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 will be published on the TGA website in accordance with regulation 42ZCZL.

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 3 October 2017 are published here in accordance with regulation 42ZCZQ of the Regulations. Also in accordance with the regulation 42ZCZQ, the Secretary has removed information that the Secretary considers confidential.

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]

Interim decision & reasons for decisions by delegate of the secretary to the Department of Health

Comments to the proposed amendments referred by the delegate for scheduling advice

Esomeprazole

October 2017

[redacted]

National Secretariat

[redacted]

Ref: SP1006-18-1608

INTERIM DECISION 1.4 – 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-esophageal reflux disease, in packs containing not more than 14 days' supply.

Overview

As stated in our pre-meeting submission, the Guild does not support this proposal and believe that Proton Pump Inhibitors (PPIs) should not be available as Schedule 2 medicines.

Since the pre-meeting submission we have become aware of a recently published paper that highlights the dangers of PPIs and we would like to bring this information to the attention of the Committee.

The paper was published in the British Medical Journal on 4 July 2017 and is titled *"Risk of Death Among Users of Proton Pump Inhibitors: a Longitudinal Observational Cohort Study of United States Veterans"* Xie Y Bowe B, Li T, et al.[1] The full paper is attached (SEE ATTACHMENT 1).

We highlight the following points made in the study as these are relevant to Section 52(e) of the Act and reinforce our argument that PPIs should not be available as Schedule 2 medicines.

The article makes the following statements:

- Several observational studies suggest that PPI use is associated with increased risk of a number of adverse health outcomes.
- A number of studies have shown that PPI use is associated with significant risk of acute interstitial nephritis.
- Recent studies established an association between exposure to PPI and risk of chronic kidney disease (CKD), kidney disease progression and end-stage renal disease.
- Results from a large prospective observational German cohort suggest that patients receiving PPI had a higher risk of incident dementia.
- Several reports highlighted a rare but potentially fatal risk of hypomagnesemia among users of PPIs.
- PPI use has been associated with increased risk of both incident and recurrent *Clostridium difficile* infections.
- Several observational analyses have shown that PPI use was also associated with increased risk of osteoporotic fractures, including hip and spine fractures.

The article also showed:

- The results suggest excess risk of death among PPI users, risk is also increased among those without gastrointestinal conditions and with prolonged duration of use. Limiting PPI use and duration to instances where it is medically indicated may be warranted.

The authors made the following observations:

- PPIs are widely used by millions of people for indications and durations that were never tested or approved; they are available over the counter (without prescription) in several countries and generally perceived as safe class of therapeutics. They are often overprescribed, rarely

[1] http://bmjopen.bmj.com/content/7/6/e015735

deprescribed and frequently started inappropriately during a hospital stay, and their use extended for long-term duration without appropriate medical indication

- Although the results should not deter prescription and use of PPI where medically indicated, they may be used to encourage and promote pharmacovigilance and emphasise the need to exercise judicious use of PPI and limit use and duration of therapy to instances where there is a clear medical indication and where benefit outweighs potential risk.
- Standardised guidelines for initiating PPI prescription may lead to reduced overuse, regular review of prescription and over-the-counter medications and de-prescription where a medical indication for PPI treatment ceases to exist may be a meritorious approach.

Given these findings in this paper we suggest that esomepazole should not be available without the intervention of a health care professional to ensure that it is not overused which could quite easily occur if these types of products are sold without supervision.

We note the following in the Delegate's interim decision:

- *"esomeprazole is a safe and effective first line treatment for the common symptoms of GORD and heartburn".*

However, the comments made in the Xie et al article highlight a number of adverse health outcomes.

- *"risks are primarily with longer term use"*

As the medicine will be Schedule 2 and in packs of 14 days' supply there is no restriction on the length of treatment. Consumers could use these medicines for long term use without the opportunity for a health care professional to review use and de-prescribe.

- *"available information does not suggest that OTC PPI use that is consistent with label instructions is associated with substantial health risks"*

We contend that the information published by Xie et al would suggest that there are substantial health risks if consumers do not use PPIs consistent with label instructions and use these medicines long term.

