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 November 2017 meetings of the Advisory Committee on Chemicals Scheduling (ACCS #21) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #17), was made available on the TGA website on 6 September 2017 and closed on 6 October 2017..

Public submissions received on or before 6 October 2017 are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulation 42ZCZL, the Secretary has removed information that the Secretary considers confidential.

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

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

Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must also invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the November 2017 meetings of the Advisory Committee on Chemicals Scheduling (ACCS #21) and the Joint Advisory Committee on Medicines and Chemicals Scheduling (ACMS #17) was made available on the TGA website on 5 February 2017 and closes on 5 March 2018. Public submissions received on or before this closing date will be published on the TGA website in accordance with regulation 42ZCZQ.

Privacy statement

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

with products), information about any alleged unlawful activity or that may be defamatory or offensive.

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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]

Australian Self-Medication Industry Ltd.
[redacted]

6 October 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.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, November 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 November 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 November 2017 meetings:

1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives

> *To create a new Schedule 6 entry 1-deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives to restrict the use in cosmetic rinse-off and household cleaning preparations and to create new entries in Appendices E and F.*

Phenyl methyl pyrazolone

> *To create a new entry in Schedule 5 or 6 for phenyl methyl pyrazolone for hair dye and eyebrow/eyelash preparations with an exemption cut-off of 0.25% and to create new entries in Appendices E and F.*

[redacted]

Salts of boric acid

To amend the current entry for boric acid in Schedule 5, removing "excluding its salts" so the salts of boric acid are captured by the entry

Polihexanide

To amend the Schedule 6 entry cut-off of polihexanide from 5 per cent to 0.3 per cent or less of polihexanide, and to amend the Appendix F, Part 3 entry to include Warning Statement 28 (Repeated exposure may cause sensitisation).

Clotrimazole

To:

- *Amend the Schedule 2 entry for clotrimazole to include the phrase "in vaginal preparations";*
- *Delete the Schedule 3 entry and Appendix H listing for clotrimazole;*
- *Amend the Schedule 4 entry for clotrimazole to delete the reference to Schedule 3; and*
- *Amend the Appendix F listing for clotrimazole to change the reference from Schedule 3 to Schedule 2.*

Ibuprofen

To:

- *Amend the Schedule 2 entry for ibuprofen to restrict no more than 30 dosage units when in divided preparations containing 200 mg or less of ibuprofen in a primary pack (down from current 100 dosage units);*
- *Delete the exemptions in the Schedule 2 entry for ibuprofen that currently allow general sale of up to 25 dosage units of 200 mg ibuprofen; and*
- *Amend the Schedule 3 entry for ibuprofen to allow up to 100 dosage units containing 200 mg or less of ibuprofen in a primary pack.*

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) - 1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives

To create a new Schedule 6 entry 1-deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives to restrict the use in cosmetic rinse-off and household cleaning preparations and to create new entries in Appendices E and F.

ASMI Comment

This substance is not entered in the TGA eBS ingredients list, nor is it entered in the TGA Permitted Ingredients List. ASMI therefore assumes that the above scheduling proposal will not impact therapeutic goods. Should any inadvertent impact be revealed, we would like to provide comment during the public consultation on the Interim Decisions.

Agenda item 1 (ACCS) - Phenyl methyl pyrazolone

To create a new entry in Schedule 5 or 6 for phenyl methyl pyrazolone for hair dye and eyebrow/eyelash preparations with an exemption cut-off of 0.25% and to create new entries in Appendices E and F.

ASMI Comment

This substance is not entered in the TGA eBS ingredients list, nor is it entered in the TGA Permitted Ingredients List. ASMI therefore assumes that the above scheduling proposal will not impact therapeutic goods. Should any inadvertent impact be revealed, we would like to provide comment during the public consultation on the Interim Decisions.

Agenda item 2 (ACCS / ACMS) - Salts of boric acid

> *To amend the current entry for boric acid in Schedule 5, removing "excluding its salts" so the salts of boric acid are captured by the entry*

ASMI Comment

ASMI assumes that this scheduling proposal aims to achieve consistency in the wording of the Schedule 5 and Schedule 4 entries and to capture all boric acid salts under Schedule 5 and to the extent that this proposal aims to achieve consistency in wording between the schedules, we do not object to it.

However, there are existing non-therapeutic products (for example dental adhesive products) which contain borax (as a preservative and viscosity controlling agent) and which will be adversely affected by the proposal.

On this basis, the following statement in the published agenda materials appears to be incorrect (since there are affected products already on the market here):

> *"Although there is no specifically identified use in cosmetic and domestic products in the Australian marketplace, the chemicals are known to be used in cosmetic and domestic products internationally."*

For this reason, we request that either:

1. The decision be deferred pending a thorough investigation of the impact, or

2. An appropriate transition period of 24 to 30 months be applied, so as to allow sufficient time for affected manufacturers to:

    a. investigate alternative ingredient(s), and
    b. develop new formulations, and
    c. perform the required testing to ascertain the optimal formulation, and
    d. manufacture test batches, and
    e. perform the associated stability / quality control on test batches
    f. All before going to market.

We would further like to point out that borax is present in many complementary medicines, such as mineral supplementation products, in small quantities that are below the 6 mg or less of boron per recommended daily dose scheduling cut-off as specified in the current scheduling entries (i.e. Schedule 4 and Schedule 5).

We assume that the scheduling proposal will have no impact on therapeutic goods.

Agenda item 2 (ACCS / ACMS) - Polihexanide

To amend the Schedule 6 entry cut-off of polihexanide from 5 per cent to 0.3 per cent or less of polihexanide, and to amend the Appendix F, Part 3 entry to include Warning Statement 28 (Repeated exposure may cause sensitisation).

ASMI Comment

Polihexanide is included in the TGA's Permitted Ingredients list and in the TGA eBS ingredients list; it is allowed as an excipient in over the counter and listed medicines for topical dermal use, in a concentration of 0.3% or less.

We therefore assume that the proposed scheduling amendment will not have any impact on therapeutic goods.

Agenda item 3 (ACMS) - Clotrimazole

To:

- *Amend the Schedule 2 entry for clotrimazole to include the phrase "in vaginal preparations";*
- *Delete the Schedule 3 entry and Appendix H listing for clotrimazole;*
- *Amend the Schedule 4 entry for clotrimazole to delete the reference to Schedule 3; and*
- *Amend the Appendix F listing for clotrimazole to change the reference from Schedule 3 to Schedule 2.*

Introduction

ASMI supports the proposal to amend the Schedule 2, 3 and 4 entries for clotrimazole (together with the consequent amendments to Appendices F and H).

The effect of the proposal would be to include clotrimazole vaginal preparations in Schedule 2, and for the reasons outlined below ASMI supports such an outcome.

ASMI Comment

Clotrimazole was first approved in Australia 50 years ago for topical use and continues to be available for the treatment of mucocutaneous fungal infections, in dermal creams, solutions, vaginal creams and pessaries. Clotrimazole has been available in Australia as an S2 medicine for the topical treatment of fungal infections since 1991, and as an unscheduled medicine for dermal tinea pedis infections since 2005.

The long history of S3 availability means that women will be familiar with the product and not all women will require pharmacist counselling at the point of purchase.

Clotrimazole is an antimycotic drug with proven efficacy against *Candida albicans*, and lesser activity against other species of *Candida*.

