Part 1

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 July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16), was made available on the TGA website on 17 May 2017 and 7 June 2017, closing on 15 June 2017 and 7 July 2017 respectively.

Public submissions received on or before these closing dates (15 June 2017 and 7 July 2017) are published here in accordance with regulation 42ZCZL. Also in accordance with the 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 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 July 2017 meetings of the Advisory Committee on Medicines Scheduling (ACMS #21), the Advisory Committee on Chemicals Scheduling (ACCS #20), and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #16) was made available on the TGA website on 15 September 2017 and closed on 3 October 2017. Public submissions received on or before this closing date will be published on the TGA website in accordance with regulation 42ZCZQ of the Regulations.

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]

The Delegate of the Secretary of the Department of Health for Chemical Scheduling
Advisory Committee on Chemicals Scheduling
Department of Health
MDP 71
GPO Box 9848
Canberra ACT 2601
Australia
chemicals.scheduling@health.gov.au

5th June 2017

Dear Delegate

'Proposed Amendments to the Poisons Standard (Chemicals)
ACCS/ACMS July Meeting- Basic Red 76

I write on behalf of La Biosthetique Australia Pty Ltd and Laboratoire Biosthetique Kosmetik GmbH & Co. The company and brand La Biosthetique was founded in Paris in 1947. We are now a global supplier and marketer of hair colorant products and other hair and skin products to hair salons in Australia and to hair salons in x countries around the world.

We formulate all our products to meet the requirements of the European Regulations for Cosmetic Products. Basic Red 76 is approved in the European Union for use in non oxidative hair dyes up to 2%. [redacted] It is also approved in the United States, in New Zealand and in all ASEAN countries. We are not aware of any countries other than Australia where this hair dye is banned. [redacted]

We support the proposal to amend the Poison Standard by including an entry in Schedule 6 for Basic Red 76 of:

Basic Red 76 (CAS No 68391-30-0) ***except***

a) *In non oxidative hair dye preparations with a maximum on head concentration of 2% and when the immediate container and primary pack are labelled with the following statements:*

KEEP OUT OF REACH OF CHILDREN, and
WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made

[redacted]

before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

b) *In eyelash and eyebrow tinting products at a maximum concentration of 2% when the immediate container and primary pack are labelled with the following statement:*

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

We also support appropriate entries to allow the reinstated use of colour CI 26100, Red 17 or Sedan III for general use in cosmetic products as a colorant. This colour has also been caught by the current Schedule 7 entry for AZO dyes.

We are a member of Accord Australasia, the Australian Industry Body representing cosmetics, and support also the detailed submissions they have made in support of Basic Red 76 and CI26100.

[redacted]

LA BIOSTHETIQUE AUSTRALIA PTY LTD - UNIT 4, 5 - 15 EPSOM ROAD, ROSEBERY NSW 2018 - PO BOX 6491, ALEXANDRIA NSW 2015
T: 1300 55 40 69 - F: 61 2 9935 6995 - ABN: 47 101 810 842 - WWW.LABIOSTHETIQUE.COM.AU
BIOSTHETICS NEW ZEALAND LTD - 36 CHESHIRE STREET, PARNELL, AUCKLAND - PO BOX 37 151, PARNELL, AUCKLAND
T: 64 9 357 3506 - 0800 522 467 - F: 64 9 357 3507 - WWW.LABIOSTHETIQUE.CO.NZ

[redacted]

[redacted]

The Delegate of the Secretary of the Department of Health for Chemical Scheduling
Advisory Committee on Chemicals Scheduling
Department of Health
MDP 71
GPO Box 9848
Canberra ACT 2601
Australia
chemicals.scheduling@health.gov.au

5 June 2017

Dear Delegate

'Proposed Amendments to the Poisons Standard (Chemicals)
ACCS/ACMS July Meeting- Basic Red 76

I write on behalf of Dateline Imports Pty Ltd. The company was found in 1977 and we are now a leading supplier of hair care products to the Australian and New Zealand market.

We import products which are formulated to meet the requirements of the European Regulations for Cosmetic Products. Basic Red 76 is approved in the European Union for use in non-oxidative hair dyes up to 2%. Our suppliers have used this hair dye in a number of product ranges and it's essential to providing a full range of colours for use by professional hairdressers in salons. Without it the range of colours would be incomplete. This product is also used to colour shampoos and other cosmetic products. It is also approved in the United States, in New Zealand and in all ASEAN countries. We are not aware of any countries other than Australia where this hair dye is banned.

Our understanding is that the carcinogen, o-anisidine, is not formed during the use of this hair dye in hair colorant products as this would destroy the colour provided by Basic Red 76 and result in the unsatisfactory consistency and appearance of the colour.

We support the proposal to amend the Poison Standard by including an entry in Schedule 6 for Basic Red 76 of:

Basic Red 76 (CAS No 68391-30-0) except

a) *In non oxidative hair dye preparations with a maximum on head concentration of 2% and when the immediate container and primary pack are labelled with the following statements:*

KEEP OUT OF REACH OF CHILDREN, and
WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

[redacted]

b) *In eyelash and eyebrow tinting products at a maximum concentration of 2% when the immediate container and primary pack are labelled with the following statement:*

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.

c) *In other cosmetic products with a maximum concentration of 1%.*

We also support appropriate entries to allow the reinstated use of colour CI 26100, Red 17 or Sedan III for general use in cosmetic products as a colorant. This colour has also been caught by the current Schedule 7 entry for AZO dyes.

Yours faithfully

[redacted]

David Taylor
Managing Director
Dateline Imports Pty Ltd

[redacted]

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Madam/Sir

Public Comment Submission to the July 2017 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 17 May 2017 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the July 2017 meeting of the ACCS:

- Butyl benzyl phthalate
- Basic Red 76.

Please see the attached submission for details.

We look forward to further advice from the ACCS and the Delegate. Should the Committee or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me [redacted].

Yours sincerely

[unsigned for electronic submission]

Dusanka Sabic
Director Regulatory Reform

15 June 2017

[redacted]

ACCS meeting: July 2017

Butyl benzyl phthalate

Accord notes that the IMAP Tier II Human Health Assessment[1] for butyl benzyl phthalate (CAS number 85-68-7) was a group assessment of 8 related substances:

Chemical Name	CAS Number
1,2-Benzenedicarboxylic acid, dicyclohexyl ester	84-61-7
1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester	84-69-5
1,2-Benzenedicarboxylic acid, dibutyl ester	84-74-2
1,2-Benzenedicarboxylic acid, dihexyl ester	84-75-3
1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester	85-68-7
1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester	117-82-8
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich	71888-89-6

Of these substances that were assessed, only butyl benzyl phthalate was recommended for control by scheduling. On this basis, to ensure that none of the related chemicals are inadvertently captured in the new Schedule 10 entry, salts and derivatives must be explicitly excluded.

We are not aware of the use of butyl benzyl phthalate in cosmetics in Australia, and therefore have no objections to the proposed Schedule 10 entry for cosmetic use of butyl benzyl phthalate in line with the prohibition in the EU Cosmetics Regulation.

[1] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1126#

[redacted]

ACCS meeting: July 2017

Basic red 76

In November 2015, the delegate issued a final decision confirming a new Schedule 7 entry be created for AZO DYES that are derivatives by diazotisation of any of the following substances:

- *o*-anisidine (CAS No. 90-04-0)
- *o*-toluidine (CAS No. 95-53-4)
- *p*-aminoazobenzene (CAS No. 60-09-3)
- *o*-aminoazotoluene (CAS No. 97-56-3)
- 2,4-toluenediamine (CAS No. 95-80-7)
- 5-nitro-*o*-toluidine (CAS No. 99-55-8)
- *p*-chloroaniline (CAS No. 106-47-8)
- 4-chloro-*o*-toluidine (CAS No. 95-69-2)

During the consultations for this scheduling application, Accord raised concerns that this entry would capture 2 colourant ingredients currently in use in Australia and widely used around the world at levels that had been determined safe by risk assessment. These substances were basic red 76 (CAS number 6831-30-0) and D&C Red 17 (CAS number 85-86-9).

The final decision included the following commentary from the Delegate:
The submission lists two dyes (CAS 85-85-9 and Basic Red 76 CAS 6831-30-0) that are on an EU list of substances allowed in hair dye products, with a maximum concentration proposed. Only Basic Red 76 is on the NICNAS list, and would be affected by the proposed Schedule 7 entry. The delegate suggests that if this dye is of importance to the Australian industry, a submission should be made to exempt this specific substance from the proposed Schedule 7 generic entry, with proposals on how it should be regulated.

Basic red 76 (CAS number 68391-30-0) is a common colourant used in hair dye formulations. Under the EU Cosmetics Regulation, it may be used at concentrations up to 2% in non-oxidative hair dye preparations.

In 2011, the SCCS found that *"Based on the data provided, Basic Red 76 containing up to 18% methyl sulphate does not pose a risk to the health of the consumer when used as a non-oxidative hair dye with a maximum on-head concentration of 2.0%. A sensitising potential of Basic Red 76 cannot be excluded." "Based on the criteria of the test system, C008 was found to be a non-sensitizer when tested up to a concentration of 10% (w/v) in ethanol:water (7:3 v/v) in mice."*

The SCCS opinion also included consideration of impurities, including *o*-anisidine in 3 different batches of basic red 76, and in 1 material used in the market (i.e. a formulated product):

Impurity	**Batch 0050644101 (SAT 040267)**	**Batch 0057891101 (SAT 050017)**	**Batch 12/13B (SAT 050529)**	**material used in the market**
o-anisidine	5 ppm	19 ppm	11 ppm	<10 ppm

It has been noted that if this substance were to decouple to release the carcinogen of concern, *o*-ansidine, this reaction would be accompanied by a colour change on application, rendering the substance colourless, and therefore of little use as a colourant. As the performance of hair dye products containing basic red 76 continues to be satisfactory, this also demonstrates the lack of *o*-ansidine formation occurring.

Given the above information, we believe basic red 76 should be excluded from the current Schedule 7 Azo Dyes entry, and be included in Schedule 6 with exemption concentrations in line with the EU levels, and warning statements in line with other scheduled hair dye substances i.e.

> *Schedule 6*
>
> *Basic Red 76 (CAS No 68391-30-0) except*
> *a) In non-oxidative hair dye preparations with a maximum on head concentration of 2% and when the immediate container and primary pack are labelled with the following statements:*
>
> *KEEP OUT OF REACH OF CHILDREN, and*
> *WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.*
>
> *written in letters not less than 1.5 mm in height; or*
>
> *b) In eyelash and eyebrow tinting products at a maximum concentration of 2% when the immediate container and primary pack are labelled with the following statement:*
>
> *WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.*
>
> *written in letters not less than 1.5 mm in height.*

Given the current problems industry is facing identifying which derivatives may or may not be captured by an entry, compounded by conflicting advice from the regulatory agencies, the entry should exclude salts and derivatives (unless these can be clearly articulated).

[redacted]

June 14, 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: chemicals.scheduling@health.gov.au

Re: Personal Care Products Council Comments related to proposed amendments to the Poisons Standard referred to the Advisory Committee on Chemicals Scheduling (ACCS), the Advisory Committee on Medicines Scheduling (ACMS) and the Joint ACCS-ACMS.

Dear Sir or Madam:

On behalf of the Personal Care Products Council ("the Council") we would like to thank the Therapeutic Goods Administration of the Australian Ministry of Health for this opportunity to comment on proposed amendments to the Poisons Standards (the Standard for the Uniform Scheduling of Medicines and Poisons - SUSMP).

Based in Washington, D.C., the Personal Care Products Council is the leading national trade association that represents the $250 billion global cosmetics and personal care industry. We represent more than 600 member companies of personal care products, including manufacturers and distributors of finished products, suppliers of ingredients, raw materials, packaging and other services used in the production and marketing of finished personal care products. We have member companies that manufacture and distribute personal care products in Australia.

The U.S. Council is actively engaged in international efforts to align global regulatory standards for consumer products, to eliminate trade barriers, and to ensure a level playing field for member companies while at the same time reinforcing consumer confidence in product safety.

We work with [redacted], our sister trade association in Australia, on label harmonization, the reduction of duplicative testing, and the alignment of safety standards for a wide range of consumer and health products, including pharmaceuticals and personal care products. In addition to our comments, we also support [redacted] public comments regarding the substances in this submission.

1. Butyl benzyl phthalate (CAS No. 85-68-7)

Butyl benzyl phthalate is a synthetic aromatic ester that has a reported function as a plasticizer used in nail polishes and enamels as reported in the 2016 International Cosmetic Ingredient (INCI) Dictionary which provides the most comprehensive listing of ingredients used in cosmetic and personal care products. This ingredient has no reported uses in the U.S. FDA Voluntary Cosmetic Reporting Program (VCRP) and it is an Annex II, 1152 prohibited ingredient in the European Union's Cosmetic Regulation EC No. 1223/2009 - List of Substances Prohibited in Cosmetic Products.

[redacted]

The Cosmetic Ingredient Review (CIR) safety assessment states that Butyl benzyl phthalate could be a contaminant of other phthalates due to migration from the plastic container and that this substance is safe in current practices of use and concentration, as detailed in the report. We do not have any objections to including Butyl benzyl phthalate as a new Schedule 10 entry for cosmetic use with no exemption cut-off, as this aligns with other phthalates that are considered hazardous in this chemical class.

2. Basic red 76 (CAS No. 68391-30-0)

Basic red 76 is a monoazo color additive with reported functions as hair colorants and conditioners as reported in the 2016 International Cosmetic Ingredient (INCI) Dictionary. The VCRP lists twenty-four reported uses since 2015. It is in Annex III, 267 of the European Union's Cosmetic Regulation EC No. 1223/2009 - *List of substances which cosmetic products must not contain except subject to the restrictions laid down*, and Basic red 76 has a maximum concentration in ready for use preparations of 2.0% when used as a hair dye substance in non-oxidative hair dye products. This is based on an European Union Scientific Committee for Consumer Safety (SCCS) review in 2011.