- *"The safety and tolerability of esomeprazole are well-established. The majority of adverse events are mild and transient in nature. Esomeprazole has low toxicity when used for 14 days' treatment at a dose of 20 mg per day. The risks are primarily associated with longer term use"*

It may well be true that risks are associated with longer term use but this assumes that consumers will only ever purchase one packet of 14 days' treatment at a dose of 20 mg per day. As the product is Schedule 2, the consumer can buy multiple packs and buy them repeatedly without health care professional oversight. The risks are primarily associated with longer tem use and this is what might very well happen if the product is Schedule 2. There is no guarantee that consumers will use the product in accordance with the labelling and provision of CMI.

[redacted]

Australian Self-Medication Industry Ltd.
[redacted]

3 October 2017

The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au and Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, July 2017

We refer to the notice inviting further comment under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the July 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

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 has considered the Delegate's Interim Decisions and Reasons for Decisions and would like to comment on the following scheduling proposals:

1.1 Sildenafil

ASMI does not support the Delegate's interim decision regarding sildenafil.

In our view, a new Schedule 3 entry should have been prepared as proposed by the applicant.

In reviewing the summary of the ACMS advice, and the delegate's subsequent considerations, we note that:

- Although sildenafil has a well-established safety profile, the ACMS and the Delegate placed too much emphasis on the risks associated with the substance (without a proper consideration of the mitigating effects of the advice from the pharmacist, the warning statements on the labelling and the availability of the CMI).

- The ACMS and the Delegate also placed too little emphasis on the potential benefits of re-scheduling (for example: increased awareness of ED, increased awareness of treatment options, reduced reliance on unsafe internet purchases, increased use of appropriately trained pharmacists).

- The ACMS and the Delegate ignored the positive results from New Zealand.

- Neither the ACMS not the Delegate appeared to consider, at all, the UK regulator's current proposal to re-classify sildenafil as a Pharmacy Medicine.

1.2 Vardenafil

ASMI does not support the Delegate's interim decision regarding vardenafil.

In our view, a new Schedule 3 entry should have been prepared as proposed by the applicant.

In reviewing the summary of the ACMS advice, and the delegate's subsequent considerations, we note that:

- Although vardenafil has a well-established safety profile, the ACMS and the Delegate placed too much emphasis on the risks associated with the substance (without a proper consideration of the mitigating effects of the advice from the pharmacist, the warning statements on the labelling and the availability of the CMI).

- The ACMS and the Delegate also placed too little emphasis on the potential benefits of re-scheduling (for example: increased awareness of ED, increased awareness of treatment options, reduced reliance on unsafe internet purchases, increased use of appropriately trained pharmacists).

- The ACMS and the Delegate ignored the positive results from New Zealand in relation to sildenafil.

- Neither the ACMS nor the Delegate appeared to consider, at all, the UK regulator's current proposal to re-classify sildenafil as a Pharmacy Medicine. Mistakenly reporting that the "British Medicines and Healthcare Products Regulatory Agency is considering an application to re-schedule sildenafil, to make it available over-the-counter in pharmacies." In fact, the UK regulator has already indicated that they "consider that this product can be available as a Pharmacy medicine"[1].

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

1.3 Ibuprofen combined with Paracetamol

ASMI does not support the Delegate's interim decision regarding ibuprofen combined with paracetamol.

In our view, the Schedule 2 entry should have been amended as proposed by the applicant.

In reviewing the summary of the ACMS advice, and the delegate's subsequent considerations, we note that:

- The ACMS and the Delegate have missed an opportunity to better reflect the current scheduling principles. Current policy and scheduling principles for products containing more than one poison[2] are clear and in ASMI's view 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.

- The ACMS and the Delegate have also missed an opportunity to move towards closer alignment with the New Zealand scheduling of the combination. 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.

1.4 Esomeprazole

For the reasons outlined in our submission of 15 June, ASMI supports the Delegate's interim decision that the Schedule 2 pack size limit for esomeprazole be increased from 7 days' supply to 14 days' supply.

2.6 Methylisothiazolinone

ASMI does not support the Delegate's interim decision regarding Methylisothiazolinone.

The proposed implementation date (1 June 2018) does not allow affected manufacturers sufficient time to develop new formulations, despite the Delegate's statement that:

> *"A later implementation date allows for industry alignment."*

As identified in our submission of 15 June, an appropriate transition period would be at least 24 months and preferably 30 months.