The scheduling proposal will impact the vaginal preparations currently approved and marketed for vulvovaginal candidiasis (VVC).

VVC is a prevalent women's health issue, with 70-75% of women experiencing at least one episode (and with 82% of women with VVC being repeat sufferers). VVC is also a source of embarrassment, with this embarrassment being reported as a contributing factor leading to delays in seeking treatment. However, the symptoms of VVC are easily recognised and can be simply treated with clotrimazole.

Clotrimazole is available over-the-counter (without mandatory pharmacist intervention) in more than 70 other countries (and is available as a general sale item – GSL - in the US and the UK).

Clotrimazole in vaginal preparations meets the scheduling factors for S2 medicines:

> Factor 1: 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 medicine is for minor ailments or symptoms that

can easily be recognised and are unlikely to be confused by the consumer with other more serious diseases or conditions. Treatment can be managed by the consumer without the need for medical intervention. However, the availability of a pharmacist at the point of sale supports the consumer in selecting and using the appropriate medicine.

Women who have been previously diagnosed with VVC will be capable of recognising their VVC symptoms without pharmacist verification.

Factor 2: The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low. Suitable for diagnosis and treatment by the consumer in the management of minor ailments.

Clotrimazole has a well-established safety profile, low systemic absorption when used vaginally and there are no reports of Candida sp resistance.

Factor 3: 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.

There is no evidence of dependence, misuse or abuse.

Factor 4: 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.

Clotrimazole has a well-established safety profile and a very low ADR rate.

Factor 5: The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.

While the risk of masking a serious disease is low, there is a risk of delaying the diagnosis of a non-Candidal infection by a few days. It is very unlikely, however, that a short delay in diagnosis will have any material impact on the clinical prognosis of any likely alternative conditions. This risk will not be appreciably altered by a change from S3 to S2 availability and can be easily managed through label content.

Conclusion

ASMI supports the scheduling proposal because:

- Clotrimazole is effective and has a well-established safety profile.
- Identification and treatment of VVC, without mandatory recourse to a pharmacist, is something that consumers can reasonably be expected to manage.
- Clotrimazole in vaginal preparations meets the scheduling factors for S2 medicines.
- Amending the scheduling as proposed would bring Australian's access to clotrimazole into line with other comparable markets.

Agenda item 3 (ACMS) - Ibuprofen

To:

- *Amend the Schedule 2 entry for ibuprofen to restrict no more than 30 dosage units when in divided preparations containing 200 mg or less of ibuprofen in a primary pack (down from current 100 dosage units);*
- *Delete the exemptions in the Schedule 2 entry for ibuprofen that currently allow general sale of up to 25 dosage units of 200 mg ibuprofen; and*
- *Amend the Schedule 3 entry for ibuprofen to allow up to 100 dosage units containing 200 mg or less of ibuprofen in a primary pack.*

Overview

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used as an analgesic, antipyretic, and anti-inflammatory.

Over-the-counter (OTC) Ibuprofen is indicated for relief of pain and discomfort associated with headache, back pain, muscle pain, period pain, dental pain, cold & flu and fever. These products are intended for short term use.

Customer and consumer safety is of paramount concern to ASMI and our members.

Ibuprofen, like all medicines, has risks and benefits.

Labelling requirements and supply restrictions both play a role in mitigating risks.

Pharmacists also play an important role in educating consumers about risk.

ASMI has significant concerns in relation to the consideration given to this agenda item. ASMI absolutely respects the integrity of the process and the professionalism of the committee members. It is, however, unclear how the item has been listed for discussion, who listed it, the reasoning behind it and the evidence that the committee is considering as part of the decision.

ASMI requests that the documentation should be made available to the public and be considered as part of an open and transparent consultation process.

ASMI suggests that if the ACMS recommends to the Delegate that the scheduling of ibuprofen should change, the Delegate should make no immediate interim decision and the materials used by the ACMS in making its recommendation should be published for a thorough public examination. This way, all affected stakeholders will be given a fair and reasonable opportunity to address the issues raised as part of the rescheduling proposal.

This submission outlines the clear reasoning why existing regulation and scheduling of ibuprofen should prevail. Furthermore, the submission highlights additional challenges associated with up scheduling.

Summary

- ASMI believes that the current scheduling of ibuprofen is appropriate.

- Ibuprofen has been available in Australia as an OTC medicine for around 30 years, and in grocery for approximately 15 years

- Internationally, it has been available in comparable overseas jurisdictions for similar timeframes

- The safety profile of ibuprofen is well established following the many years of experience with this medicine

- The TGA (in 2014 and 2016) and the European Medicines Agency (EMA) (in 2015) have both recently conducted safety reviews of NSAIDs, including ibuprofen; these reviews have stated that there is minimal cardiovascular risk associated with ibuprofen when used at recommended OTC doses and duration

- The reviews did not recommend that any changes to access are warranted and proposed new labelling warning statements to improve consumer awareness of risks associated with use by people who have risk factors or use for prolonged periods of time

- Since the reviews were published there has been no evidence of any significant public health concern that could have altered the risk vs benefit profile of ibuprofen, to warrant a departure from the current scheduling arrangements

- Any change to scheduling will have a significant impact on consumer choice and convenience; it will reduce competition and increase cost to consumers with no evidence of any incremental benefit provided

- Ibuprofen is currently available from pharmacies in larger pack sizes, allowing consumers to obtain advice when required

- For consumers, OTC medicine labels provide the single most important source of information. Australian medicines that contain ibuprofen must be labelled in accordance with the *Required Advisory Statements for Medicine Labelling* (RASML), which contains detailed mandatory warning statements in language that consumers are able to understand and act upon

- The scheduling proposal does not articulate the problems it presumably seeks to address. ASMI believes that any increase in regulation should be based on sound evidence that (i) the concerns are based on accurate evidence and (ii) that scheduling changes are the only mechanism for addressing these concerns

- Given the strong evidence, ASMI believes that small packs of ibuprofen that are currently exempt (i.e. 25 dosage units / approximately 4 days' supply) can be appropriately selected and used by the reasonable consumer with acceptable safety

- ASMI recommends a thorough and transparent public examination of the evidence behind this scheduling proposal and that any regulatory decisions are consistent with the principles of best practice regulation.

The three key areas addressed in the following part of the submission are:

1. The evidence base;
2. Consumer access and choice;
3. The regulatory impact;

1. The Evidence Base

Safety of Ibuprofen

ASMI believes that the current scheduling of ibuprofen is appropriate and that ibuprofen in the currently available pack sizes meets the scheduling factors and is consistent with other substances and products within the respective schedules and exemptions.

TGA Review of Safety of NSAIDS

The TGA has recently undertaken the following safety reviews that include ibuprofen:

- 7th October 2014: Review of cardiovascular (CV) safety of NSAIDs[1]
- 11th October 2016: Safety review of NSAIDs and risk of spontaneous abortion[2]

It is beyond the scope of this response to go into detail on the findings of these reviews, however we would like to raise the following salient points about the conduct of the reviews:

- The TGA Office of Product Review (OPR) conducted a comprehensive review of CV safety of all NSAIDs marketed in Australia. The review was based on a comprehensive literature search conducted by the TGA and follows on from the reviews conducted in 2005-2006.
- The review included approximately 200 relevant papers, published from 2005 onwards
- It included additional data forwarded by sponsors, including unpublished data and adverse event data
- The review also included PIs and CMIs
- The review of CV safety of NSAIDs relevantly addressed the safety of OTC ibuprofen, which is used intermittently, at lower doses and shorter duration than prescription ibuprofen.