Basic Red 76 is captured by the Schedule 7 entry for azo dyes:

Schedule 7: AZO DYES that are derivatives by diazotisation of any of the following substances:

- p-aminoazobenzene (CAS No. 60-09-3)
- o-aminoazotoluene (CAS No. 97-56-3)
- o-anisidine (CAS No. 90-04-0)
- p-chloroaniline (CAS No. 106-47-8)
- 4-chloro-o-toluidine (CAS No. 95-69-2)
- 6-methoxy-m-toluidine (p-cresidine) (CAS No. 120-71-8)
- 2-naphthylamine (CAS No. 91-59-8)
- 5-nitro-o-toluidine (CAS No. 99-55-8)
- 2,4-toluenediamine (CAS No. 95-80-7)
- o-toluidine (CAS No. 95-53-4)
- 2,4,5-trimethylaniline (CAS No. 137-17-7)

The Advisory Committee on Chemicals Scheduling (ACCS) proposes to amend the Schedule 7 entry for azo dyes to exclude Basic Red 76 from being captured and to include a new Schedule 6 entry for Basic Red 76 for use in non-oxidative hair, eyelash and eyebrow dye products with a cut-off concentration of 0.001% free o-Anisidine.

We have no objection to adding Basic Red 76 to Schedule 6 to allow the use of Basic Red 76 as a non-oxidative hair dye with a maximum concentration of 2.0% in ready for use preparations.

Related to the Basic Red 17, we also support appropriate entries to allow the reinstated use of color CI 26100, D&C Red 17 or Sudan III for general use in cosmetic products as a colorant. This color has also been caught by the current Schedule 7 entry for AZO dyes. D&C Red 17 meets US FDA certification requirements which limit the presence of p-aminoazobenzene to not more than 0.1%. Furthermore, a

random sampling of certificates of analysis for this substance found that p-Aminoazobenzene was not detected at all.

We do not believe that the carcinogens included in the scheduling entry are formed during the use of these hair dyes in hair colorant products as this would destroy the color provided by the dye and would result in variable color being delivered by the product. We are confident this does not happen and that the color as delivered by the products is consistent.

To address the issue of trace carcinogens, we suggest that the operation of the existing Schedule 7 entry be modified by the creation of a Schedule 6 entry that would allow the use of these dyes where the percentage of free p-Aminoazobenzene is no more than 0.001%. Furthermore, a Schedule 10 entry directly targeting the free carcinogen p-Aminoazobenzene could be created. This would bring the treatment of p-Aminoazobenzene and dyes releasing this carcinogen in-line with the present controls on o-Toluidine and -Anisidine and associated dyes. We propose the same general wording for this Schedule 10 entry as the o-Toluidine and o-Anisidine Schedule 10 entries. Alternatively, a derogation for a certified grade of azo-containing dyes can be considered for azo-containing dyes such as Basic Red 76 and D&C Red 17 that comply with the purity criteria, and also a sample lot that has been certified by governmental agencies such as the United Stated Food & Drug Administration (USFDA).

The benefit of this proposal is that it allows the continued use of these dyes under Schedule 6 where the risk in doing so is low. Furthermore, it establishes appropriate controls under Schedule 7 and Schedule 10 for dyes containing more than trace amounts of the carcinogen, and for the free carcinogen respectively.

3. Chloroacetamide (CAS No. 79-07-2)

Chloroacetamide is a synthetic aliphatic amide with the function as a preservative in a wide variety of cosmetics and personal care products as reported in the 2016 International Cosmetic Ingredient (INCI) Dictionary. The VCRP in the U.S. lists nineteen reported uses of Chloroacetamide since 2015. It is listed in Annex V, 41 of the European Union's Cosmetic Regulation EC No. 1223/2009 - List of Preservatives Allowed in Cosmetic Products at a maximum concentration in ready for use preparations of 0.3%. There is a requirement to have the warning "Contains chloroacetamide" on the packaging label in the E.U. This ingredient is prohibited for use in cosmetic products in Canada and the CIR has recommended (1991) that this ingredient should not be used in cosmetic products.

There is no objection to a new Schedule 6 entry for chloroacetamide with no exemption cut-off and appropriate label warning statements.

4. Docusate sodium (CAS No. 577-11-7; INCI: Diethylhexyl Sodium Sulfosuccinate)

Docusate sodium is the sodium salt of the diester of 2-ethylhexyl alcohol and sulfosuccinic acid. The INCI Dictionary lists the following reported functions: Surfactants - Cleansing Agents; Surfactants – Hydrotropes. The VCRP lists a frequency of use of 72 since 2015.

There are currently no restrictions for Docusate sodium in Appendix B, Part 3 - Substances considered not to require control by scheduling. The proposed amendments by the Joint Advisory Committees on Chemicals and Medicines Scheduling recommend a new Schedule 6 entry that restricts the use of

[redacted]

Docusate sodium in cosmetic and domestic products that is similar to Lauryl sulfate salts, currently listed in Schedule 6 for leave-on or wash-off preparations above 5 per cent and for other preparations above 5 per cent. More clarity is needed from the Joint ACCS-ACMS committee regarding restrictions for Docusate sodium so that industry may comment.

We can support the current CIR recommendations that products containing dialkyl sulfosuccinate salts (including Docusate sodium), be used in cosmetic products at concentrations up to 5.0 % with the caution that manufacturers are aware that 'care should be taken to avoid irritancy, especially in those products intended for prolonged contact with the skin' (CIR, 2013).

5. Epidermal growth factor (CAS No. 1807528-51-3)

We believe that the term "Epidermal growth factor (EGF)" is a common name for human single chain recombinant human peptides derived from various sources, including animal; synthetic; bacteria, fungi, or other single cell organisms.

There are two INCI names that may describe cosmetic uses:

RH-Oligopeptide-1 (human derived peptide) (CAS 62253-63-8)
SH-Oligopeptide-1 (synthetically derived peptide) (No CAS given.)

These ingredients are not used commonly in cosmetic products in the United States. We are aware that there is a current international limit of 0.001% for some cosmetic uses. The proposed amendment to the existing Schedule 7 entry to include a topical preparation containing 0.0002% or less of transgenic, plant-made EGF would not harmonize with current known practices for cosmetics. We recommend that the joint ACCS-ACMS committee allow for current usage of these ingredients for topical preparations and restrict its availability to only authorized or licensed persons.

6. Methylisothiazolinone (MIT), CAS No. 2682-20-4

Methylisothiazolinone is a heterocyclic organic compound that is reported as a preservative ingredient in cosmetics and has a VCRP frequency of use of 4556 uses since 2015. We are aware that this substance will be restricted for use in rinse-off cosmetic products only, which harmonizes with the proposed European Union regulations. We suggest that any decisions by the Joint ACCS-ACMS committee be deferred until the European Union finalizes its restrictions so that the timing of the respective regulations in Australia and the E.U. coincides.

7. Quinine and its salts

We have no objection to the scheduling of Quinine and its salts in Schedule 6 with the exemption concentration cut-offs for leave-on and rinse-off hair preparations in alignment with international regulations/standards and skin sensitisation warning labels. Currently, Quinine is listed in Annex III, 21 of the European Union's Cosmetic Regulation EC No. 1223/2009 - *List of substances which cosmetic products must not contain except subject to the restrictions laid down*, and has a maximum concentration of 0.5% (as quinine base) for rinse-off hair products and a maximum concentration of 0.2% (as quinine base) for leave-on hair products.

[redacted]

[redacted]

We encourage the Joint ACCS-ACMS committee to adopt these international standards.

8. Vinyl acetate, CAS No. 108-05-4

We have no objections regarding the recommendation to schedule Vinyl acetate with a 1% exemption concentration cut-off for use in domestic products; and a new Schedule 10 entry for cosmetic use.

Conclusions

We greatly appreciate the opportunity to comment on these ingredient issues that are of importance to our members. If there are any changes in ingredient requirements, we respectfully request that there is adequate time for companies to make the necessary changes. When appropriate, we encourage the development of guidance documents by the regulators to assure a smooth transition to any changes to the TGA regulations. We hope that TGA will review and consider our remarks, and if there is any need for more information or clarity, please feel free to contact us at any time.

Sincerely,

Glenda Williams

[redacted]
Sr. Director of International Regulatory Affairs,
Global Strategies

[redacted]

[redacted]

Australian Self-Medication Industry Ltd.
[redacted]

15 June 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: Medicines.Scheduling@tga.gov.au and to: chemicals.scheduling@health.gov.au

Dear Sir or Madam,

Notice inviting public submissions under Reg 42ZCZK of the *Therapeutic Goods Regulations* 1990 Scheduling proposals to be considered at the ACCS, ACMS and ACCS/ACMS Meetings, July 2017

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide comment on six of the scheduling proposals that will be referred to the July 2017 meetings of the ACCS, ACMS and ACCS/ACMS.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates the opportunity to provide public comment in relation to ACCS, ACMS and ACCS/ACMS agenda scheduling proposals. We wish to address relevant matters under section 52E of the *Therapeutic Goods Act* 1989.

Please find enclosed, under cover of this letter, ASMI's comments in relation to the following scheduling proposals that will be considered by the ACCS, ACMS and ACCS/ACMS at the July 2017 meetings:

Basic red 76

> *To amend the Schedule 7 entry for azo dyes to exclude Basic Red 76 from being captured and to include a new Schedule 6 entry for Basic Red 76 for use in non-oxidative hair, eyelash and eyebrow dye products with a cut-off concentration of 0.001% free o-anisidine.*

Esomeprazole

> *A request has been made to down-schedule esomeprazole from Schedule 3 to Schedule 2 in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and*

other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

Ibuprofen combined with Paracetamol

A request has been made to amend the current Schedule 2 entry for ibuprofen when combined with paracetamol to increase the pack size of preparations for oral use when labelled with a recommended daily dose of 1200 mg or less from 12 to 24 dosage units.

Sildenafil

An applicant has proposed that a new Schedule 3 entry for sildenafil in oral preparations containing 50 mg of sildenafil per dosage unit in packs containing not more than 8 dosage units be created.

The proposal is also to include sildenafil in Appendix H and to include additional warning statements in Appendix F for Schedule 3 sildenafil.

Vardenafil

A request has been made to create a new Schedule 3 entry for vardenafil in oral preparations containing up to 10 mg per dosage unit in packs containing not more than 8 dosage units.

Methylisothiazolinone

Proposed amendment to the Schedule 6 as follows:

METHYLISOTHIAZOLINONE except:

a) *In rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or*
b) *In other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylisothiazolinone.*

Each of these agenda items is presented as a separate attachment.

As an industry representative, ASMI is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Regulatory and Legal Director

Agenda item 1 (ACCS) - Basic red 76

> *To amend the Schedule 7 entry for azo dyes to exclude Basic Red 76 from being captured and to include a new Schedule 6 entry for Basic Red 76 for use in non-oxidative hair, eyelash and eyebrow dye products with a cut-off concentration of 0.001% free o-anisidine.*

Introduction

ASMI suggests that the Schedule 7 entry for azo dyes (along with the Schedule 5 and Schedule 6 entries) should all be amended to exclude therapeutic goods.

ASMI Comment

ASMI notes that the objective of this particular agenda item is to amend the Schedule 7 entry for azo dyes to exclude Basic Red 76 only and to include a new Schedule 6 entry for Basic Red 76 for use in hair dye products. However, in preparing our response to this item we have identified what appears to have been an oversight in the previous scheduling assessment for azo dyes.

The current Schedule 7 entry resulted from the NICNAS IMAP report. At least two dyes affected by the NICNAS IMAP report and the current Schedule 7 entry are currently approved for use in therapeutic goods, as follows:

- Solvent Red 1 (CAS 1229-55-6)
- Sudan Red III (CAS 85-86-9)

It is unclear how many therapeutic goods include these two dyes.

It is also unclear how many other dyes used in therapeutic goods are affected by the Schedule 7 entry for azo dyes (given the various nomenclatures employed).

It is therefore unclear exactly how many products that are currently registered and listed on the ARTG have the potential to be affected by scheduling decisions relating to azo dyes.

The decision to create the Schedule 7 entry for azo dyes was made in late 2015 with an implementation date of February 2016. However, Solvent Red 1 and Sudan Red III remain permitted for use in listed medicines and only last month the TGA amended the permissible ingredients determination to restrict Sudan III to topical use (a decision which is apparently at odds with the scheduling decision).

It seems that there is a certain amount of confusion surrounding the scheduling decision and the Schedule 7 entry (perhaps because the entry does not list all the known dyes which are captured).

ASMI also notes that the Scheduling Delegate's final decision from the ACCS meeting of November 2015 did not include any examination of the impact on therapeutic goods.

ASMI makes the following comments:

- ASMI suggests that therapeutic goods should be excluded from any schedule entry for azo dyes. The TGA registration and listing process provides the most appropriate mechanism for regulating therapeutic goods on a product by product basis, considering the relevant benefits and risks.
- ASMI requests that the TGA engages in transparent consultation with industry regarding azo dyes, noting that there are significant commercial implications and long lead times needed if re-formulation is required.
- ASMI requests that the Delegate publishes an interim decision and requests further public consultation when further information on the use of these ingredients has been obtained.
- The use of these ingredients in existing products should be considered; reformulation should not be needed for medicines that have had a history of safe use.
- Realistic implementation dates should be proposed, providing industry with adequate lead times to implement changes to labelling or formulations. Changes to formulation require long lead times for product development and stability testing.
- Scheduling decisions that have such a significant impact should be subjected to a RIS.

Conclusion

ASMI suggests that there needs to be a comprehensive review of the impact of the Schedules 5, 6 and 7 entries for azo dyes on therapeutic goods, with the preferred outcome being that therapeutic goods should be excluded from any schedule entry for azo dyes.

Agenda item 2 (ACMS) - Esomeprazole

> *A request has been made to down-schedule esomeprazole from Schedule 3 to Schedule 2 in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.*

Introduction

ASMI supports the proposal to increase the Schedule 2 pack size limit for esomeprazole from 7 days' supply to 14 days' supply.

ASMI notes that a 14 day supply would be consistent with the Schedule 2 Scheduling Factors, would be consistent with comparable overseas regulation and would be consistent with the current scheduling of other similar ingredients (e.g. the H2 Receptor Antagonist, Ranitidine).

ASMI Comment

ASMI understands that about 4 million Australians aged 18 years and above suffer from heartburn and other symptoms of gastro-oesophageal reflux disease (GORD), with approximately 1.6 million Australians suffering from frequent heartburn, defined as heartburn occurring 2 or more times a week.

Heartburn and other symptoms of GORD can be appropriately identified and managed by consumers. Currently consumers can self-select treatment options from grocery and pharmacy channels, as follows:

- Antacids and antacid/alginate combinations (unscheduled)
- Ranitidine (7 days' supply unscheduled and 14 days' supply as Schedule 2)
- Proton pump inhibitors (7 days' supply as Schedule 2).

