and the recommendation is for people with heart failure to avoid NSAIDs. Between 3% and 9% of the adult population has heart failure and the incidence is rising. The proportion of Australians aged over 65 years (in whom heart failure prevalence is > 10%) will double over the next 50 years.¹⁵

US data has shown that consumers are largely unaware of NSAID adverse effects and in one study, one in five consumers admitted that they did not advise clinicians of any over-the-counter (OTC) NSAID use, including 8% who reported daily use.¹⁶

Combination Products

Acknowledging that combination products containing paracetamol and phenylephrine are currently exempt from scheduling, this should not be seen as a precedence for other combination products to have the same exemption. [REDACTED] does not believe that there is any community need for a phenylephrine-ibuprofen combination product that cannot be addressed by products already exempt from scheduling and that the cardio-vascular risks with ibuprofen and phenylephrine is enhanced in combination products, warranting supply through pharmacies.

Informing Consumers

[REDACTED] is concerned with the level of reliance on product labelling to convey important health related product information to consumers. A 2002 survey in the US¹⁷ identified that while 95% of Americans using non-prescription medicines read some portion of the product label, they do so selectively when they first buy the product and when they first use the product.

When they first buy a non-prescription medicine, only 34% read the label for the active ingredient, 19% for usage directions, 16% for dosage level, 10% for side-effects and only 7% reads the label for usage warnings.

When taking a non-prescription medicine for the first time, only 25% read the label for dosage instructions, 22% for usage directions, 20% for active ingredient, 9% for side-effects and again, only 7% reads the label for usage warnings.

The same report indicates a third of Americans would take more than the recommended dose, believing it to be more effective, and 36% are likely to take multiple non-prescription medicines when they have multiple symptoms.

If a similar pattern is demonstrated by Australian consumers, there is a significant risk that Australians will be largely unaware of safety warnings and directions. They are also likely to be unaware of the active ingredient, increasing the likelihood of taking multiple medicines with the same active ingredient and increasing the possibility of adverse outcomes. Particularly with the availability of numerous branded products with the same active ingredient that are marketed and promoted for the treatment of different conditions e.g. [REDACTED] product range with products containing ibuprofen for migraine, back pain and period pain, for example.

In addition, there seems to be a trend to include even more information for consumers on the labels of products that are exempt from scheduling, as per the proposed advisory statements for medicine labels for fexofenadine and loperamide¹⁸. It is interesting to note that with loperamide in particular, the current proposal is to include 10 advisory statements on the pack. Considering the premium of shelf space within supermarkets, it is unlikely that manufacturers will be increasing pack size to accommodate these requirements. The end result is likely to be highlighted brand and condition and very difficult to read health and safety information. [REDACTED] is concerned that this attitude may actually result in consumers heeding less and less the safety warnings on these products, emphasising the need to facilitate access to pharmacist advice.

Recommendation

Combination products containing phenylephrine and ibuprofen should remain as scheduled medicines, and given the risk profile highlighted, a recommendation should be put to the delegate to review the exemption status for ibuprofen as a single active ingredient.

¹⁰ www.drugs.com – Phenylephrine [accessed May 2012]

¹¹ KD Rainsford; Ibuprofen: pharmacology, efficacy and safety; *Inflammopharmacology*; 2009 Dec; 17(6):275-342. Epub 2009 Nov 21; <http://www.ncbi.nlm.nih.gov/pubmed/19949916>

¹² http://www.kidney.org/atoz/content/painMeds_Analgesics.cfm [accessed May 2012]

¹³ Kidney Health Australia; [accessed May 2012]

<http://www.kidney.org.au/HealthProfessionals/CKDinAustralia/tabid/622/Default.aspx>

¹⁴ Ingrid Hopper; Cardiac effects of non-cardiac drugs; *Australian Prescriber* 2011; 34:52-4

¹⁵ H Krum & S Stewart; Chronic heart failure: time to recognise this major health problem; *MJA* 2006; 184(4):147-148