The review included a comprehensive Benefit-risk assessment in relation to non-prescription NSAIDs. Regarding non-prescription use of ibuprofen, the review states:

> *"In considering risk associated with non-prescription (OTC) use of NSAIDs, it is important to consider three factors: safety at low doses, with short duration of treatment and in patients with low background risk of CV disease. The maximum recommended daily doses for OTC NSAIDs are: ibuprofen: 1200 mg/day; naproxen: 750 mg/day and diclofenac: 75 mg/day. The CV risk estimates in this review were based on prescription data and not a survey of non-*

[1] Review of CV safety of NSAIDs
[2] Safety review of NSAIDs and risk of spontaneous abortion

prescription drug users and the variable dose cut-off points used by different authors made interpretation of dose effects difficult. Ibuprofen at 1200 mg/day or less appears to have minimal CV risk, while naproxen did not significantly elevate CV risks at low or high doses. Of the three NSAIDs available without a prescription, ibuprofen and naproxen were free of CV risk at low doses…" (section 13.1, Comparative benefit-risk analysis)

In relation to reports of CV adverse events of ibuprofen, the report states:

"Post-marketing pharmacovigilance safety data submitted by sponsors of OTC diclofenac and ibuprofen indicate a low incidence of CV events compared to the widespread sales of these OTC NSAIDs." (section 13.1, Comparative benefit-risk analysis)

The reviewers also stated that:

"Overall, OTC NSAIDs are safe and effective for the temporary relief of pain and inflammation when used as per the label. The lower doses of OTC NSAIDs and their short-term use mean that their safety profiles are different to their higher dose, prescription counterparts. But even the OTC NSAIDs can be dangerous when taken too often and/or in high doses regularly. The impact of this potential misuse (if prolonged use is not on medical advice) is difficult to assess. Although there are no studies that quantify the extent of the inappropriate or unsafe use of NSAIDs, overuse of non-prescription and/or prescription NSAIDs could have significant safety implications. Hence, it is important to increase awareness about the CV risk profile of OTC NSAIDs (diclofenac, ibuprofen and naproxen) just as the knowledge about their GI risks is widespread, especially when used more often or for longer than recommended" (section 13.1, Comparative benefit-risk analysis).

In section 14.2, the TGA commented on the availability and warning statements on labelling of OTC NSAIDs. In commenting on the issue of availability and access, the reviewers stated that:

"Based on the current evidence, there are no major changes suggested to the availability and warnings on labels for OTC diclofenac, ibuprofen and naproxen. These drugs provide effective pain relief when used according to the label at recommended doses for short durations. However, inappropriate, unsafe and overuse of these OTC NSAIDs could pose a significant health hazard. Hence, it is important to increase awareness about the CV profile of OTC NSAIDs (diclofenac, ibuprofen and naproxen) just as the knowledge about their GI risks is widespread."

Following on from this review, an updated advisory statement is now required on labels of all OTC oral NSAIDs medicines, to inform consumers that excessive or prolonged use can increase the risk of heart attack or stroke:

"*Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage*."

This statement has been added to the Medicines Advisory Statement Specifications (MASS), also known as RASML and is part of a comprehensive list of contraindications and warning statements required for all NSAIDs.

In relation to the risk of miscarriage or spontaneous abortion, the TGA review conducted in October 2016[3] recommended that the warning statements in relation to use in pregnancy should be updated to inform women not to use NSAIDs except on medical advice if they are trying to become pregnant or in the first 6 months of pregnancy, and that NSAIDs should not be used in the last 3 months of pregnancy. The review also recommended that the labelled precautions regarding use by women who are pregnant or planning to become pregnant should be expanded to cover products that are labelled exclusively for use in dysmenorrhoea, thereby achieving consistency across labelling of all NSAIDs.

The TGA safety reviews of NSAIDs have been conducted openly and rigorously and looked at the entire body of scientific data, thus providing confidence in the recommendations. The reviews also did not conflate prescription and high dose use with low dose short term OTC use, separately addressing risks in each of these scenarios. The safety reviews recommended no changes to access or availability, recognising instead the importance of informing consumers and the role of labelling in providing appropriate information for consumers.

ASMI believes that if there are additional, unpublished data showing a safety signal with respect to OTC ibuprofen, then it should be made public and openly consulted so that an informed discussion can take place before any interim decision is made.

<u>European Medicines Agency Review of ibuprofen, 2015</u>

In 2014, the UK MHRA requested that the EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the European Committee responsible for the evaluation of safety issues on medicines, to conduct a review of ibuprofen following concerns that high doses of ibuprofen could have a similar cardiovascular risk to that of COX-2 inhibitors and diclofenac.

The safety of NSAIDs including ibuprofen has been reviewed regularly by EU regulatory authorities over the past several years. Reviews carried out in 2005, 2006, and 2012 confirmed that NSAIDs as a class are associated with a small increase in the risk of arterial thromboembolic events (blood clots in the arteries) especially in patients with underlying heart or circulatory conditions or with certain cardiovascular risk factors, particularly if used at high doses. These previous reviews did not result in any actions to limit OTC availability of ibuprofen.

PRAC published its review and recommendations in 2015[4]. This review of data from accumulated evidence in the form of meta-analyses and epidemiological studies suggests that there is a small increased risk of cardiovascular problems, such as heart attacks and strokes, in patients taking high doses of ibuprofen (at or above 2,400 mg per day; two times the maximum OTC dose).

No increase in cardiovascular risk was seen with ibuprofen at doses of up to 1,200 mg per day, which is the highest dose generally used for over-the-counter (OTC) preparations taken by mouth in the European Union (EU), Canada and Australia.

PRAC stated that in order to minimise cardiovascular risk, high doses of ibuprofen (2,400 mg per day or higher) should be avoided in patients with serious underlying heart or circulatory conditions, such as heart failure, heart disease and circulatory problems or in those who have previously had a heart

[3] TGA review

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Ibuprofen_and_dexibuprofen_containing_medicines/human_referral_prac_000045.jsp&mid=WC0b01ac05805c516f

attack or stroke. In addition, prescribers should carefully assess a patient's risk factors for heart or circulatory conditions before initiating long-term treatment with ibuprofen, particularly if high doses are required. Risk factors include smoking, high blood pressure, diabetes and high blood cholesterol. It should be noted that doses of 2,400 mg per day are prescription doses and represent two times the allowable OTC dose.

The review stated that a class warning of this risk is already in place and the product information for all NSAIDs, including ibuprofen, recommends that these medicines be used at the lowest effective dose and for the shortest period of time necessary to control symptoms.

No further regulatory action was taken by either by the MHRA in the UK or other European regulatory agencies following the PRAC review.

Canada – Drug Scheduling Review of NSAIDs, 2011

The Canadian National Drug Scheduling Review (NDS) conducted a review of the scheduling of NSAIDs in 2011, following a request by the National Association of Pharmacy Regulatory Authorities (NAPRA).