Proton Pump Inhibitors (PPIs) are recognised as an appropriate first-line treatment for typical GORD symptoms.

Esomeprazole has a wide therapeutic index. The safety and tolerability of esomeprazole are well-established in doses up to 160 mg daily and supported by the extensive clinical (and post-marketing) experience in various indications, populations and age groups.

Information on overdose with esomeprazole indicates that the drug causes only minor symptoms such as vomiting, nausea, abdominal pain and drowsiness.

Esomeprazole does not produce euphoric, stimulant, sedative or other addictive effects most commonly associated with abuse or misuse. No potential for misuse for illegal purposes has been identified.

Long-term exposure (up to 1 year) to prescribed esomeprazole has not raised any safety concerns.

There is no evidence of the development of resistance to esomeprazole.

A 14 day supply of Esomeprazole, would meet the following Schedule 2 scheduling factors:

- The risk profile of the medicine is well defined and the risk factors can be identified and managed by a consumer through appropriate packaging and labelling and consultation with a medical practitioner if required.
- The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist is available to maximise the safe use of the medicine
- The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.
- The use of the medicine at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.
- The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.

ASMI notes that a number of published guidelines (both in Australia and overseas) recommend an initial PPI course of at least two weeks for individuals with frequent heartburn or other typical symptoms of GORD. A 14 day pack size would therefore be consistent with these guidelines.

ASMI also notes that consumers in other comparable overseas markets such as the UK and the US can self-select 14 days' supply of PPIs, and it is appropriate that consumers in Australia be afforded similar access in the pharmacy setting.

Conclusion

ASMI supports the proposal to increase the Schedule 2 pack size limit for esomeprazole from 7 days' supply to 14 days' supply.

We support the proposal because a 14 day supply would be consistent with the Schedule 2 Scheduling Factors, would be consistent with comparable overseas regulation and would be consistent with the current scheduling of other similar ingredients (e.g. the H2 Receptor Antagonist, Ranitidine).

Agenda item 2 (ACMS) - Ibuprofen combined with Paracetamol

> *A request has been made to amend the current Schedule 2 entry for ibuprofen when combined with paracetamol to increase the pack size of preparations for oral use when labelled with a recommended daily dose of 1200 mg or less from 12 to 24 dosage units.*

Introduction

ASMI supports the proposal to increase the pack size of the Schedule 2 entry from 12 to 24 dosage units. ASMI also supports retaining a scheduling cut-off based on the number of dosage units (as opposed to a scheduling cut-off based on a number of days' supply).

Not only will this better reflect the current scheduling principles, but it will be a move towards closer alignment with the New Zealand scheduling of the combination.

The individual components have a long history of use and a well-documented, favourable safety profile.

ASMI Comment

The interim decision from the ACMS meeting of November 2015 (ACMS #16) proposed a scheduling cut-off based on 3 days' supply. In the ASMI response of 18 February 2016, we suggested that the scheduling entry be based on the number of dosage units, for the following reasons:

- All the other scheduling entries for divided preparations of paracetamol and ibuprofen are based on maximum pack sizes and maximum quantities of active ingredient per tablet or capsule (thereby ensuring consistency of the maximum amount of active per pack). For the sake of this consistency the same approach should be taken here.
- The active ingredient quantities and dosing instructions for the two currently marketed combination products are different, so that a 3 day supply of Nuromol is a maximum of 9 tablets and a 3 day supply of Maxigesic is a maximum of 24 tablets. To avoid confusion in the marketplace and to ensure that products in the same schedule contain similar total quantities of active ingredients, the scheduling of the combination should be based on pack size.

ASMI continues to hold this view.

Paracetamol 500mg tablets (when labelled with appropriate warnings and dosage instructions) are currently exempt from scheduling when included in packs containing not more than 20 tablets.

Ibuprofen 200mg tablets (when labelled with appropriate warnings and dosage instructions) are currently exempt from scheduling when included in packs containing not more than 25 tablets.

Current policy and scheduling principles for products containing more than one poison[1] states:

> *"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 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"*

On this basis, ASMI continues to believe that the scheduling of these combination products should be consistent with the scheduling of the individual components, i.e. they should be exempt from scheduling in packs of not more than 20 dosage units.

Paracetamol and ibuprofen individually both have a long history of use in Australia, and are well tolerated and have favourable safety profiles. The low risks associated with these ingredients are such that they are unscheduled in small pack sizes.

It is ASMI's position that the low risks individually associated with paracetamol and ibuprofen will similarly be associated with the combination of the two. This view is supported by published studies[2] and by post-marketing data.

ASMI acknowledges that combination products may contribute to unintentional overdose (with consumers taking multiple products containing the same active). However, this issue can be adequately dealt with through product labelling, which is the domain of the regulator, and pharmacist advice at the point of sale.

The labelling of these products contains appropriate warning statements, as per the TGA Medicines Advisory Statement Specifications (MASS 2014) to facilitate appropriate use. Pharmacists are also available at the point of supply to provide advice and referral if needed.

ASMI is unaware of any evidence of dependence, abuse, misuse or illicit use of the combination paracetamol and ibuprofen product. To the contrary, this combination offers an alternative to codeine containing analgesics.

Consumers are familiar with the use of OTC analgesic products to assist them with the short term relief of muscular aches and pains, mild to moderate pain of osteoarthritis, dental pain, headache, migraine etc. These conditions are suitable for short term management by consumers.

Harmonisation – New Zealand

ASMI notes that in New Zealand, combination paracetamol and ibuprofen products are Pharmacy Medicines in packs of 21 to 100 tablets / capsules, and suitable for general sale (GSL) in packs of up to 20 tablets / capsule.

---

[1] Standard for the Uniform Scheduling of Medicines and Poisons. http://www.tga.gov.au/industry/scheduling-poisons-standard.htm#electronic

[2] De Vries F, Stetakis E, van Staa TP. Concomitant use of ibuprofen and paracetamol and the risk of major clinical safety outcomes. Br J Pharmacol. 2010;70(3):429-38

ASMI supports measures to more closely align Australian schedules with New Zealand and other comparable markets, where there is alignment in scheduling principles.

The marketing history of this combination product in New Zealand adds further support to the safety study referred to above. It would be anticipated that sponsors of these combination products in New Zealand will have post-marketing data that further demonstrates the favourable safety profile of this combination product.

Conclusion

ASMI supports the proposal for amendment of Schedule 2.

Agenda item 2 (ACMS) - Sildenafil

> *An applicant has proposed that a new Schedule 3 entry for sildenafil in oral preparations containing 50 mg of sildenafil per dosage unit in packs containing not more than 8 dosage units be created.*
>
> *The proposal is also to include sildenafil in Appendix H and to include additional warning statements in Appendix F for Schedule 3 sildenafil.*

Introduction

ASMI supports the proposal for a new Schedule 3 entry for sildenafil.

ASMI supports the proposal to include sildenafil in Appendix H.

ASMI Comment – S3

Sildenafil is a phosphodiesterase type 5 (PDE-5) inhibitor which is used to treat erectile dysfunction (ED). Sildenafil has been available in Australia as a prescription medicine (Viagra) since 1998 and has a well-established safety profile (it is well tolerated, with adverse events that are mild, transient and easily managed). ASMI understands that there has been no evidence of dependence with sildenafil.

Erectile dysfunction is defined as an inability to get and/or keep an erection that allows sexual activity with penetration. The nature of the symptoms means that affected men will be able to identify them and be able to advise their healthcare professional whether the product provides the desired benefit or not. ED can adversely impact sexual intimacy, reduce quality of life and decrease working productivity.

A significant proportion of men suffering from ED are not currently seeking professional advice. More convenient access through the pharmacy has the potential to lead men who currently remain untreated into the healthcare system. This has the potential for more frequent conversations with men about the underlying conditions leading to ED and therefore to better health outcomes. It also enables pharmacists to play a vital role in referring men earlier for further discussions with their GP about their health.

Furthermore, there are a growing number of TGA alerts relating to contaminated, adulterated and counterfeit ED products and the men who purchase these products are doing so without the supervision of a healthcare professional. Increased access via pharmacy will provide men with a legitimate product and advice from a pharmacist.

Sildenafil has been available without a prescription in New Zealand since 2014. ASMI also notes the UK MHRA's proposal of 28 March 2017 to make sildenafil available as a Pharmacy Medicine[3]. In their public consultation the MHRA state (at page 13) that the benefits of provision of sildenafil via pharmacists "*brings a hard to reach group into healthcare environment with the potential to increase earlier identification of heart disease and also reducing the risks associated with use of counterfeits obtained via the internet.*"

[3] https://www.gov.uk/government/consultations/proposal-to-make-sildenafil-50mg-film-coated-tablets-available-from-pharmacies

ASMI understands that any re-scheduling of sildenafil in Australia would be accompanied by pharmacist training and that pharmacists would be provided with appropriate screening and support tools to ensure Quality Use of Medicines principles were applied and to ensure that referral to a GP occurs where appropriate. ASMI notes the concerns from the November ACMS meeting (in relation to vardenafil) that "additional pharmacist training and use of a specific supply protocol cannot be mandated for the supply of pharmacist-only Schedule 3 medicines". ASMI suggests that such concern is misplaced in relation to whether or not a substance should be included in Schedule 3. This concern effectively ignores the network of legal, professional and ethical obligations already acting on pharmacists to make sure that: (a) they are involved in the S3 transaction, and, (b) they recommend the appropriate product in the circumstances. The existence of this network makes mandating training and supply protocols unnecessary.

ASMI Comment – Appendix H

ASMI believes that raising public awareness of Schedule 3 medicines will deliver a range of benefits – firstly for consumers by increasing awareness of a broader range of therapeutic options; secondly, for pharmacists by promoting their professional role in managing conditions for which Schedule 3 medicines are available.

A recent study commissioned by ASMI and conducted by the Centre for Health Economics Research and Evaluation (CHERE), University of Technology Sydney[4] examined the impact of S3 advertising and found the following:

- Advertising raises awareness of therapeutic options and pharmacy services which can result in improved disease management.
- The pharmacist's recommendation had a positive and significant impact on the consumers' choice of preferred product.
- Consumers are comfortable talking to pharmacists about their disease management.
- Advertising is unlikely to drive inappropriate demands for brands.
- Pharmacists showed confidence in handling a direct request from consumers for a particular product, and this was not a significant factor in their recommendations.
- Advertising will not have a significant impact on the recommendations made by pharmacy professionals
- S3 advertising is unlikely to lead to inappropriate use of the medicine.

The TGA Schedule 3 Advertising Guidelines (dated November 2000) refer to the following criteria that should be used when determining suitability of a medicine for inclusion in Appendix H. These include:

- Potential public health benefit
- Likelihood of advertising leading to inappropriate patterns of use
- Provisions relating to the Therapeutic Goods Advertising Code
- Whether the entry may result in advertising of goods for an indication other than those included in the ARTG
- Ability of the consumer to appropriately use through labelling / CMI etc.

ASMI believes that Schedule 3 access to sildenafil fulfils the above criteria.

[4] https://www.uts.edu.au/sites/default/files/CHERE_report_S3_final.pdf

Re-scheduling alone will not necessarily result in improved access to a medicine and it is important for consumers to be made aware of the non-prescription availability of sildenafil.

Without inclusion of sildenafil in Appendix H, the opportunity to undertake important consumer education initiatives will be severely diminished. Advertising of Schedule 3 sildenafil can encourage more health conversations between consumers and pharmacists, lead to earlier referral to a GP for earlier diagnosis of any potential underlying conditions such as CVD and diabetes, and encourage men to improve their lifestyle and take other positive preventative actions to reduce their risk factors.

As with all Schedule 3 medicines, the labelling of the product is approved by the TGA and a Consumer Medicines Information document will be available from pharmacists in order to assist consumers.

Conclusion – S3

Sildenafil has a well-established safety profile (it is well tolerated, with adverse events that are mild, transient and easily managed).

Symptoms of ED can be identified by patients and managed by appropriately trained pharmacists with referral to a GP where necessary.

A similar scheduling arrangement to that proposed already exists in New Zealand and the results there have been positive. Additionally, the UK regulator is proposing to re-classify sildenafil as a Pharmacy Medicine.

For these reasons, the scheduling proposal should be supported.

Conclusion – Appendix H

ASMI supports the proposal to include sildenafil in Appendix H, and believes that there are benefits for both consumers and pharmacists with increasing awareness of Schedule 3 medicines in general.

ASMI believes that there are potential public health benefits in advertising the Schedule 3 product to consumers.

The advice from the pharmacist, together with appropriate warning statements on labelling and the availability of the CMI will help ensure that consumers have the information they need to manage their use of this product.

Agenda item 2 (ACMS) - Vardenafil

> *A request has been made to create a new Schedule 3 entry for vardenafil in oral preparations containing up to 10 mg per dosage unit in packs containing not more than 8 dosage units.*

Introduction

ASMI supports the proposal for a new Schedule 3 entry for vardenafil.

ASMI supports the inclusion of vardenafil in Appendix H.

ASMI Comment – S3

Vardenafil is a second generation phosphodiesterase type 5 (PDE-5) inhibitor which is used to treat erectile dysfunction (ED). Vardenafil has been available in Australia as a prescription medicine (Levitra) since 2003 and has a well-established safety profile (it is well tolerated, with adverse events that are mild, transient and easily managed). ASMI understands that there has been no evidence of dependence with vardenafil.

Erectile dysfunction is defined as an inability to get and/or keep an erection that allows sexual activity with penetration. The nature of the symptoms means that affected men will be able to identify them and be able to advise their healthcare professional whether the product provides the desired benefit or not. ED can adversely impact sexual intimacy, reduce quality of life and decrease working productivity.

A significant proportion of men suffering from ED are not currently seeking professional advice. More convenient access through the pharmacy has the potential to lead men who currently remain untreated into the healthcare system. This has the potential for more frequent conversations with men about the underlying conditions leading to ED and therefore to better health outcomes. It also enables pharmacists to play a vital role in referring men earlier for further discussions with their GP about their health.

Furthermore, there are a growing number of TGA alerts relating to contaminated, adulterated and counterfeit ED products and the men who purchase these products are doing so without the supervision of a healthcare professional. Increased access via pharmacy will provide men with a legitimate product and advice from a pharmacist.