¹⁶ RJ Adams, SL Appleton, TK Gill et al; Cause for concern in the use of non-steroidal anti-inflammatory medications in the community – a population-based study; *BMC Fam Pract.* 2011;12:70; <http://ukpmc.ac.uk/articles/PMC3166902/>

¹⁷ Attitudes and beliefs about the use of over-the-counter medicines: a dose of reality; A national survey of consumers and health professionals; Prepared for the National Council on Patient Information and Education; Jan 2002; http://www.bemedwise.org/survey/final_survey.pdf

¹⁸ <http://www.tga.gov.au/newsroom/consult-otc-fexofenadine-loperamide-120504.htm>

2. Omeprazole – Proposal to amend the current Schedule 3 omeprazole entry to increase the maximum allowed pack size from 14 to 28 dosage unit.

██████ does not support the proposal to increase the pack size for Schedule 3 omeprazole. Acknowledging that a 28 dosage unit quantity is permitted within the equivalent schedule in New Zealand, ██████ does not support the proposal merely to align with New Zealand allowances.

██████ supports the availability of proton pump inhibitors (PPI) as Schedule 3 medicines, requiring pharmacist intervention to ensure their safe and appropriate use. In May 2008, pantoprazole became the first PPI available in Australia without a prescription for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease (GORD) in packs containing no more than 14 days supply. Subsequently, a number of other PPIs, including omeprazole, have been down-scheduled to Schedule 3 with similar pack size limitations.

██████ believes that the proposal to increase the non-prescription pack size is contrary to the intent of the down-scheduling decision to increase consumer access to PPIs for short-term relief of acute heartburn and GORD symptoms. Also of note is the recent UK advisory¹⁹ about PPIs and hypomagnesaemia with the recommendation that OTC PPIs should not be used for more than 4 weeks without consulting a doctor and if symptoms are not relieved within 2 weeks of continuous treatment, a doctor should also be consulted. The advisory also notes that provided OTC PPIs are taken short-term and according to the recommended directions, their use is not expected to significantly increase the risk of hypomagnesaemia. But do consumers follow the recommended directions? Overseas data²⁰ indicates that many consumers believe that taking more than the recommended dose increases the effectiveness of the product. Having access to larger pack sizes may facilitate this practice.

Larger packs of omeprazole are available as prescription only medicines and packs of 30 of the 10mg and 20mg strengths are subsidised on the PBS.

██████ does not believe there is any public benefit in providing larger pack sizes without a prescription. We believe in fact that this could significantly impact on consumers seeking medical review for more chronic symptoms. It would also make monitoring by pharmacists more difficult, particularly as supply of Schedule 3 medicines are not recorded.

While consumers can purchase two packs of 14 in a single transaction, such requests would prompt questions from a pharmacist to ensure safe and responsible use.

While there may be some small financial benefit for consumers to have a double treatment pack available, this may be off-set by the fact that OTC purchases cannot be recorded on a person's Safety-Net, particularly impacting high PBS users with GORD.

██████ also notes that risks and benefits with non-prescription supply of PPIs were considered by the Committee in February 2012 in response to an application for Schedule 2 listing for pantoprazole. We believe that the risk-benefit analysis is

similar for this proposal, noting that there are greater risks of drug-drug interactions with omeprazole. We also agree that limiting pack sizes of PPIs to 14 mitigates risk of repeated chronic use of PPIs which could mask more serious conditions as well as mitigating risk of adverse outcomes from exceeding the recommended dose.

Recommendation

██████ recommends that Schedule 3 is appropriate for PPIs, including omeprazole, for packs of up to 14 days supply, and larger pack sizes should remain as Schedule 4.

¹⁹ MHRA Drug Safety Update; Proton pump inhibitors in long-term use: reports of hypomagnesaemia; April 2012; <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON149774>

²⁰ Op Cit Attitudes and beliefs about the use of over-the-counter medicines

3. *Vibrio cholera* and enterotoxigenic E-coli vaccine (oral cholera vaccine) – Proposal to down-schedule cholera vaccine from Schedule 4 to Schedule 3 to harmonise with New Zealand. This consideration includes a new specific entry for both *vibrio cholera* vaccine and for enterotoxigenic *Escherichia coli* vaccine in Schedule 3.