The data reviewed by the NDS indicated that the risk of serious adverse events remains low for oral OTC NSAIDs when used for the approved indications at the recommended dose and duration of use. According to the minutes of the meeting, the review data indicates that the rate of adverse events for oral OTC NSAIDs increases with higher dose and longer duration of use.

The committee members expressed concern about the potential impact of inappropriate use of oral NSAIDs (e.g. at doses exceeding the maximum recommended daily dose, longer duration of use or chronic use) particularly in a subset of the population that may have risk factors such as the elderly and those with co-morbid diseases.

There was no documented evidence to indicate how pack size and place of sale may influence appropriate use. However, despite the absence of documented evidence there was consensus that the potential for inappropriate use exists and that segments of the population, particularly the elderly and those with co-morbid conditions may benefit from healthcare professional advice. The committee acknowledged that the labelling provides information for consumers on safe and appropriate use.

Following consideration of the Canadian scheduling factors it was decided that unscheduled status should be retained for ibuprofen, but with limits on pack size, unit doses and duration of use. Larger packs would be available only from a pharmacy.

The recommendations were:

> *Unscheduled:*
> Ibuprofen and its salts, containing ≤400 mg per oral dosage unit, when sold in pack sizes of up to 18,000 mg (this is equivalent to 90 tablets of ibuprofen 200 mg, or 45 tablets of 400 mg ibuprofen)

Schedule III (equivalent to the Australian S2):
Ibuprofen and its salts, containing ≤400 mg per oral dosage unit, when sold in pack sizes exceeding 18,000 mg (this is equivalent to >90 tablets of ibuprofen 200 mg, or >45 tablets of 400 mg ibuprofen)

The Canadian scheduling has not been amended since that time and is still current.[5]

Overseas regulation

The current scheduling of ibuprofen is appropriate and is comparable to the scheduling / classification of ibuprofen in similar overseas markets, including New Zealand, UK and EU countries, Ireland, Canada and the US.

Each of the above countries allow ibuprofen to be supplied in pharmacies, with carrying cut-offs allowed for general sale ibuprofen based on strength of the dosage forms and pack sizes.

Many sponsors in Australia supply ibuprofen in harmonised labelling, allowing supply to New Zealand in the same packs, thus allowing reduction in costs involved in supplying two small markets. Any departure from harmonised scheduling would result in increased cost of different pack sizes, different labelling, different supply chain requirements, all of which would increase cost of doing business in both markets and increased cost to consumers.

Adverse event information

Sponsors of all medicines must comply with the Australian Pharmacovigilance requirements, which specify the requirements for sponsors to monitor and collect reports of adverse events, as well as document, assess and report to the TGA as required.

The TGA also has in place procedures that encourage healthcare professionals to report adverse events to the TGA. Reports of adverse events are published in the TGA Database of Adverse Event Notifications (DAEN).

A search of DAEN for the time period of 1971 till 2017, refined to include all single ingredient ibuprofen products (irrespective of whether these are prescription or OTC), has revealed 1384 reports of adverse events with 921 of these reports where ibuprofen was the single suspected medicine. In 38 cases, death was an outcome. These results should be viewed in the following context:

- The results do not discriminate between low dose, short term OTC use and prescription use at high doses; there is no indication of how many patients had complicated medical conditions or co-morbidities.
- The incidence of adverse events cannot be extrapolated from the data; there is no "denominator" with DAEN reports. It is well known that since first marketed in 1973 there have been many millions of patient exposures.
- A medicine which is marketed for a long period of time and is widely used may be the subject of a larger number of reports.

[5] http://napra.ca/pages/schedules/search.aspx

These considerations are outlined on the TGA's DAEN page.

Sponsors are required to maintain pharmacovigilance records and adverse event reports, and for OTC medicines the sponsors' own data in the form of Periodic Safety Update Reports (PSURs) may be of relevance. This data generally includes all global reports of patient exposures for each of the products, as well as cumulative exposures. In addition, the data can identify new risks or safety signals.

Based on information provided by PSUR data for ibuprofen held by ASMI members, ASMI understands that:

- there have been many millions of exposures over the past few years and thousands of millions of patients exposed since ibuprofen was first marketed
- there were no new signals detected following "down-scheduling" in the Australian market (from S4 to S3 in 1989, from S3 to S2 in 1995 and an exemption from S2 in 2003)
- there are no data to indicate that there may be misuse or abuse arising from OTC use
- there have been no new, important or potential risks identified that are associated with ibuprofen products
- there is no new information to suggest that the risk-benefit profile has recently changed
- there is no information that would suggest that a departure from the current scheduling is warranted

Scheduling factors

While it is clear that ibuprofen meets the scheduling factors for Schedule 2 medicines, the Scheduling Policy Framework does not include factors for "exempt" or unscheduled medicines. It may therefore be relevant to consider how exempt medicines are defined in other, comparable jurisdictions.

The UK defines general sale (GSL) medicines in the following manner:

> *GSL is appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist. The term "with reasonable safety" has been defined as: "where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser."*

ASMI believes that ibuprofen in divided doses of not more than 200 mg per dosage unit, in pack sizes of not more than 25 dosage units, clearly meets the above definition, in that it can be supplied other than from a pharmacist with reasonable safety.

The TGA's risk-benefit analysis as part of the comprehensive safety review concluded that the maximum recommended OTC daily dose of 1200 mg per day, when used in a short duration, appears to have minimal cardiovascular risk. Previous TGA safety reviews, conducted in 2006, have similarly reviewed gastrointestinal, cardiovascular and cutaneous safety and recommended enhanced labelling statements (ultimately adopted by RASML at the time), but no requirement for any change to access.

The "reasonable consumer" is able to understand the labelling statements and use ibuprofen according to label instructions, for a short duration. The OTC product indications refer to temporary relief of self-limiting conditions, such as headache, period pain, back pain, muscular pain, fever, sore

throat – which are readily recognisable by consumers. The contraindications and precautions provide the consumer with sufficient information that would prompt them to seek advice from a doctor or pharmacist if necessary.

ASMI does not believe that it is necessary for consumers to visit the pharmacy for every purchase of ibuprofen, as most consumers are able to read the label and use the product safely and for an appropriate duration, for conditions which they can easily recognize. The risks can be well managed through labelling and there is no evidence that ibuprofen products are subject to misuse or abuse.

Impact on combination products containing ibuprofen – cold & flu medicines

Ibuprofen is also available as a component in combination cold and flu products that contain ibuprofen with phenylephrine hydrochloride. Many of these products are exempt from scheduling based on the applicable pack sizes.

Any changes to scheduling would also apply to combination cold & flu products, thereby removing these products from general sale as well.

There is no evidence to suggest that any changes to scheduling are warranted for these products, for which there is no evidence of abuse, misuse or inappropriate use.

As with the ibuprofen products used for temporary relief of pain and fever, cold and flu is a self-limiting and easily recognisable condition which the reasonable consumer is able to manage without pharmacist involvement and counselling with every purchase.

2. Consumer access and choice

The scheduling proposal covers two separate changes to the scheduling arrangements – (i) the removal of the scheduling exemption, and loss of ibuprofen from the grocery / general retail channel, and (ii) the up-scheduling of ibuprofen in packs of >30 and ≤100 from S2 to S3.

The potential impact from both of these proposed amendments should be considered separately.