Sildenafil has been available without a prescription in New Zealand since 2014. ASMI also notes the UK MHRA's proposal of 28 March 2017 to make sildenafil available as a Pharmacy Medicine[5]. In their public consultation the MHRA state (at page 13) that the benefits of provision of sildenafil via pharmacists "*brings a hard to reach group into healthcare environment with the potential to increase earlier identification of heart disease and also reducing the risks associated with use of counterfeits obtained via the internet.*"

ASMI understands that any re-scheduling of vardenafil in Australia would be accompanied by pharmacist training and that pharmacists would be provided with appropriate screening and support tools to ensure Quality Use of Medicines principles were applied and to ensure that referral

[5] https://www.gov.uk/government/consultations/proposal-to-make-sildenafil-50mg-film-coated-tablets-available-from-pharmacies

to a GP occurs where appropriate. ASMI notes the concerns from the November ACMS meeting that "additional pharmacist training and use of a specific supply protocol cannot be mandated for the supply of pharmacist-only Schedule 3 medicines". ASMI suggests that such concern is misplaced in relation to whether or not a substance should be included in Schedule 3. This concern effectively ignores the network of legal, professional and ethical obligations already acting on pharmacists to make sure that: (a) they are involved in the S3 transaction, and, (b) they recommend the appropriate product in the circumstances. The existence of this network makes mandating training and supply protocols unnecessary.

ASMI Comment – Appendix H

ASMI notes that the ACMS agenda item for vardenafil did not include a proposal for an Appendix H entry. Nevertheless, ASMI offers the following comments in relation to a potential Appendix H entry for vardenafil.

ASMI believes that raising public awareness of Schedule 3 medicines will deliver a range of benefits – firstly for consumers by increasing awareness of a broader range of therapeutic options; secondly, for pharmacists by promoting their professional role in managing conditions for which Schedule 3 medicines are available.

A recent study commissioned by ASMI and conducted by the Centre for Health Economics Research and Evaluation (CHERE), University of Technology Sydney[6] examined the impact of S3 advertising and found the following:

- Advertising raises awareness of therapeutic options and pharmacy services which can result in improved disease management.
- The pharmacist's recommendation had a positive and significant impact on the consumers' choice of preferred product.
- Consumers are comfortable talking to pharmacists about their disease management.
- Advertising is unlikely to drive inappropriate demands for brands.
- Pharmacists showed confidence in handling a direct request from consumers for a particular product, and this was not a significant factor in their recommendations.
- Advertising will not have a significant impact on the recommendations made by pharmacy professionals
- S3 advertising is unlikely to lead to inappropriate use of the medicine.

The TGA Schedule 3 Advertising Guidelines (dated November 2000) refer to the following criteria that should be used when determining suitability of a medicine for inclusion in Appendix H. These include:

- Potential public health benefit
- Likelihood of advertising leading to inappropriate patterns of use
- Provisions relating to the Therapeutic Goods Advertising Code
- Whether the entry may result in advertising of goods for an indication other than those included in the ARTG
- Ability of the consumer to appropriately use through labelling / CMI etc.

[6] https://www.uts.edu.au/sites/default/files/CHERE_report_S3_final.pdf

ASMI believes that Schedule 3 access to vardenafil fulfils the above criteria.

Re-scheduling alone will not necessarily result in improved access to a medicine and it is important for consumers to be made aware of the non-prescription availability of vardenafil.

Without inclusion of vardenafil in Appendix H, the opportunity to undertake important consumer education initiatives will be severely diminished. Advertising of Schedule 3 vardenafil can encourage more health conversations between consumers and pharmacists, lead to earlier referral to a GP for earlier diagnosis of any potential underlying conditions such as CVD and diabetes, and encourage men to improve their lifestyle and take other positive preventative actions to reduce their risk factors.

As with all Schedule 3 medicines, the labelling of the product is approved by the TGA and a Consumer Medicines Information document will be available from pharmacists in order to assist consumers.

Conclusion – S3

Vardenafil has a well-established safety profile (it is well tolerated, with adverse events that are mild, transient and easily managed).

Symptoms of ED can be identified by patients and managed by appropriately trained pharmacists with referral to a GP where necessary.

A similar scheduling arrangement to that proposed already exists in New Zealand (albeit with sildenafil) and the results there have been positive. Additionally, the UK regulator is proposing to re-classify sildenafil as a Pharmacy Medicine.

For these reasons, the scheduling proposal should be supported.

Conclusion – Appendix H

ASMI supports the inclusion of vardenafil in Appendix H, and believes that there are benefits for both consumers and pharmacists with increasing awareness of Schedule 3 medicines in general.

ASMI believes that there are potential public health benefits in advertising the Schedule 3 product to consumers.

The advice from the pharmacist, together with appropriate warning statements on labelling and the availability of the CMI will help ensure that consumers have the information they need to manage their use of this product.

Agenda item 3 (ACCS / ACMS) - Methylisothiazolinone

Proposed amendment to the Schedule 6 as follows:

METHYLISOTHIAZOLINONE except:

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

b) In other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylisothiazolinone.

Introduction

ASMI supports the proposed amendment to the scheduling of methylisothiazolinone (MIT) to the extent to which it aligns with international requirements.

ASMI seeks clarification about the ongoing requirement in relation to the Appendix F warning.

Should there be a change to the scheduling entry, ASMI suggests an appropriate transition period to allow affected manufacturers sufficient time to develop new formulations.

ASMI Comment

ASMI notes that MIT is used in cosmetic products and in therapeutic goods and is entered as an ingredient on the ARTG. MIT is used as a preservative in topical products, such as sunscreens, antiseptic hand washes, moisturisers, shampoos, conditioners and disinfectants.

ASMI supports harmonisation of requirements with comparable overseas markets.

- ASMI notes that currently, both key regulators (US and European) allow MIT in rinse off preparations at a concentration of up to 0.01% (100ppm). The US CIR Expert Panel (US) recommendations[7] allow for a cut-off in rinse-off preparations of 0.01% (100 ppm), as do the current EU regulations[8], adopted in July 2016.
- MIT is not permitted in leave-on products such as “wet wipes”.
- As a result, the key global regulators are currently aligned on a cut-off of 0.01% for rinse-off preparations and a move to a cut-off of 0.0015% currently represents a unique Australian requirement, not aligned with the rest of the world.
- ASMI notes the opinion of the EU Scientific Committee on Consumer Safety (SCCS)[9], which has concluded that a concentration of 0.0015% (15 ppm) is safe in rinse-off topical products. ASMI understands that this opinion is being considered for adoption into European legislation.

ASMI understands that MIT is not an effective preservative / biocide at 15 ppm (0.0015%). A proposed cut-off of 0.015% (15 ppm) is therefore below the level at which the preservative is effective. This means that topical products that contain MIT at levels below 0.01%, but over 0.0015% will require re-formulation.

[7] http://www.cir-safety.org/sites/default/files/mthiaz062014tent_0.pdf
[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1198
[9] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf

Should a new scheduling entry for MIT result, then ASMI requests that the Delegate allow at least 24 months and preferably 30 months transition period so as to give affected manufacturers sufficient time to investigate alternative preservative systems, develop new formulations, perform the required testing to ascertain the optimal formulation and preservative systems, manufacture test batches and perform the associated stability / quality control on test batches before going to market.

Should a new scheduling entry for MIT result, then ASMI suggests that the requirement to include an Appendix F warning be removed (as is apparently being considered in the scheduling proposal). The SCCS opinion recognises that "For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy". A warning statement in relation to sensitisation would therefore seem unnecessary.

Conclusion

ASMI supports the proposed amendment to the scheduling of methylisothiazolinone (MIT) to the extent to which it aligns with international requirements.

Should a new scheduling entry for MIT result, then ASMI requests that the Delegate allow at least 24 months and preferably 30 months transition period so as to give affected manufacturers sufficient time to develop and launch re-formulated products.

The Secretary,
Scheduling Secretariat
GPO Box 9848
Canberra A.C.T. 2601

Public Comment Submission to the Proposed Amendments to the Poisons Standard ACCS meeting, July 2017

Dear Sir / Madam,

[redacted] wishes to provide comment on the following substance for consideration at the July 2017 meeting of the ACCS:

- **Basic Red 76**

[redacted] notes and supports the proposal to amend the Schedule 7 entry for azo dyes to exclude Basic Red 76 from being captured and to include a new Schedule 6 entry for Basic Red 76 for use in non-oxidative hair, eyelash and eyebrow dye products.

We support the proposal to amend the Poison Standard by including an entry in Schedule 6 for Basic Red 76 and suggest that the following entry will allow international alignment for these type of products:

Basic Red 76 (CAS No 68391-30-0) ***except;***

a) *In non-oxidative hair dye preparations with a maximum on head concentration of 2% and when the immediate container and primary pack are labelled with the following statements:*

   KEEP OUT OF REACH OF CHILDREN, and
   WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

   Written in letters not less than 1.5 mm in height; or

b) *In eyelash and eyebrow tinting products at a maximum concentration of 2% when the immediate container and primary pack are labelled with the following statement:*

WARNING – This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

Written in letters not less than 1.5 mm in height.

We also support appropriate entries to allow the reinstated use of colour CI 26100, Red 17 or Sedan III for general use in cosmetic products as a colorant. This colour has also been caught by the current Schedule 7 entry for AZO dyes.

We are a member of [redacted], the Australian Industry Body representing cosmetics, and support submissions they have made regarding Basic Red 76 and CI26100.

We thank you for this opportunity to provide comments. If you have any queries, or for more information, please do not hesitate to contact me.

Yours sincerely,

[unsigned for electronic submission]

[redacted]

15.06.2017

From:	r r
To:	Medicines Scheduling
Subject:	Submmission-resp;onse to public comments on pred-meting proposals to amend the Poisons Standard folr the July Meeting of the ACMS, ACCS and Joint ACCS-ACMS [SEC=No Protective Marking]
Date:	Wednesday, 17 May 2017 4:10:44 PM
Attachments:	[redacted]

Dear Sir/Madam,
The following are my comments on the pre-meeting proposals to amend the Poisons Standard for the July Meting of the Advisory Committees- ACMS, ACCS and Joint ACCS-ACMS:

Yours Sincerely,
Ronald Batagol, PhC,FSHP,AGIA, Dip.Jnl
Senior Hospital Pharmacist, Independent Obstetric Medicines Consultant and Specialist Advisor to TGA Committees.

2. Proposed amendments referred by the delegate for scheduling advice for consideration by the Advisory Committee on Medicines Scheduling (ACMS)
MY COMMENTS AS FOLLOWS:

Esomeprazole- I agree with the proposal, as it will allow for better availability for non-prescription use via sources of pharmacist advice.

Ibuprofen combined with Paracetamol- I disagree with the proposal. 12 tablets are sufficient for initial use. The risk is well-established of potential adverse renal consequences in situations of renal compromise, including fluid depletion from any source, and also a "triple whammy" type interaction between an ACE/ARB medication with diuretic and NSAID medication. These well-established risks may amount to , albeit temporary, renal failure, even with short-term use. So, it is best for the patient to liaise with their doctor or pharmacist after initial short-term use, to verify safety for a longer course of treatment. For this purpose, the pack limited to 12 tablets would seem to be appropriate.

I would like to support the move for medicines such as Viagra being made available over the counter (OTC) at pharmacies.

There are some compelling reasons why this should be the case:

Fifty two percent of men 40 to 70 years of age report some degree of ED[1], but only 30% of these men seek medical treatment for the disease[2], leaving the majority of men untreated or choosing to access ED medicines from outside the healthcare system.

ED medicines are currently the most counterfeited medicines seized by the European Union customs[3], suggesting that the market for these drugs is large. ED medicines from uncontrolled sources are often of poor quality, containing either no, too little, too much, or the wrong ingredient and often have no appropriate patient information.[4]

ED medicines obtained from any source other than a retail pharmacy or directly from a doctor (ie, free sample) encompasses an increased risk of being a non genuine medication. This includes counterfeit medicines claiming to be branded phosphodiesterase (PDE5) inhibitors or unapproved generic versions thereof (sold as imitations, like [redacted] etc).[3, 4] Sixty five percent of the samples of ED medicines from uncontrolled sources analysed in a study by the Dutch Health Authorities were imitations, and the majority of imitations were rated as relatively high health risks.[5] Diagnosis of ED is increasingly important with the recent recognition that ED is often a precursor of underlying cardiovascular disease.[6]

By avoiding the healthcare system to obtain genuine ED treatments, men with ED may miss an opportunity to get appropriate health information regarding the importance of a medical follow-up. To better understand the factors that motivate men to purchase PDE5 inhibitors from different sources, a cross-sectional, internet based, observational study was conducted in men in the United Kingdom, Germany and France to estimate the number of men who avoid the healthcare system to purchase PDE5 inhibitors and to describe their demographic characteristics.

The survey results suggest that almost one third of men in the general population purchasing a PDE5 inhibitor are self-diagnosing and self-treating their ED without any prior interaction with a healthcare professional.

Seven out of 10 of these men have ED, which may be associated with cardiovascular risk factors, such as hypertension, dyslipidaemia or diabetes.[7] This situation has important repercussions for their future health.

By using PDE5 inhibitors from uncontrolled sources outside of the healthcare system and without any healthcare professional interaction:

- men expose themselves to the risks of using unapproved and uncontrolled products.
- men miss important information on product usage, including the mechanism of action or contraindications for PDE5 inhibitor use that are important to ensure safe usage.
- men miss an opportunity for appropriate health information regarding the importance of medical follow-up for unrecognized cardiovascular disease.

The factors that motivate men to purchase PDE5 inhibitors through uncontrolled channels deserve further investigation so that appropriate strategies can be developed to bring men seeking treatment for ED into the HCS.[8, 9]

In addition to this, we know that men with known cardiovascular disease (CVD), two thirds have ED for average for 5 years before the heart attack and only half have ever spoken about it. A window of opportunity is being missed to address CVD risk factors.[10] This study demonstrated that cardiac rehabilitation staff are only occasionally asking individuals about ED and that the patients themselves are not reporting their ED for a variety of reasons.[11, 12, 13]

In view of the prevalence in our populations and its impact, ED should be a condition that patients can feel free to visit their pharmacist and discuss. GPs are perceived as being very busy and sexual problems are perceived as lifestyle issues rather than a medical condition leading to delay in presentation and missed opportunities. The increasing number of female GPs may also be a barrier.