The final scheduling decision will not be published until 27 October 2016 and manufacturers cannot reasonably act until that final decision is known. The 1 June 2018 implementation date therefore only allows seven months during which affected manufacturers will have to:

- Investigate alternative preservative systems, and
- Develop new formulations, and

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

- Perform the required testing to ascertain the optimal formulation, and
- Manufacture test batches, and
- Perform the associated stability / quality control on test batches before going to market.

Seven months is a manifestly inadequate timeframe in which to complete all these tasks (at least 24 months is required). To add further complexity to this process, one ASMI member (whose affected products come from the US) has advised that they have a 9 month lead time for production alone.

2.9 Benzyl salicylate

ASMI supports the exclusion of therapeutic goods from the schedule 6 entry for benzyl salicylate. 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.

2.10 Cinnamaldehyde

ASMI supports the exclusion of therapeutic goods from the schedule 6 entry for cinnamaldehyde. 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.

2.11 Anise alcohol

ASMI supports the exclusion of therapeutic goods from the schedule 6 entry for anise alcohol. 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.

2.12 Resorcinol

ASMI supports the exclusion of therapeutic goods from the schedule 6 entry for resorcinol. 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.

2.13 Trans-anethole

ASMI supports the Delegate's decision to defer the interim decision for trans-anethole to allow for further consideration of its use in therapeutic goods (among other things).

3.7 Basic red 76

ASMI believes that the Delegate's interim decision regarding Basic Red 76 does not go far enough.

There has been no examination of the potential impact of this decision on therapeutic goods, despite the issue having been raised in our submission of 15 June and despite other items on the

July agenda being closely examined in terms of their potential impact on therapeutic goods (and in one case being deferred for that specific purpose - see trans-anethole above).

For the reasons outlined in our submission of 15 June, we request that therapeutic goods be excluded from the schedule entries for azo dyes, at least until a comprehensive review can be conducted into the impact of the Schedules 5, 6 and 7 entries for azo dyes on therapeutic goods.

Thank you for the opportunity to comment on the above interim decisions.

Please contact me should you have any further queries.

Yours sincerely,

[redacted]
[redacted]

[redacted]

[redacted]

5th October 2017

The Secretary

Scheduling Secretariat

GPO Box 9848

Canberra ACT 2601

Email: Medicines.Scheduling@tga.gov.au and Chemicals.Scheduling@health.gov.au

Dear Sir or Madam,

Re: Scheduling delegates' interim decisions and invitation for further comment: ACCS/ACMS, July 2017

We refer to the notice inviting further comment under subsection 42ZCZP of the Therapeutic Goods Regulations 1990 and would like to provide comment on the Delegate's Interim Decisions arising from the July 2017 meeting of the ACCS/ACMS. The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*. I would also like to thank the secretariat for the opportunity to provide a late submission, as per email of Thursday 28th September, 2017.

1.3 Ibuprofen combined with Paracetamol

RB does not support the Delegate's interim decision regarding ibuprofen combined with paracetamol.

[redacted]

[redacted]

[redacted]

In our view, the Schedule 2 entry should have been amended as proposed by the applicant.

In reviewing the summary of the ACMS advice, and the Delegate's subsequent considerations, we note that:

- There is no evidence to support a risk of overdosing nor increased risk of potential adverse effects if the pack sizes of the combination are increased to 24 dosage units

- Contact with NSW Poisons Information Centres is in relating to dosing errors and relates to consumer confusion when branded and generic ibuprofen/paracetamol combinations are on the market with different posology; ibuprofen/paracetamol (200/500mg I tablet, versus 150/500mg 2 tablet). It is not in relation to potential for overdose. In relation to the number of packs sold these 'dosing errors' were very small. In addition, direction of use on pack are very clear. There is no risk to a consumer if they were to take 2 tablets of the higher ibuprofen dose combination, given that this posology has been approved in many other markets in the world. This dose has been marketed in NZ in the grocery environment for X years with no known safety issues or risk to the consumer.

- Sponsors have gone to significant efforts to educate consumers on appropriate usage to avoid confusion in dosage and in our experience this is working and there are fewer consumer contacts in relation to dosage.

- The benefit/risk equation for the proposed 24 dose unit pack in Schedule 2 is positive. There remains a very low incidence of post-market adverse event reports worldwide.

