Public submissions on scheduling matters referred to the Joint ACMS-ACCS #18 meeting in March 2018

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the Act) to amend the current *Poisons Standard* and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice. Such a notice relating to the scheduling proposals initially referred to the March 2018 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #18) was made available on the TGA website on 21 December 2017 and closed on 2 February 2018.

Public submissions received on or before 2 February 2018 are published here in accordance with regulation 42ZCZL of the Regulations. Also in accordance with regulations 42ZCZL of the Regulations, the Secretary has removed information that the Secretary considers confidential.

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

Under regulation 42ZCZP of the Regulations, the Secretary must, among other things, publish (in a manner the Secretary considers appropriate) the scheduling interim decision, the reasons for that decision and the proposed date of effect (for decisions to amend the current *Poisons Standard*, this will be the date when it is expected that the current *Poisons Standard* will be amended to give effect to the decision). Also in accordance with regulation 42ZCZP of the Regulations, the Secretary must invite the applicants and persons who made a submission in response to the original invitation under paragraph 42ZCZK(1)(d), to make further submissions to the Secretary in relation to the interim decisions by a date mentioned in the notice as the closing date, allowing at least 10 business days after publication of the notice. Such a notice relating to the interim decisions of substances initially referred to the March 2018 meeting of the Joint Advisory Committee on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #18) will be made available on the TGA website on 7 June 2018, closing on 5 July 2018. Public submissions received on or before this closing date are will be published on the TGA website in accordance with regulation 42ZCZQ.

Privacy statement

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

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

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

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

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

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

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

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

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

From:	r r
To:	Medicines Scheduling
Subject:	Fw: Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018-Invitation to comment [SEC=No Protective Marking]
Date:	Tuesday, 30 January 2018 9:51:16 AM
Attachments:	TGApublic-submission-cover-sheet_0 (2).docx

Subject: : Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018-Invitation to comment

30/1/2018

To: TGA Medicines Scheduling Section,

at medicines.scheduling@health.gov.au

Re: Consultation: Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018

Invitation to comment

Please find attached the Public Submission Coversheet

I refer to the following item and the invitation to comment:

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

Scheduling medicines and poisons

	Due to inconsistencies with the inclusion of prostaglandins that have obstetric/gynaecological indications in Appendix D Item 1, it is proposed to standardise the scheduling of all applicable prostaglandins with obstetric/gynaecological indications with one of the following options: • place all applicable prostaglandins in Appendix D Item 1 and include a general entry in Appendix D Item 1 for PROSTAGLANDINS "when used in obstetrics/gynaecology". • OR • remove those prostaglandins currently listed in Appendix D Item 1;

In October 2017, I wrote to the Department of Health on 2nd. October, 2017, noting that that Carboprost, a Prostaglandin analogue, used in obstetric hospitals to manage post-partum haemorrhage, is not listed in Appendix D as available only from or on the prescription or order of, an ***authorised*** medical practitioner.

The specific issue that I referred to was as follows:

In reading the latest (October 2017) version of the National Poisons Standards (SUSMP), I note that Dinoprost and Dinoprostone are listed in Schedule 4, with a hash symbol (#) , indicating that prescribing restrictions apply to these medications, as detailed in Appendix D of the SUSMP (Copy of entries below). However, Carboprost, also listed in Schedule 4, does not have the hash symbol reference to Appendix D against its entry, (copy of entry below), even though it clearly falls within the category of Prostaglandin analogues.

In the interests the consideration of uniformity in managing medication safety, can you advise if it is intended that this discrepancy is to be corrected.

I therefore suggested that, due to inconsistencies with the inclusion of prostaglandins that have obstetric/gynaecological indications in Appendix D Item, 1 ACMS recommends the option of placing all applicable prostaglandins in Appendix D Item 1 and include a general entry in Appendix D Item 1 for PROSTAGLANDINS "when used in obstetrics/gynaecology".

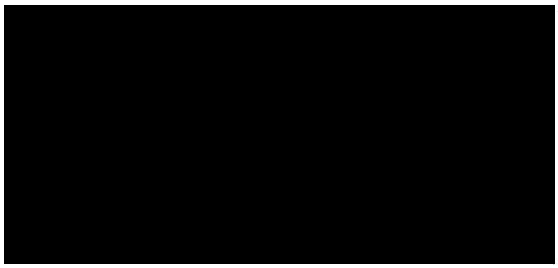
In summary, therefore, I wish to endorse the option of placing all applicable prostaglandins in Appendix D Item 1 and to include a general entry in Appendix D Item 1 for PROSTAGLANDINS "when used in obstetrics/gynaecology.

Yours Sincerely,

Ronald Batagol, PhC, FSHP, AGIA,Dip.Jnl.

Pharmacist and Obstetric Medicines and Medication Safety Consultant.

(Also, although not submitting these comments in that capacity, I was appointed as Specialist Advisor to TGA Committees in January 2017).



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01 February 2018

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,

Vinyl Acetate - Proposed Amendments to the Poisons Standard - ACCS, ACMS and Joint ACCS-ACMS meetings, March 2018

Chemistry Australia is the peak national body representing the chemistry industry in Australia. Chemistry Australia members include chemicals manufacturers, importers and distributors, logistics and supply chain partners, raw material suppliers, plastics fabricators and compounders, recyclers, and service providers to the sector and the chemistry and chemical engineering schools of a number of Australian universities.