The PDE5 inhibitor class of drugs are very safe and indeed cardio-protective as demonstrated in two recent studies that suggested that these drugs when used on a when necessary basis in men with diabetes and in cardiovascular patients were very beneficial. The diabetes study in the UK concluded that in a population of men with type 2 diabetes, use of PDE5 was associated with lower risk of overall mortality and mortality in those with a history of acute myocardial Infarction.[14] The Swedish cardiovascular study concluded, treatment for ED after a first MI was associated with a reduced mortality and heart failure hospitalisation. Only men treated with PDE5 inhibitors had a reduced risk, which appeared to be dose-dependent.[15]

The pharmacist can easily and safely exclude any reasons why the man should not take the drug and point out the importance of the man knowing his numbers in relation to blood pressure, cholesterol and blood glucose.

It is also an opportunity to provide lifestyle advice. There is good and compelling evidence that a healthy lifestyle not only prevents erectile dysfunction (ED), but improves erectile function, and there is evidence that pharmacists have an important role to play.

A multicentre, observational, cross-sectional study was conducted in Spanish community pharmacies September–November 2008.[16] Of men asking for ED advice or treatment, each investigator recruited one with and one without PDE5 inhibitor prescription. Study pharmacists completed a questionnaire of patient demographic, clinical, and behavioural data including the Sexual Health Inventory for Men.

Five hundred and seventy-four pharmacists recruited 1,147 patients; 1,113 were included for analysis. There were no statistical differences between the groups regarding weight, hypertension, diabetes mellitus, hypercholesterolemia, dyslipidaemia, depression or stress. There were no statistical differences in severity of ED ($P = 0.7892$) or proportion of men without ED in each group ($P = 0.5755$). ED symptoms had been present for a mean of 26 months in both groups before first consultation with a healthcare professional. This is quite typical!

The visit to the pharmacy was the first discussion about ED for 60.2% of the non-prescription group, and 50% of those who had previously discussed ED had done so with a pharmacist in the first instance. In the non-prescription group, 85.1% of men asked for a PDE5 inhibitor.

The researchers concluded that many men approached a community pharmacist for ED treatment and those with and without a PDE5 inhibitor prescription had an equivalent ED severity and comorbidity profile. Community pharmacists should be trained in current concepts underlying the diagnosis and management of ED to enable them to educate men and encourage them to seek further medical care, increasing the chance of early detection of undiagnosed comorbidities such as cardiovascular disease.[16]

References:

1. Feldman HA, et al. J Urol. 1994;151:54-61.
2. Kubin M, et al. Int J Impot Res. 2003;15(1):63-71.
3. Opinion on Parliamentary Assembly Recommendation 1673 (2004): Counterfeiting: problems and solutions. Council of Europe. Available at: http://www.coe.int/t/e/legal_affairs/legal_co-operation/transnational_criminal_justice/2_pc-oc/PC-OC%20(2006)%2004%20Rev%20E.asp.
4. Blok-Tip L, et al. Counterfeits and imitations of Viagra and Cialis tablets: Trends and risks to public health. A survey of the analysis carried out at the Dutch National Institute for Public Health and the Environment in the time period 2000-2004. Available at: http://www.rivm.nl/bibliotheek/rapporten/267041001.pdf
5. Venhuis B, et al. Recent developments in the counterfeits and imitations of Viagra, Cialis and Levitra. A 2005-2006 update. RIVM. Available at: http://www.rivm.nl/bibliotheek/rapporten/370030001.pdf.
6. Kirby M, et al. Int J Clin Pract. 2001;55(9):614-618.
7. Burchardt M, et al. Int J Impot Res. 2001;13(5):276-281.
8. O'Donnell AB, et al. J Gen Intern Med. 2005;20(6):515-519
9. Banks I, Kirby M. Abstract ESSM/ISSM 2008 Brussels, Belgium December 7–11, 2008
10. Hodges L, Kirby M. Int J Clin Pract, December 2007, 61, 12, 2019–2025
11. De Berardis G, Franciosi M, Belfiglio M et al. Erectile dysfunction and quality of life in type 2 diabetic patients: a serious problem too often overlooked. Diabetes Care 2002; 25: 284–91.
12. Risen CB. A guide to taking a sexual history. Psychiatr Clin North Am 1995; 18: 39–53.
13. Jackson G, Betteridge J, Dean J, Eardley I, Hall R, Holdright D. A systematic approach to erectile dysfunction in the cardiovascular patient: a consensus statement – update 2002. Int J Clin Pract 2002. 56: 663–71.
14. Anderson SG, Hutchings DC, Woodward M, Rahimi K, Rutter MK, Kirby M, Hackett G. Heart doi: 10.1136/heartjnl-2015-309223

15. Anderssen et al Heart Online First, published on March 22, 2017 as 10.1136/heartjnl-2016-310746

16. Martín Morales A, Ibáñez J, Machuca M, Pol-Yanguas E, Schnetzler G, and Renedo VP. Pharmacies in Spain characterising patient profiles of men asking for erectile dysfunction medication. J Sex Med 2010; 7:3153–3160.

[redacted]

AUSTRALIAN MEDICAL ASSOCIATION

[redacted]

AMA submission to ACMS re Vardenafil and Sildenafil downscheduling proposal

The AMA strongly opposes the proposal to create new Schedule 3 entries so that low dose/small packs of Vardenafil and Sildenafil are available over the counter without a prescription from a medical practitioner.

Erectile dysfunction (ED) is complex medical condition not a simple health issue.

ED is a marker of the state of the blood vessels in other parts of the cardiovascular system and should be thoroughly investigated before phosphodiesterase inhibitors are prescribed. This is best investigated by the patient's usual medical practitioner in a consultation where this issue can be teased out and if appropriate alternatives discussed.

ED may also be caused by many other prescription medicines.

It is also crucially important to explore whether there are psychological causes of ED which can be a very significant reason for presentation.

The above issues cannot be addressed by answering a simple check list of questions posed by a pharmacist.

It is argued that men will be more likely to seek help with ED problems if they can access medicines over the counter at a pharmacy, rather than make an appointment with their general practitioner. However accessing these medicines from a pharmacist does not avoid initiating a conversation about ED issues. Conversations with men regarding erectile dysfunction can be very difficult to initiate where there is not a well-developed therapeutic relationship between doctor and patient. It is most unlikely that a pharmacist delivered checklist will facilitate the confidence and trust and emotional security to entertain such a delicate discussion.

Once ED issues are broached, a consultation with a general practitioner will ensure that a full health assessment is undertaken, risk factors are identified and holistic advice is provided. A medical practitioner consultation to obtain a prescription of vardenafil and sildenafil also provides an opportunity to screen for diabetes mellitus and sexually transmissible infections, as well as undertake unrelated but important health prevention activities.

The Advisory Committee on Medicines Scheduling (ACMS) will also be well aware that both vardenafil and sildenafil are known to have serious adverse interactions with a range of other

medicines. While theoretically a pharmacist may know about a patient's usual medicines, a patient's regular general practitioner will also know the full range of medicines currently prescribed, why those particular medicines were prescribed, and be able to discuss safe alternative approaches knowing the full medical history of the patient. A pharmacist identifying a potential adverse drug interaction will, in any event, have to refer the patient to their general practitioner.

ACMS will also be aware of the potential, and serious, adverse reactions associated with use of vardenafil and sildenafil, and the significant range of contraindications.

The AMA does not have confidence that a pharmacist-administered questionnaire will mitigate the risks to patient safety or ensure dispensing and use that is consistent with quality use of medicines principles. Relying on pharmacists to control the use of low-dose codeine products was unsuccessful in stemming the increase in codeine-related deaths post 2010.

It should also be noted that pharmacists will gain financially from the dispensing of these medicines; there is an inherent conflict of interest.

Finally, Bayer submitted an application only last year to downschedule vardenafil but the ACMS recommended against any change to scheduling. The question must be asked - what has changed? If there is new evidence available, then this should be shared publicly so that stakeholders making submissions can be fully informed.

Contact

[redacted]

15 June 2017

[redacted]

Consultation: Proposed amendments to the Poisons Standard - Advisory Committee on Medicines Scheduling meeting, July 2017

JUN
2017

Purpose

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

PSA's comments relate to proposed amendments to: esomeprazole, stiripentol, sildenafil and vardenafil.

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.

[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 October 2016 – 31 December 2016. At: www.pharmacyboard.gov.au/documents/default.aspx?record=WD17%2f22786&dbid=AP&chksum=6tglf5%2b1PY5fnmPNgcDM0g%3d%3d

[redacted]

Summary of PSA's position

Esomeprazole *– PSA does not support the proposal to reschedule esomeprazole (20 mg or less per dosage unit and 14 days' supply or less per pack) from Schedule 3 to Schedule 2. While the substance (esomeprazole) itself has a good safety and efficacy profile, patient factors require careful consideration to determine therapeutic appropriateness and this is best facilitated through the current Schedule 3 arrangements.*

Stiripentol *– PSA agrees with the proposal to create a new entry for stiripentol in Appendix K.*

Sildenafil and vardenafil *– PSA supports the creation of new Schedule 3 entries of sildenafil and vardenafil as proposed. PSA does not support the inclusion of sildenafil or vardenafil in Appendix H.*

Comments on specific substances

Esomeprazole

Proposal to down-schedule esomeprazole from Schedule 3 to Schedule 2 in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

Non-prescription medicines for the treatment of heartburn and symptoms of gastro-oesophageal reflux disease (GORD) are widely available to Australian consumers. Proton pump inhibitors (PPIs) are regarded as first line therapy and considered to be more effective than histamine-2 receptor antagonists.[2]

Preparations containing 20 mg or less per dosage unit of esomeprazole are currently available in Schedule 2 and Schedule 3 for pack sizes of no more than seven and 14 days' supply, respectively. To our knowledge there have not been any reports of significant safety concerns with esomeprazole in these schedules. Schedule 3 esomeprazole is also included in Appendix H of the Poisons Standard.

The inherent safety and risk profile of esomeprazole and its efficacy data are all favourable. However, the use of esomeprazole requires careful consideration of patient factors.

PSA has previously recommended that esomeprazole in 14 day supply quantities are clinically appropriate for inclusion in Schedule 3. The arrangement as a Pharmacist Only Medicine provides for the pharmacist to consider therapeutic appropriateness in the context of patient factors before a decision is made to commence or extend therapy. This means issues such as

---

[2] Sigterman KE, van Pinxteren B, Bonis PA, Lau J, Numans ME. Short-term treatment with proton pump inhibitors, H2-receptor antagonists and prokinetics for gastro-oesophageal reflux disease-like symptoms and endoscopy negative reflux disease. Cochrane Database of Systematic Reviews, 2013, Issue 5. Art. No.: CD002095. DOI: 10.1002/14651858.CD002095.pub5.

the following are taken into account to ensure supply occurs where safe and appropriate and patients are provided with relevant information and advice for therapy:

- following consideration of the nature and frequency of symptoms, the recommended initial therapy for the relief of heartburn and other symptoms of GORD is 20 mg once daily for two weeks (i.e. 14 days' supply)
- recommend immediate referral if:
    - atypical (e.g. cardiac-type chest pain) or alarm symptoms (e.g. painful or difficulty in swallowing) are reported
    - symptoms are severe enough to impair quality of life
    - there has been long term use or the need for a higher dose
- refer for further investigation if:
    - two weeks of continuous therapy has failed to adequately control symptoms
    - symptoms recur following an initial course of therapy
- identify risk factors and consider any lifestyle modifications which may enhance the outcomes of esomeprazole use.

In summary PSA does not support a rescheduling of esomeprazole from Schedule 3 to Schedule 2 as proposed. The need to carefully consider patient factors means the arrangements which are in place for supply as a Pharmacist Only Medicine is the best option for patient safety and health outcomes.

Stiripentol

Proposal to create a new entry in Appendix K.

PSA understands stiripentol is currently approved in a number of countries in Europe, Canada and Japan. It is used for the management of epilepsy, particularly Dravet syndrome (severe myoclonic epilepsy in infancy), usually as adjunctive therapy. One of the main effects of stiripentol is on the central nervous system e.g. sedation. Stiripentol also enhances central depressant effects of other substances such as chlorpromazine.[3]

Given these characteristics, PSA agrees to the inclusion of stiripentol in Appendix K of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons; SUSMP) which provides for a list of human medicines required to be labelled with a warning regarding their sedation potential.

---

[3] Brigo F, Igwe SC, Bragazzi NL. Antiepileptic drugs for the treatment of infants with severe myoclonic epilepsy. Cochrane Database of Systematic Reviews. Issue 5. Art. No.: CD010483. 2017. DOI: 10.1002/14651858.CD010483.pub4.

Sildenafil and vardenafil

Proposal to create a new Schedule 3 entry for sildenafil in oral preparations containing 50 mg per dosage unit in packs containing not more than 8 dosage units. Proposal to also include sildenafil in Appendix H and to include additional warning statements in Appendix F for Schedule 3 sildenafil.

Proposal to create a new Schedule 3 entry for vardenafil in oral preparations containing up to 10 mg per dosage unit in packs containing not more than 8 dosage units.

Safety and efficacy

Sildenafil and vardenafil are oral phosphodiesterase type 5 inhibitors currently registered in Australia and indicated for the treatment of erectile dysfunction in adult males. Both substances are regarded to be generally safe and well tolerated, with no significant difference in their treatment effect.[4]

Proposed pack size

The rescheduling proposals for sildenafil and for vardenafil both include a maximum pack size of eight tablets. The upper limits of doses per dosage unit are consistent with the starting dose for the respective substances. With a recommended maximum of one dose per 24 hours, the maximum pack sizes represent eight days' therapy. PSA is aware that the UK proposal currently under consideration also has an eight tablet maximum. In New Zealand, trained pharmacists are able to supply a manufacturer's original pack containing no more than 12 dosage units.

Key considerations

PSA recently commented on a similar proposal to reschedule vardenafil. The core recommendations provided in that earlier submission remain the same here and the principles and rationale associated with those points apply equally to sildenafil. Thus, PSA supports the rescheduling proposals for both sildenafil and vardenafil in relation to the creation of new entries in Schedule 3.

PSA notes that specific concerns were raised previously by the ACMS in their advice to the delegate as outlined below.

Risks of possible underlying medical conditions

With erectile dysfunction being a possible manifestation of other medical conditions, the ACMS suggested that assessment by a medical practitioner prior to (or concurrent with) initiation of treatment was necessary.