- We note the Delegate's comments with respect to Pharmacist advice and intervention to manage acute pain, including inflammation and/or aches and pains associated with cold and flu. This is not current practice and in pharmacies consumers can and do self-select S2 without pharmacy intervention for this condition. In fact consumer can access products in a grocery environment to treat these conditions.

- We question the evidence for the Delegate's view of an increased risks of potential delay in consumers seeking health practitioner advice and potential increase in duration of inappropriate use given that currently 100 tablets of paracetamol can be purchased as S2 for the same condition. Product with paracetamol for treatment of osteo-arthritis is currently available in packs of 96 and it is indicated for use in a

[redacted]

chronic condition which one could argue would require seeking health practitioner advice and ongoing management.

- The ACMS and the Delegate have missed an opportunity to better reflect the current scheduling principles. Current policy and scheduling principles for products containing more than one poison[1] are clear and in ASMI's view 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. Given the similar safety profile when used at OTC doses.

- The ACMS and the Delegate have also missed an opportunity to move towards closer alignment with the New Zealand scheduling of the combination. 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.

- RB are disappointed with the lack of evidence and transparency around the decision and for the reasons given above do not support the Delegates interim decision.

Yours sincerely,

[redacted]

[redacted]

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

[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 Delegate's Interim Decisions from the July 2017 meeting of the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 15 September 2017 of the Delegate's interim decisions under subsection 42ZCZP of the Therapeutic Goods Regulations 1990, inviting public submissions, with respect to certain substances, addressing a matter raised in section 52E of the Therapeutic Goods Act 1989.

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

Accord provided comments on the following agenda items for the July 2017 meeting:

- Butyl benzyl phthalate
- Basic red 76

Please find further comments on these items below.

We look forward to further advice from the Delegate. Should any additional information from Accord be required 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

3 October 2017

ACCS meeting: July 2017

Butyl benzyl phthalate

We note the Delegate's interim decision to create a new Schedule 10 entry for this substance.

As noted in our pre-meeting submission, Accord has no objections to the to the proposed Schedule 10 entry for this substance for cosmetic use. The reasons for the committee's advice and the delegate's interim decision address the risks of this substance when used in cosmetics, but this is not reflected in the proposed wording of the new entry as currently drafted.

We suggest the proposed Schedule 10 entry be amended to limit the entry to preparations for cosmetic use, in line with other phthalates listed in Schedule 10 i.e.

Schedule 10 – new entry

BUTYL BENZYL PHTHALATE for cosmetic use.

ACCS meeting: July 2017

Basic red 76

We note the Delegate's interim decision to exempt Basic Red 76 from the current Schedule 7 entry for AZO DYES, and to include a new entry in Schedule 6.

We are supportive of this approach which will allow the use of this substance as a hair dye at the same in-use concentrations as are permitted in the EU.

As noted in our pre-meeting submission, the warning statements and safety directions should be consistent with those for other Schedule 6 colorants used in hair dyes with similar risk profiles, and with those required in the EU for products containing this substance to allow for harmonisation.

The proposed Appendix F, Part 3 entry requires the Warning Statement:

"Wear protective gloves when mixing or using"

This does not seem to be consistent with those applied for other Scheduled hair dye substances, nor with the low toxicity of the substance and therefore should not be required.

This warning statement appears to be based on addressing the potential and seemingly theoretical risk of the formation of the genotoxic carcinogen *o*-anisidine by bacteria on the skin. It has been noted that if this substance were to decouple to release the carcinogen of concern, *o*- anisidine, this reaction would be accompanied by a colour change, 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*-anisidine formation occurring.

Under the circumstances of the scheduling of this substance, and given the global availability of products containing Basic Red 76, we are supportive of the earliest possible implementation date i.e. 1 February 2018 as included in the interim decision.

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

Public Comment Submission to the interim decisions arising from the July 2017 meeting of the Advisory Committee on Chemicals Scheduling (ACCS #20) and March 2017 and July 2017 Joint meeting of the Advisory Committees on Chemicals and Medicines Scheduling (ACCS-ACMS #15 and #16 respectively)

Dear Sir / Madam,

[redacted] wishes to provide comment on the interim decisions arising from the July 2017 meeting of the ACCS and the and March 2017 and July 2017 Joint meeting of the Advisory Committees on Chemicals and Medicines Scheduling (ACCS-ACMS #15 and #16):

- **Basic Red 76**
- **Benzyl salicylate**
- **Cinnamaldehyde**
- **Anise alcohol.**

Basic Red 76

Unilever 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 thank the committee for considering this substance.