██████ supports the proposal to include the oral cholera vaccine in Schedule 3. We note that a similar decision has been supported in New Zealand on the proviso that pharmacists are provided with an appropriate education pack. ██████ agrees that there should be a similar condition in Australia, with the product sponsor/manufacture having the responsibility to ensure such an educational pack is available. Although it is likely for the New Zealand education pack to have similar application in Australia, it is still essential that there is consultation and collaboration with the Australian pharmacy profession to ensure application to the Australian pharmacy sector.

Cholera is an acute intestinal infection caused by ingestion of food or water contaminated with the bacterium *Vibrio cholera*. It has a short incubation period, from less than one day to five days, and produces an enterotoxin that causes a copious, painless, watery diarrhoea that can quickly lead to severe dehydration and death if treatment is not promptly given.²¹

Many developing countries in Africa and Asia, and to a lesser extent in central and South America are affected, however the risk of cholera for most travellers is low, provided that simple precautions are taken (i.e. avoiding potentially contaminated food, drinks and drinking-water). Cholera vaccination is not required as a condition of entry to any country, however, studies of travellers to countries or areas reporting cholera outbreaks found the available oral vaccines induced approximately 50% short-term protection against diarrhoea caused by enterotoxigenic E-coli. Emergency or relief workers travelling to affected areas are high risk.²²

In 2011, 7.8 million Australian residents departed Australia for short-term trips and 6 million left for long-term stays overseas. While nearly 25% of Australians visited New Zealand and the USA, significant numbers visited countries such as Indonesia (11.3%), Thailand (7.1%) and Malaysia (3.3%).²³

Creditable travel information is widely available on line, such as from the World Health Organisation²⁴ and Travel Clinics Australia²⁵. Many community pharmacists already provide travel support services and information (non-prescription and first-aid supplies as well as information and advice). The availability of the oral cholera vaccine as a Schedule 3 medicine is likely to see improved awareness by pharmacists of travel support as they ensure their competence for managing requests for oral cholera vaccine. Providing consumers with easy access to a broad network of skilled health professionals with well-directed training on travel health issues will bring a significant public benefit. Pharmacists could provide general advice such as vaccination needs for low risk countries, referring to doctors or travel clinics to complete any further vaccination requirements and to assess other prescription travel medicine requirements such as malaria prophylaxis. With access to appropriate resources, pharmacists would also be able to advise of low-risk situations for which vaccination and/or malaria prophylaxis is not recommended. This would save

consumers having to unnecessarily pay money to visit a travel clinic or doctor to be told they don't need any specific travel medicines.

Should the proposal for Schedule 3 listing of the oral cholera vaccine be supported, [REDACTED] would also support listing in Appendix H. Permitting advertising of a travel medicine may prompt greater opportunistic interaction between travellers and a healthcare professional. Travellers are often unaware that vaccines may require a course for completion some weeks before departure. Pharmacists would be well placed to identify these needs and where appropriate, recommend timely attendance to a doctor or travel clinic.

Recommendation

The oral cholera vaccine should be listed in Schedule 3 and Appendix H, on the condition that the product sponsor/manufacturer develops and provides pharmacists with an appropriate education package with relevance to the Australian sector. [REDACTED] [REDACTED] would be happy to assist with the development of any such support materials for pharmacists.

²¹ <http://www.who.int/topics/cholera/en/> [accessed May 2012]

²² International travel and health 2012; Chapter 6.2';

²³ http://www.who.int/ith/chapters/ith2012en_chap6.pdf [accessed May 2012]

²³ <http://www.abs.gov.au/ausstats/abs@.nsf/products/961B6B53B87C130ACA2574030010BD05?OpenDocument> [accessed May 2012]

²⁴ <http://www.who.int/ith/en/> [accessed May 2012]

²⁵ <http://www.travelclinic.com.au/> [accessed May 2012]

4. Cetirizine – Proposal to reschedule from Schedule 2 to unscheduled to harmonise with New Zealand. This consideration includes divided forms of cetirizine for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose in packs containing 5 days supply for the treatment of seasonal allergic rhinitis.