For Schedule 3 supply of sildenafil or vardenafil, pharmacists would be guided by an appropriate protocol which clearly outlines patient eligibility or exclusion criteria. PSA outlined this previously in its submission that, in practice, there would be application of clear parameters by pharmacists

---

[4] Yuan JQ, Zhang RJ, Yang ZY et al. Comparative effectiveness and safety of oral phosphodiesterase type 5 inhibitors for erectile dysfunction: a systematic review and network meta-analysis. Eur Urol 2013; 63:902–12.

in the screening and risk assessment step to determine whether it is appropriate to supply the medicine to the patient. There would also be criteria around immediate or conditional referral to a medical practitioner. Advice to those who are not suitable to use the medicine and have not been supplied with a product will be important so that they clearly understand the outcome of the pharmacist's assessment. Appropriate communication with, for example, the patient's usual GP (separate to a referral) would also be a key requirement. Patients would also be supported by the pharmacist in monitoring their response to the medicine and understanding how to identify and manage side effects if they experience any.

The development of rigorous, comprehensive and educative practice support tools is a core role for PSA and pharmacists expect and value these resources. Protocols and other professional practice tools produced by PSA will guide pharmacists through risk assessment and minimisation steps and provision of tailored advice for the patient. PSA understands the implementation of a pharmacist protocol has worked well in New Zealand with the regulatory change[5] for sildenafil. The UK Medicines and Healthcare products Regulatory Agency is similarly progressing a proposal[6] and a 'checklist' is included as a possible resource that pharmacists could use in determining patient suitability for sildenafil treatment.

As the standards setting body for the profession, PSA will develop a Schedule 3 guidance document should the rescheduling proposals be accepted. PSA is confident that appropriate risk mitigation steps undertaken by pharmacists will support other risk management measures including post-rescheduling pharmacovigilance activities by sponsors and the regulator, packaging and labelling, Consumer Medicine Information leaflet, communication to pharmacists and other health professionals and any post-rescheduling studies or emergence of new evidence.

Harm through misuse

In the context of the original proposal for rescheduling of vardenafil, the ACMS reportedly advised that this class of medicine is commonly misused (e.g. with other drugs).

While PSA believes there is a level of non-therapeutic use of erectile dysfunction therapies, we are not aware of any data which shows they are "commonly misused", nor any information that would corroborate their use in combination with other drugs such as MDMA except for reports of low level co-administration.

PSA notes that the consultation paper on the UK sildenafil proposal considered there is low risk around intentional abuse leading to harm but that this was outweighed by benefits such as bringing a hard to reach group of individuals into the healthcare environment with the potential to increase identification of heart disease.

---

[5] Note that, in New Zealand, the classification of sildenafil remains as a Prescription medicine but it is subject to an exception when "in medicines for oral use containing 100 mg or less per dose unit when sold in the manufacturer's original pack containing not more than 12 solid dosage units for the treatment of erectile dysfunction in males aged 35-70 years by a registered pharmacist who has successfully completed a training programme endorsed by the Pharmaceutical Society of New Zealand".

[6] Medicines and Healthcare products Regulatory Agency. Sildenafil 50 mg film-coated tablets. Public consultation: Proposal to make available from pharmacies. 28 Mar 2017. At: **https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/603358/Sildenafil_public_reclassification_report_for_consultation_final..pdf**

Access through other sources

The ACMS raised a point that rescheduling of vardenafil would most likely not reduce internet purchasing and access to overseas supply of vardenafil. PSA is not able to identify any data to confirm or counter this statement but would also suggest that it is unlikely such data would exist.

In Australia, there has been significant work undertaken by the Therapeutic Goods Administration (and in conjunction with the Australian Customs and Border Protection Service and the Australian Pesticides and Veterinary Medicines Authority) to educate consumers about counterfeit and illegal medicines (and the risks of procuring and using medicines from unknown sources) and to stop these products from reaching consumers. PSA believes it is possible that a legitimate (Schedule 3) access route would reduce the need to rely on overseas supply channels although, once again, we do not have any supporting data. It could, however, at least lessen the opportunity for potential harm to Australian consumers.

PSA notes that, in the UK proposal consultation paper, it is suggested that the rescheduling of sildenafil may assist in reducing the risks associated with use of counterfeit products obtained via the internet.

Pharmacist training and use of specific protocol

The decision to not approve Schedule 3 for vardenafil earlier this year appears to have been, at least in part, due to concerns around the inability to mandate specific training or use of protocols by pharmacists.

Sildenafil and vardenafil have been available in Australia for a significant period of time as Schedule 4 medicines. Pharmacists possess appropriate knowledge and competencies relating to the substance. However, additional information and advice in the context of Schedule 3 supply will be important for pharmacists. This is a fundamental role of PSA and it is paramount that such resources are evidence-based and offer contemporary, realistic and useful guidance to pharmacists to support good decision-making in practice and offer tailored and optimised health care.

The profession is subject to a rigorous framework through which the provision of Schedule 3 medicines occurs. Fundamental requirements are articulated through the profession's competency standards framework,[7] the PSA's Professional practice standards[8] and Code of ethics for pharmacists.[9] Guidelines and standards issued by the Pharmacy Board of Australia are also relevant to professional practice. The assessment and provision of Schedule 3 sildenafil and vardenafil by pharmacists will occur in this context. This framework of professional requirements is comprehensive and rigorous, and far exceeds what might be achieved through mandating specific training or a protocol relating to a Schedule 3 medicine.

---

[7] National competency standards framework for pharmacists in Australia. Canberra: Pharmaceutical Society of Australia; 2016. At: **http://advancedpharmacypractice.com.au/download/resources/5202%20National%20Competency%20Standards%20Framework%20for%20Pharmacists%20in%20Australia%20_FINAL_for_onscreen.pdf**

[8] Pharmaceutical Society of Australia. Professional practice standards. Version 4. Canberra: PSA; 2010. [Currently under review] At: **https://www.psa.org.au/downloads/standards/professional-practice-standards-v4.pdf**

[9] Pharmaceutical Society of Australia. Code of ethics for pharmacists. Canberra: PSA; 2017. At: **https://www.psa.org.au/downloads/codes/PSA-Code-of-Ethics-2017.pdf**

If sildenafil and vardenafil are rescheduled to Schedule 3, PSA would make an independent assessment of what additional training pharmacists may be required or recommended to undertake and what tools and resources would need to be developed to support best practice. This is the reason for PSA's preference to be informed of scheduling outcomes as early as practicable so that there is sufficient lead in time to plan and develop appropriate resources for pharmacists prior to the implementation date. PSA is keen to work with relevant stakeholders to ensure rigorous, consistent and user-friendly professional education and practice support tools can be developed for the pharmacy profession.

Appendix H listing

Consistent with the recommendation in our previous submission on vardenafil, PSA does not support the inclusion of sildenafil or vardenafil in Appendix H at this time given the lack of experience as Schedule 3 medicines.

Summary

PSA supports the creation of new Schedule 3 entries for sildenafil and vardenafil as outlined in the proposal. PSA protocols and practice support tools (to be developed if the rescheduling is expected to be approved) will help minimise potential risks such as the existence of an underlying condition. Although monitoring will be required to verify any flow-on benefits, PSA believes there is potential for an increase in patients being referred for medical attention or investigation. PSA also suggests that with enhanced access locally, patients will be less inclined to obtain these medicines from substandard or unsafe sources.

PSA does not support the inclusion of sildenafil or vardenafil in Appendix H at this time.

Submitted by:

Pharmaceutical Society of Australia
[redacted]

Contacts:

Dr Lance Emerson, Chief Executive Officer

[redacted]

15 June 2017

[redacted]

PROPOSED AMENDMENTS TO POISONS STANDARD

ACMS Meeting July 2017

Comments by the Pharmacy Guild of Australia

1. **Esomepazole – Schedule 2 amendment**
2. **Paracetamol in combination with ibuprofen – Schedule 2 Amendment**
3. **Vardenafil– New Schedule 3 listing**
4. **Sildenafil – New Schedule 3 listing and Appendix H listing**

Date June 2017
Contact [redacted]

[redacted]
National Secretariat
[redacted]

ESOMEPRAZOLE

Down-schedule esomeprazole from Schedule 3 to Schedule 2 in oral preparations containing 20 mg or less per dosage unit for the relief of heartburn and other symptoms of gastro-oesophageal reflux disease, in packs containing not more than 14 days' supply.

Overview

The Guild does not support this proposal and believes Proton Pump Inhibitors (PPIs) should not be available as Schedule 2 medicines. Expanding the maximum pack size for esomeprazole increases the risk that consumers will have limited monitoring of these medicines.

The risks and benefits of the use of a substance

According to the Australian Medicines Handbook[1], some epidemiological studies suggest possible associations between PPI use and increased risk of:

- Clostridium difficile infection
- pneumonia
- decreased serum vitamin B12 concentration (long-term use >2 years)
- chronic kidney disease
- fracture (long-term use); for patients at risk of osteoporosis and taking PPIs long term (>1 year), consider daily calcium intake and vitamin D status

There have also been reports of serious adverse events with short-term use such as interstitial nephritis.[2]

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

Persistent reflux that occurs more than twice a week is considered to be gastroesophageal reflux disease (GORD) and most patients need long-term treatment because the disease usually relapses.[3] In addition, cases of persistent heartburn are usually caused by obesity which may warrant discussion with a health professional.[4]

Clinical guidelines suggest that continuous PPI use should be re-evaluated regularly and patients should be counselled on possible complications when contemplating long-term therapy.[5]

NPSMedicineWISE has previously expressed concern of the overuse of PPIs with up to 30% of patients potentially being able to stop PPI therapy immediately after the initial course of treatment without experiencing symptoms.[6]

Having larger pack sizes available as a Schedule 3 medicine facilitates consumer interaction with a pharmacist that can lead to a discussion about a patient's health. Pharmacists can also advise patients whether continuing treatment with these medicines is necessary and if applicable, discuss with the patient options for stepping down their PPI medication use.

[1] Australian Medicines Handbook 2017 – Proton Pump Inhibitors
[2] Therapeutic Guidelines Online- Gastro-oesophageal reflux Accessed 9/06/2017
[3] Moayyedi, P., & Talley, N. J. (2006). Gastro-oesophageal reflux disease. *The Lancet*, *367*(9528), 2086-2100.
[4] http://www.gesa.org.au/index.cfm//resources/patients/heartburn-reflux/
[5] Benmassaoud, A., & McDonald, E. G. (2016). Potential harms of proton pump inhibitor therapy: rare adverse effects of commonly used drugs. Canadian Medical Association. Journal, 188(9), 657.
[6] https://www.nps.org.au/medical-info/clinical-topics/news/proton-pump-inhibitors-too-much-of-a-good-thing

These opportunities will be reduced if consumers are able to self-select larger packs of these medicines.

Summary

The Guild does not support this proposal and believes Proton Pump Inhibitors should only be available as a Schedule 3 medicine.

IBUPROFEN COMBINED WITH PARACETAMOL

Amend the current Schedule 2 entry for ibuprofen when combined with paracetamol to increase the pack size of preparations for oral use when labelled with a recommended daily dose of 1200mg or less from 12 to 24 dosage units.

Overview

The Guild does not support the proposal. Combination products are typically used by patients suffering more severe acute pain and increased use of these medicines should only be supplied in consultation with a pharmacist. If consumers can self-select these medicines especially in larger packs without the intervention of a pharmacist it may increase the risk of double dosing if consumers are also taking products with the same active ingredient(s).

The risks and benefits of the use of a substance

Combination ibuprofen/paracetamol products are a relatively new product and there is still a degree of patient confusion regarding appropriate dosing of combination medicines.

This is demonstrated by a recent NPSMedicineWISE report that the NSW Poisons Information Centre has recorded a ten-fold increase in calls about possible dosing errors with new combination paracetamol-ibuprofen pain relievers since mid-2016.[7] The increase in calls coincides with changes to regulations around the sale and advertising of these paracetamol/ibuprofen combinations that occurred in June 2016.

Common dosing mistakes included adults accidently exceeding the recommended dose by taking two tablets when only one is recommended or taking another medication with containing the same active ingredients.

Excessive consumption of paracetamol can result in liver damage[8] while excessive consumption of ibuprofen can result in gastric ulcers and gastro-intestinal bleeding.

These findings highlight the importance of pharmacists discussing the safe and appropriate use of these combination medicines (particularly in larger packs) with consumers to ensure appropriate use.

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

Combination ibuprofen/paracetamol products will typically be used by consumers with more severe forms of acute pain when a single ingredient analgesic product is insufficient. These consumers should therefore be directed to a pharmacist when requesting larger packs of combination products to determine if there is an underlying cause of the pain that warrants referral to a medical practitioner.

[7] https://www.nps.org.au/medical-info/clinical-topics/news/dose-confusion-with-paracetamol-ibuprofen-combinations
[8] https://www.nps.org.au/medical-info/clinical-topics/news/safe-and-appropriate-use-of-paracetamol-closing-the-consumer-knowledge-gap

Having larger packs available in the Schedule 2 category increases the risk that consumers will attempt to self-manage more severe forms of acute pain.

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

The confusion regarding correct dosing of these combination medicines mentioned above may be because the two of the main branded products ([redacted]®) have the same active ingredients but differing strengths, hence the products have different dosing instructions and different maximum daily doses. [9]

Similarities between the names and packaging of combination products and single ingredient products marketed by the same sponsor may also be contributing to patient confusion.

While labelling instructions are intended to mitigate the risk of incorrect dosing, a recent Australian study investigating consumer knowledge of OTC NSAIDs indicates there remains significant gaps in consumer knowledge of OTC analgesics, especially about the maximum daily dose, contraindications and side effects.[10]

These findings as outlined by NPSMedicineWISE emphasise the need for consumers to discuss their treatment with a pharmacist to ensure they are taking the right product in the right amount and at the right time for a patient's condition.[11]

Summary

The current Schedule 2 entry should not be amended. The risks of overdosing and the need for ongoing education regarding the safe and appropriate use of combination products warrant larger packs to be available only in consultation with a pharmacist as a Schedule 3 medicine.

VARDENAFIL

Create a new Schedule 3 entry for vardenafil in oral preparations containing up to 10mg per dosage unit in packs containing not more than 8 dosage units.