Benzyl salicylate, Cinnamaldehyde and Anise alcohol.

[redacted] wishes to raise our concerns regarding the interim decision for these fragrance allergens.

- The ingredient decision as is will affect many cosmetic and domestic products.
- The decisions are inconsistent with previous scheduling of fragrance allergens.
- The decisions are inconsistent with established allergen declaration regulations internationally.
- The introduction of ingredient labelling on domestic products which is currently not required.
- Fragrance ingredient manufacturing in Australia is limited. Most fragrances are developed and manufactured internationally and sold for use in cosmetics and domestic products. An Australian manufacturer or importer of fully finished cosmetic or domestic products may choose to reformulate using fragrances without these substances. The timing proposed in the interim decision does not appear to have considered the need for a two-step process;
    1. Identify a new or reformulate the fragrance.
    2. Reformulate the product.
- Being a multinational company who import goods from all over the globe, we also have concerns that the implementation time is shorter than the time taken to order current product (existing product without allergen declarations). Meaning that for some smaller volumed items there is not enough time to make product label changes within the proposed timeframe.

We strongly recommend referring these three fragrance ingredients back to the committee for further review.

We are a member of Accord Australasia, the Australian Industry Body representing cosmetics, and are in support submissions they have make regarding these substances.

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]

03.10.2017

[redacted]

October 3, 2017

To: Therapeutic Goods Administration
Department of Health Australian Government

JCIA Opinion on the Interim Decision under Subsection 42ZCZN/42ZCZP of the Therapeutic Goods Regulations 1990

Dear Sirs/ Madams,
Japan Cosmetic Industry Association highly appreciates for your consideration to provide us the opportunity to express our opinion on the Interim Decision under Subsection 42ZCZN/42ZCZP of the Therapeutic Goods Regulations. On behalf of JCIA representing interests of more than 1,100 cosmetic companies in Japan, I would like to submit the following comments.

Carefully reviewing your proposal, we have concerns about new entry into Schedule 6 of the following substances that require the additional labelling or warning statements.

- Benzyl salicylate
- Cinnamaldehyde
- Anise alcohol

These substances are widely used in fragrances or flavors of household goods, cosmetic and therapeutic products. However, these substances are generally present at very low concentrations in cosmetic products; it is considered low enough to minimize the potency of skin sensitization to most consumers. We believe the proposed regulation lacks any clear scientific basis and is notably inconsistent with the previous decisions of fragrance allergy ingredients under the Australian Scheduling Guideline.

In addition, the proposed requirement is different from other jurisdictions and international standards. There are no labeling regulations in most countries and regions, such as Japan, US, and EU. For example, EU Cosmetic Regulation requires the ingredient labelling in its Annex III with the cut-off level at 0.001% in leave-on cosmetic and at 0.01% in rinse-off cosmetic without any additional warning statement. This excessive labelling requirement may cause serious negative impact on international trade.

In conclusion, the proposed regulation imposes a tremendous burden on our industry without any guarantee of a better consumer protection; rather, it may cause the unnecessary threat and confusion to consumers. We highly recommend these substances are not to be scheduled using the consistent principles among the fragrance allergy ingredients with the similar toxicological profile.

JCIA sincerely hopes taking into the reconsideration our concerns.

Respectfully yours,

[redacted]

[redacted]

[redacted]

3rd October 2017

The Secretary
Scheduling Secretariat
GPO Box 9848,
Canberra ACT 2601, Australia

Email: Chemicals.Scheduling@health.gov.au

[redacted]

[redacted]

- [redacted]
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[redacted]

[redacted]

[redacted]

[redacted]

Many thanks

[redacted]

John Koppl
Regulatory Affairs Manager

[redacted]

[redacted]

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

3rd October 2017

Dear Sir/Madam,

RE: Invitation for public comment ACCS/ACMS: 15th September 2017 Interim decision (July 2017 meetings)

[redacted] 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)

[redacted] notes the proposed delegate's interim decision:

> **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.
>
> The proposed implementation date is **1 June 2018**. A later implementation date allows for industry alignment.