██████ does not support the proposal for a scheduling exemption for small packs of cetirizine. There is no public need for an exemption and we believe the risk of sedation and its potential impact on driving capacity is too great to warrant supply without facilitating access to advice from a pharmacist.

With the recent decision to exempt small packs of fexofenadine and loratadine from scheduling, there is no unmet public need that would be addressed by also exempting cetirizine from scheduling. Acknowledging that New Zealand's Medsafe has supported an exemption for cetirizine, we again advise that any decision for an exemption in Australia should be based on a balance of public need and public safety rather than harmonisation. ██████ is concerned with the company submission²⁶ in New Zealand which, although indicating somnolence occurred in up to 14% of patients, seemed to downplay any associated risks. It would seem that there is uncertainty with the experts about the level of somnolence and its impact on cognitive function as well as any additive effects from alcohol or other medicines or exceeding the recommended dose.

Although the second generation antihistamines are known to all have similar efficacy, there is a significant difference in the extent of their sedative effects, with cetirizine being 3.5 times more likely to result in sedation than loratadine. Where the risk of sedation is not desirable, loratadine and fexofenadine are preferable to cetirizine,²⁷ and ██████ believes it is important for consumers to be able to discuss this choice with a pharmacist. There are conflicting reports on the significance with which cetirizine affects cognitive and psychomotor function, with one report²⁸ indicating the different results may be due to inter individual variation. Accessing advice from a pharmacist is the best means to manage risk elements for individuals.

One study²⁹ investigating the impact of cetirizine on driving demonstrated no effect, but noted different results from other studies which had used the same driving test and had demonstrated small but significant acute impairing effects after a single dose of cetirizine. An early report³⁰ indicated that the effects of a single dose of cetirizine (10mg) on driving performance resembled that of alcohol, causing subjects to operate with significantly greater variability in speed and lateral position (weaving motion). The report also indicated that the effects of cetirizine and alcohol appear to be additive. Another report³¹ indicated that EEG activity measured during driving was altered significantly by cetirizine, with the investigators concluding that cetirizine produced acute sedation.

Within relevant Australian references³², cetirizine is listed as one of the low-to moderate medicines that can affect psychomotor and cognitive functions, potentially having an adverse influence on the ability to drive. Psychomotor skills include reaction times and hand-eye coordination while the ability to make appropriate decisions relates to cognitive skills. Combination with other impairing drugs,

including alcohol, is noted as increasing the opportunity for impairment and the risk of serious road accidents.

Tolerance to the sedative effects of second-generation anti-histamines is reported to develop after 4-5 days. However, the proposed scheduling exemption for cetirizine is for small packs for short-term, acute treatment. If used as recommended, it is unlikely that the consumer will develop tolerance and will run the risk of sedation each time the medicine is used. The 'Prevention Research Quarterly: Drugs and Driving Report'³³ found that while impairment is sometimes evident at higher than recommended doses of second-generation antihistamines, impairment is small to almost undetectable at recommended doses – however cetirizine is an exception to this. This report also indicates that cetirizine and loratadine have been shown to have additive effects and that further research is needed to assess concomitant use of antihistamines and other medicines.

Simply including warnings on the medicine packs is insufficient. Key experts in an Australian study on drugs and driving suggest warning labels should be supported by verbal information from doctors and pharmacists.³⁴ A survey of 2500 Australians showed that 21% have driven after taking prescription or OTC medicines, despite pack warning labels, with the biggest offenders (27%) aged over 55 years of age, and the next group (25%) being drivers aged 18 to 34 years.³⁵

Research has indicated that consumers do not heed the warnings or directions included on pack labels. A survey conducted in the US in 2002³⁶ indicated that a third of Americans take more than the recommended dose of non-prescription medicines, believing it will increase the effectiveness of the product. The same survey indicated that 36% of Americans are likely to combine non-prescription medicines when they have multiple symptoms, a practice that can increase the risk of consumers taking multiple products with the same active ingredient. It is not unreasonable to expect similar behaviour by Australian consumers. [REDACTED] also contends that the lack of controls in the grocery sector means that pack size restrictions has only a limited impact on managing consumer access and directing more complex cases to healthcare professional support.