Overview

The Guild believes with appropriate measures such as a mandated screening tool, vardenafil can be provided safely and appropriately as a Schedule 3 Medicine.

The Guild notes that the TGA has recommended a new Appendix in the Poisons Standard to enable additional controls or requirements for certain Schedule 3 substances to be specified. Erectile dysfunction medications such as vardenafil are appropriate molecules to include in such an appendix, hence this should be implemented as soon as possible.

For the purposes of considering this application under the current Scheduling Policy Framework and Poisons Standard, the applicant's proposal to only supply these medicines to pharmacies where pharmacists have completed additional training and committed to using a screening tool is an acceptable interim measure.

[9] https://www.nps.org.au/medical-info/clinical-topics/news/safe-and-appropriate-use-of-paracetamol-closing-the-consumer-knowledge-gap

[10] Mullan, J., Weston, K. M., Bonney, A., Burns, P., Mullan, J., & Rudd, R. (2016). Consumer knowledge about over-the-counter NSAIDs: they don't know what they don't know. Australian and New Zealand Journal of Public Health.

[11] https://www.nps.org.au/medical-info/clinical-topics/news/dose-confusion-with-paracetamol-ibuprofen-combinations

However, the preferred option is for the use of an appropriate screening tool to be mandated via the Poisons Standard and State and Territory poisons legislation.

The risk and benefits of the use of the substance

As noted by the scheduling delegate in a previous decision, vardenafil has a good toxicological profile and is well-tolerated.[12] The primary concern is in relation to risk is the aetiology of the medication condition that is being treated.

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

The fact that erectile dysfunction can be a marker of underlying cardiovascular disease, diabetes or endocrine disorder is noted.

However, allowing controlled access to this medicine without a prescription has led to an increase in discussions between men and healthcare providers in New Zealand, where erectile dysfunction medicines are already available for supply by pharmacists under certain conditions.[13] This in turn could lead to an increase in referrals to a doctor to determine whether a patient has any of the underlying conditions mentioned above.

The potential for abuse of a substance

An analysis of the *Database of adverse event notifications* (DAEN) attributable to all products containing the active ingredients tadalafil, sildenafil or vardenafil indicate that in total between 2007 and 2017 there were only 15 reported incidents that could be reasonably categorised as wilful inappropriate use of those medicines with just two of those incidents recorded specifically as intentional misuse of the product.[14]

While some consumers may attempt to purchase unregistered medicines containing these medicines from overseas websites, it is difficult to ascertain whether they are being obtained predominantly for inappropriate use or due to other reasons such as being reluctant to discuss erectile dysfunction with a doctor.

Summary

With additional controls such as a screening tool or questionnaire, the Guild considers vardenafil can be supplied as Schedule 3 medicine.

[12] https://www.tga.gov.au/book-page/34-vardenafil-0

[13] https://www.tga.gov.au/book-page/34-vardenafil-0

[14] Database of Adverse Event Notifications – medicines . Sildenafil, Vardenafil and Tadalafil adverse events occurring between 1 January 2007 and 18 February 2017. Unapproved indication, off-label use, sexual abuse and intentional product misuse categorised as inappropriate use. Database accessed 9/06/2017

SILDENAFIL

New Schedule 3 entry in oral preparations containing 50mg of sildenafil per dosage unit in packs containing not more than 8 dosage units be created.

Include sildenafil in Appendix H and include additional warning statements in Appendix F for Schedule 3 sildenafil.

Overview

The Guild believes with appropriate measures such as a mandated screening tool, sildenafil can be provided safely and appropriately as a Schedule 3 Medicine.

The Guild notes that the TGA has recommended a new Appendix in the Poisons Standard to enable additional controls or requirements for certain Schedule 3 substances to be specified. Erectile dysfunction medications such as sildenafil are appropriate molecules to include in such an appendix, hence this should be implemented as soon as possible.

The proposal to list sildenafil in Appendix H is not supported at this time. A disease-state awareness campaign (subject to approval from the TGA) may be a more suitable alternative to inform consumers of the availability of erectile dysfunction medication if a new Schedule 3 listing is created.

The Guild has no objection to including additional warning statements for sildenafil under Appendix F.

The risk and benefits of the use of the substance

As noted by the scheduling delegate in a previous decision, erectile dysfunction medications are considered to have a good toxicological profile and are well-tolerated.[15] The primary concern is in relation to risk is the aetiology of the medication condition that is being treated.

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

The fact that erectile dysfunction can be a marker of underlying cardiovascular disease, diabetes or endocrine disorder is noted.

However, allowing controlled access to sildenafil without a prescription has led to an increase in discussions between men and healthcare providers in New Zealand, where erectile dysfunction medicines are already available for supply by pharmacists under certain conditions.[16] This in turn could lead to an increase in referrals to a doctor to determine whether a patient has any of the underlying conditions mentioned above.

The potential for abuse of a substance

An analysis of the *Database of adverse event notifications* (DAEN) attributable to all products containing the active ingredients tadalafil, sildenafil or vardenafil indicate that in total between 2007 and 2017 there were only 15 reported incidents that could be reasonably categorised as wilful inappropriate use of those medicines with just two of those incidents recorded specifically as intentional misuse of the product.[17]

[15] https://www.tga.gov.au/book-page/34-vardenafil-0

[16] https://www.tga.gov.au/book-page/34-vardenafil-0

[17] Database of Adverse Event Notifications – medicines . Sildenafil, Vardenafil and Tadalafil adverse events occurring between 1 January 2007 and 18 February 2017. Unapproved indication, off-label use, sexual abuse and intentional product misuse categorised as inappropriate use. Database accessed 9/06/2017

While some consumers may attempt to purchase unregistered medicines containing these medicines from overseas websites, it is difficult to ascertain whether they are being obtained predominantly for inappropriate use or due to other reasons such as being reluctant to discuss erectile dysfunction with a doctor.

Summary

With additional controls such as a screening tool or questionnaire, the Guild considers sildenafil can be supplied as Schedule 3 medicine.

The proposal to list sildenafil in Appendix H is not supported at this time. A disease-state awareness campaign (subject to approval from the TGA) may be a more suitable alternative to inform consumers of the availability of erectile dysfunction medication if a new Schedule 3 listing is created.

The Guild has no objection to including additional warning statements for sildenafil under Appendix F.

[redacted]

16 June 2017

medicines.scheduling@tga.gov.au

RE: Proposed amendments to the Poisons Standard - ACMS meeting, July 2017

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 4,400 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practicing in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA believes that any changes to the scheduling of medicines should be driven and underpinned by the principles of consumer safety, evidence-based medicine and quality use of medicines.

SHPA has the following comments to make with respect to proposed amendments to the Poisons Standard.

Esomeprazole

SHPA does not support the down-scheduling of esomeprazole to Schedule 2. We believe that these medicines should be scheduled (at a minimum) in Schedule 3 to ensure appropriate consultation and review by a pharmacist to minimise the number of people who move to long term use of these medicines.

As part of Choosing Wisely Australia the Royal Australian College of General Practitioners (RACGP) have flagged the long term use of proton pump inhibitors (PPIs) as one of the top five tests, treatments or procedures which should be questioned by GPs and their patients. That statement is based on the evidence that a high proportion of patients are kept on maximal doses long term, and adverse effects of long term use include increased risk of gastrointestinal infection (incl. *Clostridium difficile*), community acquired pneumonia, osteoporotic fractures, interstitial nephritis, and nutritional deficiencies, particularly in the elderly or immunocompromised

SHPA notes that a similar down-scheduling amendment proposal was made to the Advisory Committee on Medicines Scheduling (ACMS) in late 2015, which was ultimately refused by the ACMS. This decision was supported by SHPA at the time, and we expect the ACMS to come to a similar conclusion in this instance.

Stiripentol

Due to stiripentol's sedative effects, SHPA supports a new Appendix K entry for this medicine.

Vardenafil, sildenafil

SHPA does not support the down-scheduling and creation of new Schedule 3 entries for vardenafil in oral preparations containing 10mg or less per dosage unit in packs containing

not more than 8 dosage units, or for sildenafil in oral preparations containing 50mg or less per dosage unit in packs containing not more than 8 dosage units.

Vardenafil and sildenafil are both phosphodiesterase type 5 inhibitors and can prolong QT intervals and increase the risk of arrhythmias, and its use is also cautioned in the setting of hepatic impairment. SHPA does not believe that pharmacies in the community setting have the adequate resources to screen for these risks.

SHPA notes that the same proposed amendment to the scheduling of vardenafil was made in the middle of 2016, and was subsequently refused by the ACMS. This decision was supported by SHPA at the time, and we expect the ACMS to come to a similar conclusion in this instance.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact [redacted]

Yours sincerely,

[redacted]

[redacted]

[redacted]

The Secretary
Medicines and Poisons Scheduling
Office of Chemical Safety (MDP 88)
GPO Box 9848
CANBERRA ACT
2601

13/06/2017

Dear Sir/Madam,

RE: Invitation for public comment ACCS/ACMS meetings (July 2017)

Johnson & Johnson Pacific Pty Ltd (JJP) would like to provide comments on the proposed amendments referred by the Delegate to the Committee of Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS).

Methylisothiazolinone (MIT)

Johnson & Johnson notes the proposed scheduling:

Schedule 6 - Amend Entry

METHYLISOTHIAZOLINONE except:
a.In rinse-off cosmetic preparations or therapeutic goods intended for topical rinse-off application containing 0.0015 per cent or less of methylisothiazolinone; or
b.In other preparations that are not intended for direct application to the skin containing 0.1 per cent or less of methylisothiazolinone.

Johnson & Johnson Pacific has the following comments:

1. JJP does not object to the proposed amendment to the scheduling of methylisothiazolinone (MIT) to the extent to which it aligns with international requirements.
2. JJP notes the opinion of the EU Scientific Committee on Consumer Safety (SCCS), which has concluded that a concentration of 0.0015% (15 ppm) is safe in rinse-off topical products. JJP understands that this opinion is being considered for adoption into European legislation and suggests that the Delegate defer on a decision until the legislation is European law.
3. Should there be a change to the entry, JJP requests realistic implementation dates (24-30 months) should be proposed, providing industry with adequate lead times to implement changes to formulations: investigate alternative preservative systems, develop new formulations, perform the required testing to ascertain the optimal formulation and preservative systems, manufacture test batches and perform the associated stability / quality control on test batches before going to market. Time also needs to be considered to have these changes implemented by the “off shelf” date.

[redacted]

These implementation timing are based on:

investigate alternative preservative systems	4 months
develop new formulations	4 months
validation batches	6 months
stability	6 months
shipping from overseas	4 months
Transitioning into trade to meet “off shelf date”	4 months
Total	28 months

Yours faithfully,

[redacted]

[redacted]

Proposed Amendments to the Poisons Standard (Medicines)

I am writing this submission to state my disagreement with this proposed scheduling of phenibut to either schedule 9 or schedule 4.

This substance has provided many improvements in my life as it has been useful for situational anxiety as well as times where I have been unable to sleep. I have noticed no problems with toxicity or dependence and most evidence points towards this being a very safe supplement when used responsibly.

This change to the scheduling will prevent my access, and that of many others to a supplement which helps us be more productive and gives many other different benefits to us.

While this supplement is unregulated it allows me to conveniently and safely access it in the legal manner. There is also no evidence of other countries looking to ban this supplement, suggesting that it is not cause for concern. All I believe placing phenibut in schedule 9 will do is remove access to a safe and beneficial supplement that many people have found to be a positive influence in their life.

Although I strongly disagree with any regulatory action towards this supplement, I feel that S4 may be the lesser of two evils if scheduling is inevitable as individuals could at least still potentially access it through the Special Access Scheme however am doubtful as to the efficiency of this. Making this supplement a schedule 9 substance alongside drugs like MDMA and heroin is just ridiculous. Especially considering cocaine is only schedule 8 alongside the notoriously potent opiate fentanyl, classing this supplement as more dangerous than these illegal drugs simply makes no sense.

I hope you take this into consideration before potentially restricting peoples access to a simple and helpful supplement.

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Madam/Sir

Public Comment Submission to the July 2017 meeting of the Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS)

We refer to the notice published on 17 May 2017 inviting public submissions, with respect to certain substances, addressing a matter raised in s.52E of the *Therapeutic Goods Act 1989.*

Accord Australasia Limited is the peak national industry association that represents the hygiene, cosmetic & specialty products industry.

Accord wishes to provide information on the following substances for consideration at the July 2017 joint meeting of the ACCS-ACMS:

- Chloroacetamide
- Docusate sodium
- Epidermal growth factor
- Methylisothiazolinone (MIT)
- Quinine and its salts
- Vinyl acetate.

Please see the attached submission for details.

We look forward to further advice from the ACCS and the Delegate. Should the Committee or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on [redacted].

Yours sincerely

[unsigned for electronic submission]

Dusanka Sabic
Director Regulatory Reform

15 June 2017

Accord Australasia Limited ACN 117 659 168 ABN 83 205 141 267
[redacted]

ACCS/ACMS joint meeting: July 2017

Chloroacetamide

Chloroacetamide has reported use as a preservative ingredient in cosmetics and domestic products. To our knowledge, only 1 cosmetic product in Australia currently contains this substance as a preservative.

Chloroacetamide is currently listed in Annex V of the EU Cosmetics Regulation "List of preservatives allowed in cosmetic products" with a maximum in-use concentration of 0.3% and a required label statement "Contains chloroacetamide".

We note that the 2011 SCCS opinion found chloroacetamide use at levels up to 0.3% was not safe for consumers, as allergic reactions may be elicited at concentrations lower than 0.3%. As we understand, this substance was not found to be in use in cosmetic products in the EU at this time.

The draft Regulation to add chloroacetamide to Annex II "List of substances prohibited in cosmetic products" of the EU Cosmetics Regulation was drafted and notified to the World Trade Organisation in early 2016, and it is expected that the ingredient will be added to Annex II with immediate effect.

The US CIR report[1] concluded that "Based on the data included in this report and the reconfirmation that Chloroacetamide is a potential human sensitizer at use concentrations, it is concluded that Chloroacetamide is unsafe for use as a cosmetic ingredient."

Accord has no objections to the proposed new Schedule 6 entry for chloroacetamide, with no exemption cut-off for cosmetic use only in line with the US CIR report and the EU SCCS opinion. An appropriate exemption cut-off should be considered for domestic products, given the lower level of direct exposure, and hence a lower risk of sensitisation associated with the use of these products.