To this interim decision [redacted] would like to make the following comments:

1. [redacted] does not object to the proposed scheduling changes as these are in line with EU restrictions. However;
2. [redacted] respectfully requests that the delegate reconsider the implementation date of 1st June 2018.

   As per our submission on 15th June 2018 we had asked for realistic implementation dates (30 months). [redacted] requests these timings be proposed, providing industry with:

   - adequate lead times to implement changes to formulations

[redacted]

- 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.

To help demonstrate this, below is a real-life timeline on a current project to replace the preservative MIT.

However, to allow a smooth transition of old to new formula and considering an “off the shelf date”, 6 months is also required by the trade to phase in the new stock.

[redacted]

Therefore, [redacted] requests that an implementation timeframe of **30 months** should be proposed to allow industry sufficient time to transition.

[redacted]

[redacted]

[redacted]

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

3rd October 2017

Dear Sir/Madam,

RE: Invitation for public comment ACCS/ACMS: 15th September 2017 Interim decision (July 2017 meetings)

[redacted] 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).

Benzyl Salicylate

[redacted] notes the proposed delegate's interim decision:

> **Schedule 6 – New Entry**
> BENZYL SALICYLATE **except**:
> a) in preparations intended for therapeutic use; or
> b) in domestic preparations:
> i) intended for skin contact containing 15 per cent or less of benzyl salicylate when declared on the label; or
> ii) not intended for direct skin contact when declared on the label; or
> c) in leave-on cosmetic and personal care preparations:
> i) containing 0.001 per cent or less of benzyl salicylate; or
> ii) when declared on the label; or
> d) in rinse-off cosmetic and personal care preparations:
> i) containing 0.01 per cent or less of benzyl salicylate; or
> ii) when declared on the label.
>
> **Appendix E, Part 2 – New Entry**
> BENZYL SALICYLATE
> Standard Statements: A (For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once)), S1 (If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water).
> **Appendix F, Part 3 – New Entry**
> BENZYL SALICYLATE
> Warning Statement: 28 ((Over) (Repeated) exposure may cause sensitisation).
> Safety Direction: 4 (Avoid contact with skin).
> The proposed implementation date is 1 June 2018

To this interim decision [redacted] would like to make the following comments:

1. We are members of Accord and endorse their submission.

2. [redacted] requests the final decision be deferred as the proposals currently drafted are:

    - Inconsistent with topical therapeutic products eg: sunscreens. These products are exempt but the safety concern remains the same as topical cosmetics.

    - Inconsistent with overseas requirements for example:

        - USA: There is no requirement to include Benzyl Salicylate on the label.

        - New Zealand: The Cosmetic Products Group Standard 2006 (as amended July 2012) Subclause 4B states:

          Despite subclause (4) a cosmetic product containing a component at reference numbers 67-92 of Schedule 5 may not be labelled with the name of that component, provided the label lists the flavours or fragrances which must be described by the words, fragrance‘ or fragrances‘ or parfum‘ or parfums‘; or the ingredients in the fragrance or fragrances.

          Benzyl Salicylate is reference number 75 of Schedule 5.

    - Inconsistent with previous scheduling considerations of fragrance allergens eg:
        - geraniol
        - isoeugenol