Loss of ibuprofen from grocery channel due to removal of the scheduling exemption

Since 2003, ibuprofen in divided preparations containing 200 mg or less has been available in the general retail / grocery environment in packs containing not more than 25 dosage units, when labelled with a recommended daily dose of 1200 mg or less ibuprofen. Packs containing not more than 100 tablets are available in pharmacy as Schedule 2 products, and ibuprofen in strengths greater than 200 mg per dosage unit are available as Pharmacist Only Medicines.

There is no evidence to suggest that there is a problem with consumers who purchase small packs of ibuprofen (equivalent to either 2 or 4 days' supply) in the grocery environment, or that there is any significant concern regarding inappropriate use or inappropriate purchase. There is no evidence that availability in pharmacies confers additional advantage to purchasers already familiar with the product who do not require advice at the time of purchase. Consumers with medical conditions who require advice will seek advice from the pharmacist or from their doctor and the current scheduling does not prevent or deter them from seeking advice.

Availability in the general retail or grocery channel offers convenience, timely access, and competition for consumers. It is a complementary channel, rather than a replacement for pharmacist advice. Grocery purchasers are generally familiar with the product and may be repeat purchasers; these consumers do not tend to navigate the grocery aisle in search of health advice. The labelling provides all of the information that is required by the consumer to ensure appropriate selection and safe use.

The scheduling proposal therefore appears to be primarily concerned with removing general retail and grocery as allowable access channels for the sale of ibuprofen, rather than based on any demonstrated incremental health benefits that would be incurred. It represents a reduction in choice, competition and convenience for consumers.

Impact due to proposed scheduling change for packs of >30 and ≤100 dosage units to S3

Under the scheduling amendments proposed in the application, pack sizes of more than 30 tablets (i.e. 5 days' supply) will be available as Pharmacist Only Medicines. The consequence of this is that every consumer who is seeking more than 5 days' supply of ibuprofen must be counselled by the pharmacist.

Ibuprofen is indicated for relief of pain and discomfort associated with headache, back pain, muscle pain, period pain, dental pain, cold & flu and fever. The products are intended for short term use, and are labelled with "do not use for more than a few days at a time". There is no requirement for a pharmacist to actively monitor every sale of 5 days' supply of ibuprofen for the above conditions. All precautions and contraindications to inform consumers on appropriate and safe use are on the labelling and there is no evidence that consumers are currently experiencing harm from the product when used as per the recommendations. Ibuprofen is not subject to misuse, abuse or illicit use.

ASMI believes that a 5 days' supply of ibuprofen does not fulfil the scheduling factors for a Schedule 3 medicine. Schedule 3 medicines are medicines that have higher risks, such that pharmacist assistance is required for every supply request. It is needed to assist with recognising the condition to be treated and ensuring that the medicine is appropriate for that condition.

ASMI does not believe that the applicant's proposal to reschedule all but 5 days' supply of ibuprofen meets these criteria. Many consumers purchase a pack of ibuprofen to have on hand, and do not use the larger pack for a single course of treatment, as the applicant may have presumed.

The increased volume of S3 requests that will arise from such scheduling as proposed will greatly impact pharmacists' workload with frequent requests and ASMI questions whether pharmacy staffing levels and interruptions to workflow will allow pharmacists to properly monitor the considerable volume of ibuprofen requests consequential to this scheduling proposal. We question whether pharmacists can properly deliver any of the safety and monitoring outcomes that have likely been put forward to justify the proposed scheduling change of certain pack sizes to S3.

Such a proposal seeks to "dilute" the Schedule 3 category and implies a deep mistrust of the capability of a reasonable person to read the label, follow the directions and understand when to seek professional advice.

Labelling

For OTC medicines, the label provides the consumer with all information required to ensure that the medicine is selected appropriately and used safely for the appropriate duration.

All OTC medicines containing ibuprofen are required to include all advisory statements detailed in the Medicines Advisory Statements Specification (MASS 2017), also referred to as the "Required Advisory Statements for Medicines Labelling" (RASML).

For OTC medicines, the labelling provides the most important information needed by consumers – it provides information on indications and uses to assist with selection, contraindications and precautions advising when it should not be used, instructions on how to use the medicine appropriately, and when to seek advice.

Given the extensive history of use of ibuprofen and its very well documented safety profile, the relevant precautions, contraindications and instructions for safe use are communicated on the labelling. RASML currently includes the following warning statements:

- Do not use [this product*/insert name of product*] if you have a stomach ulcer.
- Do not use if you have impaired kidney function.
- Do not use if you have heart failure.
- Do not use [this product*/insert name of product*] if you are allergic to ibuprofen or other anti-inflammatory medicines.
- If you get an allergic reaction, stop taking and see your doctor immediately.
- Unless a doctor has told you to, do not use [this product*/insert name of product*] if you have asthma.
- Do not use [this product*/insert name of product*] during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. *(This statement is being amended to include women planning a pregnancy)*
- Unless a doctor has told you to, do not use [this product*/insert name of product*] if you are aged 65 years or over. *(NB: This statement is not mandatory on scheduled ibuprofen products)*
- Unless advised by your doctor or pharmacist, do not use [this product*/insert name of product*] with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly.
- Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

The TGA, in the safety reviews described above, were of the view that the risk-benefit profile for NSAIDs remains positive and that the benefits of these medicines outweighs the known risks for most people. The review also supported the need to raise awareness among consumers and healthcare professionals that there are some known risks, and recommended that the addition of warning statements on labelling is the appropriate means of achieving increased awareness.[6]

Given that consumers often keep a pack of ibuprofen in their medicine cabinet, labelling warning statements are critical because they are present on the pack at a time when the consumer will be using the product. This applies to all OTC medicines irrespective of scheduling.

[6] October 2014 TGA Options for response to the review

3. The Regulatory Impact

ASMI is of the view that the scheduling of ibuprofen remains appropriate.

The Australian government has a set of guiding principles for Australian government policy makers[7]. Some of the relevant principles include:

- *Regulation should be imposed only when it can be shown to offer an overall net benefit.*
- *The cost burden of new regulation must be fully offset by reductions in existing regulatory burden.*
- *Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.*
- *Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals.*

The above principles are aligned with the COAG *Principles of Best Practice Regulation,* which additionally state that all governments should ensure that regulatory processes in their jurisdiction are consistent with the following principles:

- *Establishing a case for action before addressing a problem;*
- *A range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;*
- *Adopting the option that generates the greatest net benefit for the community;*
- *Government action should be effective and proportional to the issue being addressed.*

ASMI believes that the scheduling proposal, if adopted, represents over-regulation, a disproportionate focus on risk, and a significant cost burden and impact on industry as well as the retail environment, all of which are at odds with the above stated principles.

No details on the rationale behind the scheduling proposal have been presented as part of the invitation for public comment. It has not explained the problems the scheduling proposal is seeking to address.

In relation to this scheduling proposal, ASMI believes that the ACMS and the Delegate should consider:

- whether it is based on sound evidence of hazards arising specifically from access within the grocery / unscheduled environment
- whether the proposal is based on sound evidence that changes to scheduling are required
- whether the proposed scheduling will "solve" any of the stated concerns, or
- whether it represents regulatory over-reach.