In addition, having a number of antihistamines available in the grocery sector to provide consumers with alternatives to try if another type is ineffective is not consistent with QUM principles. If a particular medicine is not working effectively for a specific condition, it is in the consumer's interest to seek healthcare professional advice, especially as the availability and promotion of different brands may lead to consumers thinking they are trying different medicines when in fact it may only be a different brand. While maintaining cetirizine in Schedule 2 does not mean that all consumers will interact with the pharmacist, pharmacy assistants are trained to triage and ask pertinent questions to elicit which people should be seen by a pharmacist. As such, it would be expected that people taking other medicines, people for whom other treatments have not been effective, or those who are specifically concerned about the impact of sedation or other adverse effects will be referred to a pharmacist.

Recommendation

Based on the risk of sedation, particularly with short-term use, and the potential impact on driving due to impaired psychomotor and cognitive function, cetirizine

should remain as a scheduled medicine to facilitate access to a pharmacist for advice.
[REDACTED] believes Schedule 2 appropriate for all pack sizes.

²⁶ <http://www.medsafe.govt.nz/profs/class/agen46.htm>

²⁷ Sedation with 'non-sedating' antihistamines: four prescription-event monitoring studies in general practice; BMJ 2000; 320:1184; <http://www.bmj.com/content/320/7243/1184.full>

²⁸ S Gupta, B Kapoor, Z Gillani et al; Effects of Fexofenadine, Cetirizine and Diphenhydramine on Psychomotor Performance in Adult Health Volunteer; JK Science Vol6 No.4, Oct-Dec 2004; <http://jkscience.org/archive/volume64/fexofeniadine.pdf>

²⁹ EL Theunissen, A vermeeren & JG Ramaekers; Repeated-dose effects of mequitazine, cetirizine and dexchlorpheniramine on driving and psychomotor performance; Br J Clin Pharmacol. Jan 2006; 61(1):79-86; <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1884990/>

³⁰ JG Ramaekers, MMC Uiterwijk & JF O'Hanlon; Effects of loratadine and cetirizine on actual driving and psychometric test performance, and EEG during driving; European Journal of Clinical Pharmacology, Vol 42 No.4; 1992:363-369; <http://www.springerlink.com/content/x11h7u830066210h/>

³¹ TM Nolen; Sedative effects of antihistamines: safety, performance, learning, and quality of life; Clinical Therapeutics; Vol 19 Issue 1; Jan 1997: 39-55; [http://www.clinicaltherapeutics.com/article/S0149-2918\(97\)80071-9/abstract](http://www.clinicaltherapeutics.com/article/S0149-2918(97)80071-9/abstract)

³² OH Drummer; The role of drugs in road safety; Australian Prescriber; 2008;31:33-5; <http://www.australianprescriber.com/magazine/31/2/33/5>

³³ Australian Drug Foundation + Victorian Department of Health – Prevention Research Quarterly; March 2010; http://www.druginfo.adf.org.au/attachments/338_ADFPRQ0310_www.pdf

³⁴ J Mallick, J Johnston, N Goren et al; Drugs and driving in Australia: A survey of community attitudes, experience and understanding; Australian Drug Foundation; http://www.druginfo.adf.org.au/attachments/400_Drugs_and_Driving_in_Australia_fullreport.pdf

³⁵ Ibid – quoted in presentation; Dr Jenny Gowan, Northern & North East valley Divisions of general Practice April 2010; http://www.druginfo.adf.org.au/attachments/064_JennyGowan_DrugsDrivingSeminar_14Apr10.pdf

³⁶ Op Cit Attitudes and beliefs about the use of over-the-counter medicines

6. Tylosin – Proposal to reschedule tylosin from Schedule 5 to Schedule 4.

Tylosin is a macrolide antibiotic used in veterinary practice and animal husbandry. [REDACTED] is aware that the Australian Pesticides and Veterinary Medicines Authority (APVMA) began a review in December 2001 of selected macrolide antibiotics, including tylosin, because of concerns over the potential risk to human health. No report from this review is publicly available.⁴¹

The World Health Organisation has identified increasing antimicrobial resistance to antibiotics as a serious concern, and one of the causes is the inappropriate and irrational use of medicines, including in animal husbandry.⁴²

With this in mind, [REDACTED] believes that listing antibiotics for animal use in Schedule 4 of the SUSMP is reasonable as it restricts use to recommendation only on the advice of a highly trained veterinarian.