We also request that any scheduling decision include an adequate transition period of 12-24 months to allow for any labelling changes that may be required. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of this substance.

Given the current problems industry is facing identifying which derivatives may or may not be captured by an entry, compounded by conflicting advice from the regulatory agencies, the entry should exclude salts and derivatives (unless these can be clearly articulated).

[1] http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr120.pdf

ACCS/ACMS joint meeting: July 2017

Docusate sodium

Accord has long opposed scheduling of individual surfactants through the Chemical Scheduling process. It is out of step with international requirements. As far as we are aware, no other advanced economy has placed restrictions on commonly used surfactants.

When sodium lauryl sulfate (SLS) was first scheduled, it was our understanding that all current uses of the surfactant were excluded from scheduling, noting that SLS is in wide use, and has been used without raising significant health concerns over the history of its use. However, the wording of the lauryl sulfates schedule entry meant that some imported cosmetic products required separate labelling for the Australian market, and created an unintended negative consequence for products that had been safely used in Australia, and continue to be used globally without concern.

For cosmetic use, these substances are available without restriction in the EU and the US.

Accord does not support the scheduling of docusate sodium, as we do not believe that scheduling of this surfactant will lead to a better risk management outcome. We believe that the risks of surfactants are already well managed. The public have a good understanding that surfactant based products such as shampoos, soaps and detergents are irritating to skin and eyes and will wash their hands and rinse their eyes in case of accidental contact, without being prompted by the label. In fact, if accidental eye contact did occur, attempting to read any instructions on the product label may prove to be problematic.

We note the recent advice from the Committee on other surfactant substances (sodium α-olefin sulfonates and sodium alkyl sulfates) and expect this rationale to be consistently applied to the consideration of docusate sodium.

However, if the Committee believes that this surfactant requires scheduling controls, this should be considered in the context of the lauryl sulfates entry. As SLS is known to be one of the harshest surfactants in use, we would expect to see higher concentration cut-offs for these less hazardous substances. In order to ensure regulatory consistency, we would also expect the same understanding used when considering SLS to be applied, in that all current uses of the surfactant were excluded from scheduling.

We note that docusate sodium has a known industrial use as a multi-purpose surfactant at up to 65%.

We also request that any scheduling decision include an adequate transition period of 12-24 months to allow for any labelling changes that may be required. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of this substance.

ACCS/ACMS joint meeting: July 2017

Epidermal growth factor

Accord provided comments on the agenda item for epidermal growth factor considered at the November 2016 meeting of the ACMS/ACCS.

We note that the consideration and subsequent recommendation focused on a lack of data demonstrating safety, and the potential for therapeutic intent for the use of this substance.

Accord has significant concerns that the specificity of the original scheduling consideration for this substance (veterinary use only), and the subsequent unintended consequences do not appear to have been well understood. If the original Schedule 7 entry had been more specifically worded to capture veterinary use only (which was the scope of the consideration), the current proposed cosmetic use of this substance at very low concentrations would be exempt from scheduling under the provisions of Part 1 2(j):

(2) Unless the contrary intention appears a reference to a substance in a Schedule or an Appendix to this Standard includes: (a)-(g)
but does not include:
(j) any other substance included in Schedules 1 to 6, at a concentration not exceeding 10mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8;

Accord continues to support consideration of the ingredient to align Australian regulatory controls with comparable overseas jurisdictions and remains unaware of any specific safety concerns in Australia or overseas for this substance when used in cosmetics at very low concentrations. We understand additional information has been provided by the applicant to address the Committee's previous concerns.

ACCS/ACMS joint meeting: July 2017

Methylisothiazolinone (MIT)

This proposal is part of the staged implementation of the final decision for MIT made in December 2015, which noted:

The exemption cut-off for leave-on products will be withdrawn in October 2017, when the Schedule 6 entry will be amended to allow only rinse-off products that meet international standards for MI concentration to qualify for the Schedule 6 exemption. This will achieve the ultimate goal of allowing the Schedule 6 exemption to apply only to products intended to be rinsed off, and therefore present a lower risk of skin sensitization.

The same 1 October 2017 implementation date will also see the introduction of a 0.1% exemption cut-off for products other than cosmetics and therapeutic goods that are not intended to be directly applied to the skin.

We understand that in considering the previous final decision, the Delegate and Committee thought that by this time, the EU SCCS opinion on MIT in rinse-off products would have been incorporated into the EU Cosmetic Regulation, and provided an international standard for MIT concentration that the SUSMP entry could then align with.

Unfortunately, this is not the case. The draft Regulation to reduce the maximum authorised concentration of MIT in rinse-off cosmetics to 15ppm was voted on at the EU Standing Committee on Cosmetic Products (COSCOM) meeting in March, but the outcome of the vote is not yet known, and the regulation amending the Cosmetics Regulation has not yet been published.

MIT is a very widely used ingredient in rinse-off cosmetic products. As the Australian market for cosmetics is relatively small when compared to our major trading partners, making a major regulatory decision such as this ahead of the EU could have a major impact across the industry. As raised in our previous submissions, implementing a concentration exemption of 15ppm as is under consideration in the EU will effectively be a ban on the use of this substance in cosmetic products. The impact of this decision cannot be underestimated.

We propose that the Committee and Delegate defer making this decision until the EU restriction has been finalised to allow alignment of both the concentration exemption level and the implementation timing of the decision.

We also request that any scheduling decision include an adequate transition period of 12-24 months to allow for the reformulation of products that may be required, and for the sell-through of existing products already in supply as any changes will affect products currently in the Australian market.

ACCS/ACMS joint meeting: July 2017

Quinine and its salts

Quinine is used in cosmetic products as a hair conditioning agent, with such products currently available in Australia.

Quinine is naturally occurring in certain plants and these plants extracts are used in cosmetic products e.g. *cinchona calisaya* extract,

Under the EU Cosmetics Regulation, quinine is permitted for use in cosmetic products at concentrations up to 0.5 % (as quinine base) in hair rinse-off products and 0.2 % (as quinine base) in hair leave-on products. We understand that the quinine content of products available in Australia also meet these concentrations.

Accord has no objections to the proposed new Schedule 6 entry for cosmetic use with exemption concentration cut-offs for leave-on and rinse-off hair preparations in line with EU.

We also request that any scheduling decision include an adequate transition period of 12-24 months to allow for any labelling changes that may be required. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of this substance.

ACCS/ACMS joint meeting: July 2017

Vinyl acetate

Vinyl acetate has reported uses in domestic products in the Australian marketplace in paints, lacquers and varnish, adhesives and automotive products. At this point in time we are not aware of its use in cosmetic products in Australia.

Vinyl acetate is not currently listed in the Annexes to the EU Cosmetic Regulation, but was classified as a Carcinogen 2 (CMR 2 substance) and listed on Annex VI of the CLP Regulation. The classification applied from 1 January 2015. In the Cosmetic Regulation, the Article 15 requirement for a CMR 2 substance is that it must have a positive SCCS opinion to allow for continued use in cosmetics. As the requirements of Article 15 of Regulation (EC) No 1223/2009 have not been met, vinyl acetate cannot be used in cosmetic products from 1 January 2015.

It is anticipated that vinyl acetate will be added to Annex II of the EU Cosmetics Regulation "List of substances prohibited in cosmetic products" during 2017 as part of the addition of the 200 or so existing CMR substances.

Accord has no objections to the proposed new Schedule 10 entry for cosmetic use, and proposed Schedule 6 entry for domestic products with a 1% exemption concentration, to ensure that industrial uses, including as a manufacturing intermediate, is unaffected by scheduling.

We request that any scheduling decision include an adequate transition period of 12-24 months for the Schedule 6 entry to allow for any labelling changes that may be required. Any changes would affect products currently in the Australian market with an established history of safe use. To our knowledge, there is no evidence that would suggest immediate action is required for the risk management of this substance in non-cosmetic products.

Given the current problems industry is facing identifying which derivatives may or may not be captured by an entry, compounded by conflicting advice from the regulatory agencies, the entry should exclude salts and derivatives (unless these can be clearly articulated).

From: [redacted]
To: Medicines Scheduling
Subject: "Proposed Amendments to the Poisons Standard (Medicines)" [SEC=No Protective Marking]
Date: Wednesday, 28 June 2017 12:52:02 PM
Attachments: [redacted]

apologies, my previous email did not have the cover sheet, this one does.

Consultation: Proposed amendments to the Poisons Standard - Joint ACCS/ACMS meeting, July 2017

Dear Sir/Madam,

I am writing to you as a current University student and consumer of Phenibut.

I understand the public health concerns in regard to phenibut and it's potential for dependency and supposed toxicity; however I believe that it is unfair to place phenibut in schedule 9 or 4 with appendix D.

I am 19 years old, phenibut has been in my life for over 2 years now; it has allowed me to manage my anxiety in a way no other medication, be it benzodiazepines or baclofen (similar to phenibut) has ever been able to. As a consumer of phenibut, and as I have stated, I do see the potential for dependency with the substance, a scheduling is fair enough in my opinion; though I believe it should be treated, as say, Modafinil, where you would be allowed to have a couple months supply for personal use.

Phenibut should not be treated to, say, Heroin; they should not be in the same scheduling, they both very clearly have different abuse, dependency and health risk potentials.

I don't believe it is fair for me to be treated as a criminal for trying to manage my own anxiety in a way that has been so beneficial to myself.

I ask you to please, consider my proposal for a less harsh scheduling, as I and many other Australian's use phenibut responsibly to manage anxiety. I genuinely don't believe that it is far fetched to call Phenibut a life saver; it has opened my life up to so much more opportunities I would never have been able to experience without it.

Very kind regards, I would be happy to hear back from you.

Thanks, [redacted].

From: [redacted]
To: Medicines Scheduling
Subject: Proposed Amendments to the Poisons Standard (Medicines) [SEC=No Protective Marking]
Date: Wednesday, 21 June 2017 7:02:34 AM
Attachments: [redacted]

To Whom It May Concern:

I am writing to express my severe disappointment in learning that phenibut is proposed to be scheduled.

Phenibut has been a life-changing supplement for me, as it allows me to treat infrequent anxiety safely. It's my only option since plant-based medicines like kratom and cannabis are illegal; prescription medicines such as [redacted] are extremely unsafe and expensive; mild supplements like L-theanine and Ashwagandha are ineffective for moderate-severe anxiety; and as we all know, alcohol as anxiety relief is incredibly unhealthy and unsustainable.

I use phenibut for anxiety-inducing occasions such as job interviews, public speaking and being in large crowds, as do my friends who have used it to treat their anxiety. We are grown adults who have read up deeply on the product and use it with care - I don't know a single person who has ever taken phenibut that isn't a successful adult with a full-time job. Phenibut users are not hardened criminals who are recklessly using phenibut as some sort of cripple for a dead-end life. They are smart millennials looking for a leg up in their careers.

I can say for a fact that I would never have been able to get over my severe fear of needles or dentists without phenibut, nor would I ever have gotten my current job as Director of Marketing for a company that grossed $3m last year and is set to gross $10m this year. (And I'm proud to say I'm going to the dentist today and had a vaccination this year with the help of phenibut - after almost a decade of fear!) Phenibut allows me to perform at my best in high-pressure situations where I would previously have choked or shaken with anxiety. It has also improved my sleep during times when I would ordinarily have jetlag.

Like most substance bans, this one would not keep anybody safe. Rather, a ban will turn people to dangerous and expensive prescription chemicals, or the black market. If it is banned, I too will be forced to become a criminal. What's more, those who do try phenibut once it is banned may not have access to the education that is currently widely available from vendors about how to use it safely.

Since alcohol is legal for over-18s, I recommend amending the proposal to limit phenibut consumption to adults in a similar way. It would be unconscionable to ban a substance improving so many lives while alcohol remains legal. What's more, a ban would be totally unrepresentative of the will of the Australian people, since most Australians have never even heard of phenibut, and those who have - at least in my circles - are incredibly grateful for its existence.

Feel free to contact me at [redacted] if you have any questions. See attached my cover sheet.

Regards,
[redacted]

--

From: [redacted]
To: Medicines Scheduling
Subject: Phenibut [SEC=No Protective Marking]
Date: Tuesday, 4 July 2017 2:36:53 PM

I would like you to reconsider the banning of Phenibut Substance/nootropic.

I have been i long time user for over 5 years.

Phenibut is not an addictive is substance, the on set of the drug is 3-5hrs unlike Diazepam which can be addictive in a matter of days due it short onset.

I take 1.8 - 2.8g once a week, sometimes going a month without using it.

It has helped me greatly with my anxiety and sleep issues. It allows me to have a conversation with people and perform tasks without worry.
Usually taken on my days off work once week instead of drinking alcohol to relax.
Does not affect my vision or effect my skills to drive like alcohol does.

Its effects are similar to having a strong cup if coffee and a relaxing tea at the same time. But last 6-12hrs instead of needing to top up.

Many useful guides online including reddit and youtube prevent people from misusing the substance.

Should not really be used more once without a 3day break. Is written on many forums and websites as a guide.

Banning this substance would mean i would have to go back to using valium which was hell to get off from.

Please reconsider,
[redacted]

[redacted]

From: [redacted]
To: Medicines Scheduling
Subject: Scheduling of Phenibut [SEC=No Protective Marking]
Date: Tuesday, 4 July 2017 2:05:01 PM

To Whom it may concern,

I am in my mid 30's and have been using Phenibut therapeutically for over 5 years. I have been able to reduce/cease Alcohol and benzo use through the supplementation of Phenibut once or twice per week, sometimes ceasing its use for months at a time. This is a supplement that has been outstandingly positive for my relationships, career and general wellbeing. I have diagnosed PTSD after a car accident and this supplement has been my way of healing without relying on harmful substances such as alcohol and prescription medication. If Phenibut is to be scheduled it will just make myself and many, many people rely on alcohol, prescription drugs and the ever thriving black market. This alternative is a far riskier outcome than to use Phenibut. I have a good job, house and Fiancé and in some part this is due to being able to use this supplement and do not understand the idea that banning things somehow saves people? What from?. All it does is forces people to find alternatives, that are most often more dangerous. The more things you outlaw, the more outlaws run.

There are a vast many things in life that require moderation and respect. Phenibut is one of them. So is Fast Food. I am against the scheduling of this supplement for the reasons stated and would greatly appreciate you take my opinion into consideration before making a decision that effects many people.

Regards,

[redacted]

[redacted]