Any change to current access arrangements should be based on evidence of widespread hazards related to continuing access from the unscheduled retail environment. It should not be based upon a philosophical argument that "pharmacy is a more suitable channel for access to these products" or a belief that the pharmacy environment offers more supervision or protection to consumers. Pharmacists can and do offer advice however consumers who require advice specifically seek it out,

[7] https://www.cuttingredtape.gov.au/handbook/australian-government-guide-regulation

and the presence of ibuprofen in the retail / grocery environment does not prevent or deter consumers from seeking advice when it is needed.

Process

The scheduling proposal that will be considered by the ACMS and subsequently by the Delegate will have a profound impact on consumers, the pharmacy profession, the retail environment and competition in the marketplace.

The material that has triggered this scheduling proposal has not been made public, nor have the motivations of the applicant(s). There has not been any recent significant public health issue that could have altered the risk vs benefit balance of ibuprofen, to warrant such a proposal being considered. No information has been provided to stakeholders on the concerns that the proposed rescheduling and change to access seek to address or diminish.

ASMI is deeply concerned that under the current system for considering scheduling proposals, there will be no opportunity to properly assess/discuss/critique the materials put forward until after an interim decision has been made.

We therefore suggest that if the ACMS recommends to the Delegate that the scheduling of ibuprofen should change, the Delegate should make no immediate interim decision and that the materials used by the ACMS in making its recommendation should be published for a thorough public examination. This way, all affected stakeholders will be given a fair and reasonable opportunity to address the issues raised as part of the rescheduling proposal.

Conclusion

The evidence provided in this submission coupled with the issues around consumer access and the regulatory impact demonstrate that the current scheduling of ibuprofen is appropriate.

Ibuprofen has been available in the grocery / unscheduled environment for approximately 15 years and has been available as an over-the-counter medicine for approximately three decades. It is indicated for temporary relief of headache, pain, fever and sore throat – all easily recognisable minor ailments that can be easily and accurately recognised by the consumer. The product labelling contains all important information required for self-selection and appropriate use; it details when consumers should seek further advice from a healthcare professional.

Any change to existing arrangements must be made on the basis of an open and transparent review of evidence of actual harm and a demonstration that the proposed changes will address these concerns; it should not be based simply on a view that consumers cannot be trusted to use the product appropriately if it is supplied in the general retail environment.

During the many years of availability, there have been multiple reviews of NSAIDs by the TGA and overseas regulators, all of which included ibuprofen and none of which have triggered changes to access.

While ASMI is uncertain of the identity of the applicant and their possible motivations, it should be noted that the proposed scheduling changes would, if adopted, represent unnecessary regulatory burden and economic impact on many stakeholders including consumers, industry and retailers.

Rescheduling would put Australia out of step with comparable overseas jurisdictions and limit consumer choice and ease of timely access to effective pain relief.

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

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

We refer to the notice published on 6 September 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 November 2017 meeting of the ACCS:

- 1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives
- Phenyl methyl pyrazolone
- Silver oxide

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]

Rachael Linklater
Science & Technical Regulatory Associate

6 October 2017

ACCS meeting: November 2017

1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives

1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives are used as a surfactant in personal care and cleaning products at concentrations up to 12% in cleaning products and up to 7% in rinse-off cosmetics.

We note the recent advice from the Committees on other surfactants (docusate sodium, sodium α-olefin sulfonates and sodium alkyl sulfates) that *"there is no evidence of a public health risk"* from these kinds of substances, and that a review into the scheduling of all surfactants should take place.

We are therefore unsure as to why a surfactant substance such as *1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives* would be on the agenda for consideration by the Committee when a broader review has been flagged.

We do not support the scheduling of *1-Deoxy-1-(methylamino)-D-glucitol, N-C10-16 acyl derivatives*. Accord has long opposed scheduling of individual surfactants through the Chemical Scheduling process. It is out of step with international requirements for these substances and is unnecessary due to the well-established history of safe use of surfactant based products.

In principle, we support the Committee's recent advice that a review into the scheduling of all surfactants should take place, including this substance. We look forward to further consultation with industry on how such a review would be progressed.

.

ACCS meeting: November 2017

Phenyl methyl pyrazolone

Accord has no objections to aligning the scheduling controls for this substance when used in cosmetics with those for cosmetics in the EU. We note that phenyl methyl pyrazolone is included in Annex III of the EU Cosmetics Regulation, allowing its use as a hair dye substance in oxidative hair dye products with an in-use concentration (after mixing under oxidative conditions) not exceeding 0.25%.

Any warning statements and safety directions should be consistent with those for other scheduled hair dye substances with similar risk profiles, and as much as possible with those required in the EU to allow for harmonisation. i.e.

*PHENYL METHYL PYRAZOLONE **except** when used in oxidative hair dye preparations and eyebrow/eyelash colouring products containing 0.25 per cent or less of phenyl methyl pyrazolone 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 sensitisation to certain individuals. A preliminary test according to the accompanying directions should be made before use, and*
>
> *Written in letters not less than 1.5 mm in height.*

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

ACCS meeting: November 2017

Silver oxide

We note that silver oxide is used as a biocide in spa pool sanitiser products, and that the proposal is to exempt silver oxide from scheduling.

We have no objections to the scheduling proposal. An entry in Appendix B would be a straightforward way to achieve this regulatory outcome to ensure that there are no unintended effects on the regulatory status of other silver compounds and/or derivatives which may be used in other sectors.

[redacted]

Balloon Artists and Suppliers Association of NSW

[redacted]

The Manager
Therapeutic Goods Administration
Re : CAS no. 7440-59-7

3rd October 2017

Dear Sir

On behalf of the individual members and corporate company members of the Balloon Artists and Suppliers Association of Australasia Ltd (BASA-A) we wish to submit to the TPA our thoughts and concerns regarding the proposed changes to Cas number 7440-59-7 Helium.

- **Issues to be considered from BASA A**

Floatation time for decorators: driving to venues and length of function time.
Floatation time of Foil & Bubble balloons, some balloons won't float.
Floatation time in areas of higher altitude.
Floatation time for customer's pre collecting balloons the day before.
The unknown effect of an aversive on an extensively industry used product "Hi Float"; a substance added to balloons to increase flotation time
Mixed gases will be more labour (and cost) intensive to bottle by the gas companies.
Will the aversive stratify in the cylinder causing a non harmonious mixture.
There will be an obvious change in Price? What is the increase?
Helium filled with an aversive may need to be stored off premises, incurring extra costs and inconvenience & logistic unworkability.
A helium /aversive mixture will leach through the porous membrane of the latex and be a substantial negative at all celebration events from formal galas to the most intimate family events.
If a balloon pops the aversive smell or taste will dissipate throughout and linger in the venue .
Who would be able to access the poisons classification ?

- **Proposed idea's:**

Ban imported disposable DIY cylinders. They advertise that they include 20% air but **Air only contains 21% oxygen so 21% x 20% = 4.25 oxygen..THIS WILL NOT SUPPORT LIFE!**
Add a section to the BASA-A accreditation Module 1 to insist that E, F & G cylinders are not to be hired out and thus "Self Regulate" our industry. This accreditation should include a 3 yearly revision and is void immediately on leaving the industry or sale of that business.
Small cylinders D's and under should be filled by the gas suppliers to 80/20%, Air / He mixture for DIY market through those approved BASA-A accredited retailers and spot sales by gas companies.
Establish a Professional level cylinder of 95% He upwards for E F G for accredited professionals that are licensed through their accreditation. Cylinders should be marked by Suppliers accordingly as a new professional category.