Australia's entire society – businesses, consumers and governments – along with its natural environment receive enormous benefits associated with the safe, responsible and sustainable use of chemicals. To fulfil the optimal benefits of chemistry, balanced approaches are critical in stewarding effective chemical management, as supply chains are complex and can involve multiple partners through a products lifecycle.

Chemistry Australia welcomes the opportunity to provide comment on the proposed amendments to poison scheduling of Vinyl Acetate:

> Schedule 6 - Amend Entry
> VINYL ACETATE MONOMER (excluding its derivatives) **except**:
> 1. in preparations for therapeutic use; or
> 2. in preparations for domestic use containing 1 per cent or less of vinyl acetate; or
> 3. in preparations containing 0.01 per cent or less of vinyl acetate as residual monomer in a polymer used in direct contact with the body, such as cosmetic preparations.

Vinyl Acetate may be present *(typically as a residual monomer from synthesis of vinyl acetate copolymers)* in both industrial and domestic goods and can include; Paints, laquers, varnishes, cleaning agents, adhesives, glue, ink, sealants, engine oils, plastic production, etc. It is also has been noted by our membership that it may be present in some agricultural products.

Chemistry Australia consider that there is legitimacy for Vinyl Acetate Monomer to be included in the Scheduling 6 (S6), however we consider that the amended proposal still applies an overly cautious approach, which will impose undue regulatory consequences in terms of Safety Data Sheet (SDS) impact with industrial use substances, with an additional labelling burden to agricultural use substances. In particular in the case where monomer may be present as low-level residual in product(s) for industrial and agricultural uses and where the potential risks are low and as such do not warrant scheduling.

Why The change:
Under the Poison Standard, Schedule 5, 6 and 7 applies to both domestic, agricultural and industrial substances. The current proposal specifies a minimum cut-off limit of ≤1% for domestic use in terms of its non-applicability. Therefore, industrial and agricultural uses containing vinyl acetate will not be considered equal and will be governed by the lower S6 default limit of 10mg/kg (0.001%) – *that is*, *industrial and agricultural use has not been specified under the exception.* Having such low thresholds for industrial and agricultural uses, has the potential to increase costs for these substances with SDS maintenance on industry – *that is, all industrial preparations containing Vinyl Acetate above 10mg/kg will need to change their SDS's with a Schedule 6 rating.* In addition, agricultural uses will be burdened with additional S6 labelling requirements when at very low levels.

Another concern is that SDS's are commonly used by industry to communicate the Scheduling controls down the supply chain. The current proposal has the potential to miscommunicate or cause confusion down the supply chain, especially where upstream preparations (intermediates) have tighter limits to the downstream preparations (domestic) in terms of SDS communication. This may lead to overcautious labelling down the supply chain, when it may not be warranted.

Therefore, Chemistry Australia supports a slight change to the terminology as proposed below to ensure that domestic, industrial and agricultural uses substances are treated equally - as all these uses do not have intentional direct application to the body. This would minimise undue cost, ensure consistent seamless communication in the supply chain and maintain a balanced risk profile. Also, the committee may also want to consider using consistent terminology of vinyl acetate throughout the S6 entry.

Chemistry Australia's proposed change:

Schedule 6 - Amend Entry
VINYL ACETATE MONOMER (excluding its derivatives) **except**:

1. in preparations for therapeutic use; or
2. in preparations for non-cosmetic use containing 1 per cent or less of vinyl acetate; or
3. in preparations for cosmetic use containing 0.01 per cent or less of vinyl acetate as residual monomer in a polymer.

OR

Schedule 6 - Amend Entry
VINYL ACETATE MONOMER (excluding its derivatives) **except**:

4. in preparations for therapeutic use; or
5. in preparations containing 1 per cent or less of vinyl acetate; or
6. in preparations containing 0.01 per cent or less of vinyl acetate as residual monomer in a polymer used in direct contact with the body, such as cosmetic preparations.

Chemistry Australia is committed to working with the committee on any further information requirements that may be required to support a balanced outcome. For more information or if we can assist this review any further, please don't hesitate to contact me on +613 9611 5417 or by email at nzovko@chemistryaustralia.org.au

Yours sincerely,

Nick Zovko
Regulatory Policy Manager- Chemistry Australia

[redacted]

The Secretary
Scheduling Secretariat
Department of Health
MDP 71
GPO Box 9848
CANBERRA ACT 2601

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

Dear Sir/Madam

Public Comment Submission to the March 2018 joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS)

We refer to the notice published on 21 December 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 substance **vinyl acetate** for consideration at the March 2018 meeting of the ACMS/ACCS.

We understand that the previous scheduling decision for this substance (published in October 2017 and to be included in the Poisons Standard from 1 October 2018) may adversely impact a range of products currently on the market that were not identified during the previous consultation and consideration of vinyl acetate such as industrial and agricultural products.

Accord does not object to clarification of the wording of the schedule entry such that a clear and consistent risk management approach is applied to domestic, industrial and agricultural products containing vinyl acetate that have the same risk profile. For example paints, lacquers, varnishes, cleaning agents, adhesives etc.

As mentioned in our previous submissions on this substance, we are not aware of any cosmetic use of vinyl acetate in Australia.

We look forward to further advice from the ACMS, ACCS and the Delegates. Should the Committees or the Delegates require any additional information from Accord please do not hesitate to contact me on (02) 9281 2322.

Yours Sincerely

[unsigned for electronic submission]

Rachael Linklater
Science & Technical Regulatory Associate

2 February 2018

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[redacted]