Recommendation

A Schedule 4 listing for tylosin is appropriate, maintaining access on the advice of a veterinarian.

⁴¹ http://www.apvma.gov.au/products/review/current/macrolide_antibiotics.php [accessed May 2012]

⁴² WHO Antimicrobial resistance Fact Sheet no.194; Mar 2012;
<http://www.who.int/mediacentre/factsheets/fs194/en/>

PBS & RPBS Items processed from July 2010 to June 2011

PBS Code	PBS			RPBS			Total
	General - Ordinary	General - Safety Net	Concessional - Ordinary	Concessional - Free Safety Net	RPBS - Ordinary	RPBS - Safety Net	
	Services	Services	Services	Services	Services	Services	Services
Angiotensin 2 Receptor Antagonist (A2RA) + Diuretic							
2136K	133,022	13,494	246,707	59,964	10,901	2,300	466,388
2161R	66	1,003	32,469	5,181	1,323	235	40,277
2166B	136	3,742	74,699	14,629	3,300	663	97,169
2170F	44,397	3,907	60,368	14,469	2,099	592	125,832
8404H	731	12,490	378,066	69,652	20,722	3,913	485,574
8405J	2,815	57,414	1,172,155	267,556	58,227	13,367	1,571,534
8504N	2,740	24,259	523,162	111,649	24,917	5,637	692,364
8622T	195	4,361	144,110	24,469	6,634	1,291	181,060
8623W	1,117	23,556	512,547	105,224	23,875	5,332	671,651
8624X	163	2,211	47,108	9,899	2,338	628	62,347
9314F	45,315	3,088	69,399	15,131	2,911	704	136,548
9315G	20,623	1,677	30,806	7,342	1,175	336	61,959
9372G	6	113	3,727	511	149	44	4,550
9373H	13	217	6,355	983	263	62	7,893
9374J	6	133	3,232	736	132	22	4,261
9381R	151	4,382	88,131	19,184	3,579	712	116,139
9481B	0	127	2,623	444	101	23	3,318
9482C	6	158	2,044	486	61	8	2,763
Total	251,502	156,332	3,397,708	727,509	162,707	35,869	4,731,627

PBS & RPBS Items processed from July 2010 to June 2011

PBS Code	PBS			RPBS			Total
	General - Ordinary	General - Safety Net	Concessional - Ordinary	Concessional - Safety Net	RPBS - Ordinary	RPBS - Safety Net	
	Services	Services	Services	Services	Services	Services	Services
ACE Inhibitor (ACEI) + Diuretic							
2190G	37	498	28,129	5,035	1,975	368	36,042
2845R	12,499	27,859	700,119	134,754	33,259	6,742	915,232
8400D	77	923	34,341	6,367	2,446	493	44,647
8401E	1,249	9,001	198,846	45,443	11,351	2,583	268,473
8449Q	1,202	8,537	218,391	41,783	11,743	3,097	284,753
8477E	745	3,311	73,359	16,269	4,424	1,084	99,192
8589C	13	200	8,853	1,710	514	78	11,368
8590D	479	2,104	47,714	9,422	2,434	528	62,681
Total	16,301	52,433	1,309,752	260,783	68,146	14,973	1,722,388
Combined Volume (A2RA/Diuretic + ACEI/Diuretic)							
	267,803	208,765	4,707,460	988,292	230,853	50,842	6,454,015
Concessional + RPBS status			4,707,460	988,292	230,853	50,842	5,977,447

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