Use only Registered “Accredited” Balloon Professionals thru BASA-A and NZ (Australia & New Zealand), who are trained approved and accredited and that list distributed to the Gas companies (yearly) for only their access to these cylinders.
There are installations of manifolded cylinders that are piped to usage points throughout companies in Australia and these are occasionally blown down to change over cylinders. That release of Helium with an aversive would be unacceptable by the industry particularly in corporate fast food venues. OH&S.

Further the reality in our industry is that not all balloons inflate perfectly; the occasional one pops, some burst, some don’t inflate fully the first time...these all would allow a release of the aversive into the work area and would be undesirable and may result in future medical issues.

Next, to remove regulators and / or specialised inflating equipment you have to “blow down” the pressurised line to allow the disconnection. This will extremely unpleasant for all in our industry with perhaps greater significants to the high proportion of young female balloon artists.

Helium doesn't meet the criteria to be considered a poison nor to be scheduled; It sets a dangerous precedent. (Scheduling of chemicals/poisons is normally to prevent children from swallowing them requiring child proof tops etc. Helium is only dangerous if deliberately misused)

There are many uses of helium that are essential for society – MRI’s etc. the cost impact on business and society could be huge!

The National Executive of BASA-A, who represent the members around Australia and New Zealand of the various BASA Associations, wish to thank the ACCC for consideration of the points raised here. BASA-A has a history dating back to its inception in 1997 and has for many years continued to improve its Accreditation program to reflect changes to social issues. The Accreditation program currently has three (3) modules and we believe that adding support to the points here and working with the BASA-A Accreditation Program will bring a safer and workable control of the Helium market while allowing businesses to function smoothly.

We also feel the inclusion of an aversive would be impractical with our positive environmental policy Smart Balloon Practices that our members use and encourage to their clients. One action is “Pin It An Bin it” after your function. Popping a balloon with an aversive indoors would not be pleasant.

We also are concerned of the work place safety of our members & the general public who might inhale this new poisonous gas mixture.

Can you advise if the mixture of gases planned would be non flammable?

Thank you again, if our BASA-A National Executive can assist with further information we would only be too pleased to provide that and work to a viable outcome. Our best always.

Yours faithfully

Raymond Connett
Secretary BASA NSW

[redacted]

[redacted]

Our ref: D17/5444

Joint Advisory Committees on Chemicals and
Medicines Scheduling (Joint ACCS-ACMS)
medicines.scheduling@health.gov.au

To the Committee Members

Proposed Amendments to the Poisons Standard – Listing Helium as a Schedule 6 or 7 Poison (CAS Number 7440-59-7)

The Small Business Development Corporation (SBDC) is submitting comments in response to the application made by the Australian Competition and Consumer Commission (ACCC) to list helium under Schedule 6 or 7 of the Poisons Standard, as well as requiring helium gas to be in pressurised gas canisters or cylinders containing an aversive when being sold or hired by consumers intended for household or domestic use.

Role of the Small Business Development Corporation

The SBDC is an independent statutory authority established to foster the growth and development of small businesses in Western Australia. In addition to providing essential business advice and dispute resolution services, the SBDC plays an important role in advocating to government on behalf of the Western Australian small business sector.

The SBDC firmly believes that government should not create unnecessary regulatory burdens for businesses unless there is a sound policy position for doing so. In many cases it is the administration of regulation or unintended consequences that can cause most impact for businesses.

The proposal to list helium in the Poisons Standard (the Proposal) will have implications for many businesses using helium, with a particular impact on helium retailers. In order to help inform the decision of the Joint Advisory Committees on Chemicals and Medicines Scheduling, the SBDC has endeavoured to review the potential business impacts in light of the desired policy outcome.

Position of the Australian Chamber of Commerce and Industry

The SBDC understands that the Australian Chamber of Commerce and Industry (ACCI) intends to oppose the Proposal on the basis that it is impractical in nature and lacks evidence that implementation would have a meaningful impact on the rate of suicide.

[redacted]

SBDC Position

The SBDC acknowledges that there is evidence of helium causing involuntary deaths through inhalation, and that it is being used in suicides. With this in mind, the SBDC has critically assessed whether the Proposal will on balance, reduce the number of these deaths, and if the benefits to the community outweigh the impacts on businesses.

If helium is listed as a Schedule 6 poison, there will be a number of implications for businesses, including the requirement to prevent access to helium containers by children, and ensuring product labels meet the requirements of the Poisons Standard.

The SBDC considers that on the balance of things the requirements of a Schedule 6 poison are reasonable (although it is acknowledged that some costs could be incurred in meeting storage requirements), will help to educate consumers of the dangers of helium inhalation, and may go some way to reducing the number of involuntary helium deaths. It is reasonable to expect that the new packaging requirements would be borne by the manufacturers.

If helium is listed as a Schedule 7 poison, there will be considerable impacts for businesses, particularly retailers. These impacts include the requirement for licensing, storage, packaging and record keeping.

The SBDC understands that the intention of the Proposal is to include a quantity cut-off limit, whereby consumers will be able to purchase up to a certain amount of helium for domestic purposes, but will require authorisation to purchase quantities above the cut-off limit.

Given the sale of helium for domestic purposes will still be permitted up to the cut-off limit, it could be argued that imposing the onerous Schedule 7 requirements on businesses will have little impact on reducing the number of suicides using helium and rather, would make it more costly for businesses to operate. In light of this, the SBDC agrees with the ACCI and does not support helium being listed as a Schedule 7 poison.

The Proposal also seeks to require an aversive to be added to helium canisters when sold or hired to consumers for domestic use. The SBDC supports this aspect of the Proposal.

If the Committees wish to discuss this submission in more detail, please liaise directly with [redacted]

Yours sincerely

[redacted]

5 October 2017

[redacted]

05 October 2017

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety
GPO Box 9848
CANBERRA ACT 2601

Email: medicines.scheduling@health.gov.au; chemicals.scheduling@health.gov.au

Dear Sir/Madam,

Proposed amendments to the Poisons Standard - Joint ACCS/ACMS meetings, November 2017 (Helium)

[redacted]

[redacted]

[redacted]

[redacted]

Yours sincerely,

[redacted]

Nick Zovko
Regulatory Policy Manager
[redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

6 October 2017

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

medicines.scheduling@health.gov.au

Subject: Proposed amendments referred by the delegates to the Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS) for scheduling advice – Helium.

[redacted]

[redacted]

[redacted]

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- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Yours sincerely,

[redacted]

Kathryn Walton
Executive Officer

[redacted]

6 October 2017

The Secretary
Medicines & Poisons Scheduling
Office of Chemical Safety
GPO Box 9848
CANBERRA ACT 2601

Email: medicines.scheduling@health.gov.au ; chemicals.scheduling@health.gov.au

Dear Sir/Madam,

Proposed amendments to the Poisons Standard - Joint ACCS/ACMS meetings, November 2017 (Helium)

The Australian Chamber of Commerce and Industry (**Australian Chamber**) is the largest and most representative business advocacy network in Australia. We represent more than 300,000 businesses in every state and territory and across all industries. Our network employs around 4 million employees, ranging from the top 100 companies to small and medium businesses.

The Australian Chamber welcomes the opportunity to provide comment on the Scheduling Advisory Committees pre-meeting proposal for helium.