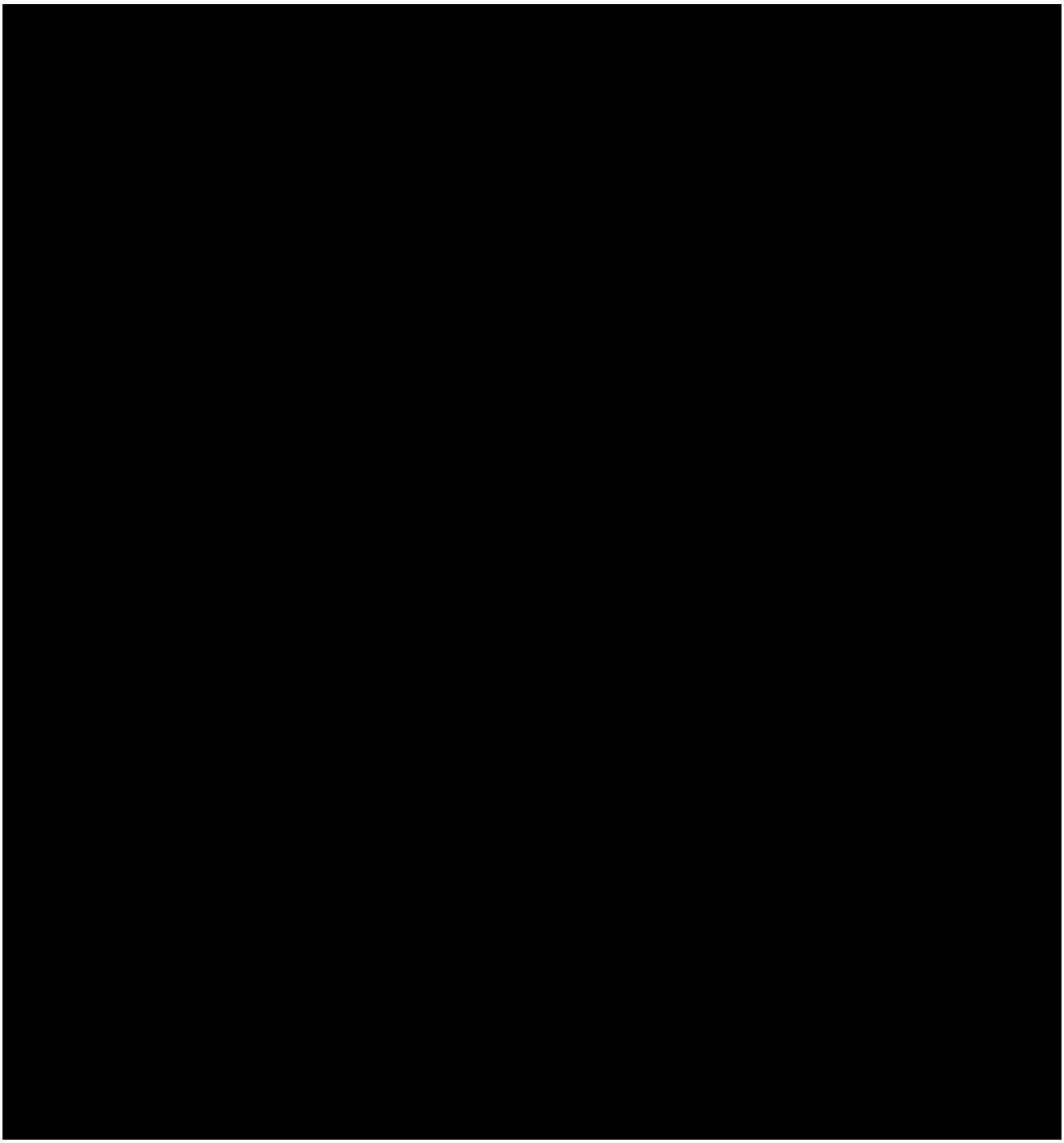
3. [redacted] requests the final decision be deferred to allow for a wider policy discussion around the public health risk management of fragrance allergens for cosmetic products in Australia with a focus on consistency and international harmonisation

4. Should the proposal go ahead, [redacted] respectfully requests that the delegate reconsider the implementation date of **1st June 2018**.

   As per our submission on 15th June we had asked for realistic implementation dates (24 months). Mandatory labelling changes with hard implementation timeframes is very difficult to manage without sufficient timeframe.

[redacted] requests these timings should be proposed, providing industry with adequate lead times to:

- create new labels to include Benzyl Salicylate as part of the ingredients list
- order new labels for production
- plan in new labels for production
- production
- shipping and release



This time line shows that we can **release** the revised label to trade October 2018.

However, to allow a smooth transition of old to new formula and considering an “off the shelf date”, 6 months is also required by the trade to phase in the new stock.

Therefore, should the proposal go ahead, [redacted] requests that an implementation timeframe of **24 months** should be proposed to allow industry sufficient time to transition.

[redacted]

Therefore, should the proposal go ahead, [redacted] requests that an implementation timeframe of **24 months** should be proposed to allow industry sufficient time to transition without the need to locally relabel products.

Yours faithfully,

[redacted]