The chemical industry is a vital part of the Australian economy now and in the future. Businesses, governments, community consumers and our natural environment all benefit from the safe, responsible and sustainable use of chemicals. Any proposed changes should ensure a balanced regulatory environment that encourages investment and innovation whilst retaining standards of protection that are proportionate to any risk.

This proposal will not only impact the chemical industry, but a significant number of other industries due to helium's various medical, industrial and scientific applications. Industries potentially impacted include:

- Manufacturing: used in semiconductor manufacturing, fiber optic cable manufacturing.
- Medical: used in MRIs & other medical devices and in the treatment of respiratory problems.
- Diving: used in scuba and deep diving breathing gases.
- Automotive: used in airbags, to detect leaks in air-con systems in cars.
- Welding: used in welding gases (i.e. arc welding).
- Scientific/Professional: laboratory equipment (such as a carrier gas for Gas Chromatography, microscopes).
- Tech: used in laser cutting, 3D printing, electronics.

[redacted]

[redacted]

[redacted]

The Australian Chamber considers mental ill-health to be an important public health issue which impacts not only on the individual, their family and the community, but also on the workplace due to the substantial amount of time spent at work. We note that the proposed scheduling seeks to mitigate the reported public health risk of suicide by asphyxiation.

Mental ill-health is a complex issue and continued research is needed into best practice prevention strategies and responses. The Australian Chamber considers the controlling of a substance that is inherently low risk and has a number of legitimate uses, in reaction to a small percentage of intentional misuse, a disproportionate response and one that may not necessarily address the root cause of the issue. The increased regulation of this commonly used gas would have a significant detrimental impact on a range of industries. Without substantiated evidence that this action would significantly improve outcomes, we strongly oppose this proposal as it is impractical and unworkable for industry. We would encourage the reviewers to explore other less prescriptive and more practical control measures.

Should you have any queries in relation to the matters raised, please do not hesitate to contact me [redacted]

Yours sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

6th October 2017

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
www.tga.gov.au

chemicals.scheduling@health.gov.au

Subject: Proposed amendments referred by the delegates to the Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS) for scheduling advice – Helium.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Yours sincerely,

[redacted]

John M Manfred
National Production Manager - IM
[redacted]

[redacted]

[redacted]

6th October 2017

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

www.tga.gov.au
chemicals.scheduling@health.gov.au

To whom it may concern,

Subject: Proposed amendments referred by the delegates to the Joint Advisory Committees on Chemicals and Medicines Scheduling (Joint ACCS-ACMS) for scheduling advice – Helium.

[redacted]

[redacted]

Yours faithfully

[redacted]

Robin Bell
Head of Health, Safety and Environment, RSP

[redacted]

[redacted]

The Secretary
Scheduling Secretariat
GPO Box 9848
CANBERRA ACT 2601

Email: chemicals.scheduling@health.gov.au

Dear Sir/Madam

Public Comment Submission to the November 2017 joint meeting of the Advisory Committee on Medicine Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 6 September 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 November 2017 meeting of the ACMS/ACCS:

- Salts of boric acid
- Polihexanide

Please see the attached submission for details.

We look forward to further advice from the ACCS and the Delegates. Should the Committee or the Delegate require any additional information from Accord at this stage please do not hesitate to contact me on (02) 9281 2322.

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

6 October 2017

Accord Australasia Limited [redacted]

ACCS/ACMS meeting: November 2017

Salts of boric acid

We note that the scheduling proposal refers to the following salts of boric acid:

- 1330-43-4 sodium borate
- 1332-77-0 potassium borate
- 26038-87-9 MEA-borate
- 26038-90-4 boric acid, monoisopropanolamine salt;
- 68003-13-4 Isopropanolamine borate

The proposed amendment to the current Schedule 5 entry for boric acid to remove "excluding its salts" so that all the salts of boric acid are captured, may result in the inadvertent regulation of substances other than those that have been listed above i.e. that have been identified to be of concern in the IMAP assessment.

Accord members have advised that these 5 substances are used at very low concentrations in cosmetics as buffering/viscosity controlling agents (sodium borate), as enzyme stabilisers in domestic detergent products and as corrosion inhibitors in industrial products.

We note that these 5 substances are currently listed in Annex III of the EU Cosmetics Regulation "List of substances which cosmetic products must not contain except subject to the restrictions laid down" with specific conditions on maximum in-use concentrations for talc (5%), oral products (0.1%) and other products (3%). Other conditions include restrictions and label statements to the effect of "*Not to be used in products for children under 3 years of age"*.

While a 2013 EU SCCS opinion[1] on "the safety of boron compounds in cosmetic products" recommended further risk management, we note that this recommendation has not yet been implemented in legislation and therefore we are unsure of the scope of any forthcoming changes.

We would therefore prefer to see an approach that scheduled only these 5 substances that have been identified as being of concern using as a guide the EU concentration cut-offs for cosmetics and those concentrations in the current Schedule 5 entry for boric acid and borax.

Depending on the extent of any changes, an adequate transition period will be required to allow for any reformulation and/or labelling changes that would be required.

[1] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_146.pdf

ACCS/ACMS meeting: November 2017

Polihexanide

Polihexanide is used as a preservative ingredient/biocide in cosmetics and domestic products and therapeutic goods including disinfectants and sanitisers.

Polihexanide 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%. We note that the recent SCCS opinion[2] recommended a reduction in this concentration, but this has not yet been finalised, nor implemented in legislation.

For cosmetic products
Accord has no objections to the proposed amendment of the Schedule 6 entry for polihexanide when used in cosmetics in line with current EU requirements for cosmetics i.e. reducing the cut-off concentration from 5% or less to 0.3% or less.

For non-cosmetic products
We are unaware of any new information since the 2015 Scheduling consideration[3] of this substance that would indicate changes are necessary to the current Schedule entry with regard to non-cosmetic products.
The Delegate's reasoning noted *"The critical toxicological endpoints driving this categorisation (acute toxicity, severe skin/eye irritancy and sensitisation potential) are consistent with SPF criteria for listing in Schedule 6, with the public health risk sufficiently ameliorated for products under 5 per cent."*

The EU SCCS opinion also noted that *"With respect to potential contribution of exposure from non-cosmetic use to the overall exposure… it is considered that the actual future consumer related exposure to PHMB is considered in practical terms to be very low."*

We therefore suggest an amended entry such as:

> Schedule 6
>
> POLIHEXANIDE except:
>
> a) in cosmetic preparations containing 0.3 per cent or less of polihexanide; or
> b) in other preparations containing 5 per cent or less of polihexanide; or
> c) when packed and labelled for therapeutic use.

There are various synonyms for these 2 substances. For clarity, entries for the following names should be included in the index and cross-referenced to the polihexanide schedule entry:

- polyhexamethylene biguanide (PHMB), CAS number 28757-47-3
- polyhexamethylene biguanide (PHMB) hydrochloride, CAS number 27083-27-8

Depending on the extent of any changes, an adequate transition period will be required to allow for any reformulation and/or labelling changes that would be needed for products that currently meet the 5% or less exception, but will become Schedule 6 poisons if the exception is reduced as proposed to 0.3% or less. Any changes would affect products currently in the Australian market with an established history of safe use.

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[2] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_204.pdf
[3] https://www.tga.gov.au/book/part-final-decisions-matters-referred-expert-advisory-committee-accs-acms-10