

## **FURTHER PUBLIC SUBMISSIONS ON THE PROPOSED AMENDMENTS TO THE POISONS STANDARD**

### **Regulation 42ZCZQ, Therapeutic Goods Regulations 1990 (the Regulations)**

A delegate of the Secretary of the Department of Health and Ageing publishes herein all valid public submissions made in response to the invitation for further public submission on the proposed amendments to the Poisons Standard. These submissions are in response to the delegates' interim decisions. The interim decision takes into account the original application, submissions received in any consultative phase and advice from the October 2012 Advisory Committee on Chemicals Scheduling (ACCS) #6, the Advisory Committee on Medicines Scheduling (ACMS) #7 and the joint ACCS and ACMS #4.

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

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

Discrete submissions have been grouped by substance. A submitter provided a submission that related to multiple substances and this has been separately grouped.

### **LIST OF SUBMISSIONS**

<b>Substance</b>	<b>Total number of public submissions</b>
Hydrogen peroxide and carbamide peroxide	2 (1 submission under 'submissions on multiple substances')
Vitamin D	1

### **SUBMISSION ON MULTIPLE SUBSTANCES**

One submission was on thymol, and hydrogen peroxide and carbamide peroxide;



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21 January 2013

Medicines and Poisons Scheduling Secretariat (Secretariat)  
DoHA Office of Chemical Safety and Office of Health Protection  
GPO Box 9848  
Canberra ACT 2601

Sent by email to: [smp@health.gov.au](mailto:smp@health.gov.au)

Dear Secretariat,

This letter by the Australian Dental Association Inc. (ADA) wishes to comment on the delegates' interim decision regarding our proposal with respect to hydrogen peroxide and carbamide peroxide. The delegates' interim decision was made following the October 2012 meeting of the joint Advisory Committee on Chemicals Scheduling (ACCS)/Advisory Committee on Medicines Scheduling (ACMS) (Committees).

As you are aware, the ADA's proposal, based upon the collective opinion of its expert Committees requests a scheduling decision that entails:

- a) That teeth whitening products (containing concentrations below or equal to 3% hydrogen peroxide or below or equal to 9% carbamide peroxide) be accessible over the counter (OTC) (without restriction);
- b) That any teeth whitening products containing concentrations of above 3% hydrogen peroxide and/or above 9% carbamide peroxide, and up to 6% hydrogen peroxide and/or up to 18% carbamide peroxide, can only be legally accessible by registered health (dental) practitioners. Also that patients can be permitted to use these products 'at home' only after consultation with their registered health (dental) practitioner;
- c) That any teeth whitening products containing concentrations of above 6% hydrogen peroxide and/or above 18% carbamide peroxide can only be legally accessed by registered health (dental) practitioners. Use of such products must be confined to use 'in surgery' and in consultation with registered health (dental) practitioners; and
- d) Scheduling arrangements developed by the Committees that would give effect to these outcomes, in the interests of public safety.

The ADA is the peak national professional body representing more than 13,000 dentists and dental students across both the public and private sectors. The primary objectives of the ADA are:

- To encourage the improvement of the oral and general health of the public and to advance and promote the ethics, art and science of dentistry, and
- To support members of the Association in enhancing their ability to provide safe, high quality professional oral health care.

### **The delegates' interim decision**

The scheduling delegates have made the following interim decision:

- To include teeth whitening preparations containing more than 18 per cent carbamide peroxide and more than 6 per cent (20 volume) hydrogen peroxide in Appendix C; and
- To exempt from this Appendix C entry for teeth whitening preparations containing 18 per cent or less carbamide peroxide and 6 per cent or less hydrogen peroxide manufacture and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.

The ADA is pleased to state that it supports this aspect of the delegates' interim decision. This decision gives effect to the proposal outlined in point (c) of our proposal.

### **Interim decision shortcomings that must be addressed**

In spite of the ADA's limited support of the interim decision, it urges the delegates to reconsider its final decision to give effect to principles (b) and (d) of our proposal.

The interim decision in its current form does not go far enough to impose adequate regulatory protections to ensure that the public are not at risk of being supplied teeth whitening products (that pose significant risk of injury) by non-health registered practitioners. The interim decision's silence on the question of "teeth whitening preparations containing 18 per cent or less carbamide peroxide and 6 per cent or less hydrogen peroxide manufacture(d)" and supplied not solely for direct in-clinic use by those who are not registered dental practitioners is very concerning. This silence suggests that the delegates endorse the recommendations of the Committees that has been outlined by the Notice containing the interim decision; that is: "[t]he Committees recommended that the current Schedule 5 and Schedule 6 entries for carbamide peroxide and hydrogen peroxide remained appropriate".

In this response the ADA will outline how in respect of each of the factors the delegates have considered, the final decision should give effect to principles (b) and (d) of our proposal.

### **The primary aim to ensure public safety**

The ADA's primary objective in its application on this issue of teeth whiteners containing hydrogen peroxide or carbamide peroxide has always been to procure a scheduling decision that protects the public from injury associated with inappropriate use of some teeth whiteners. It wished to remove any confusion around whether such products can be supplied directly to the public.

By virtue of Dental Board of Australia (DBA) regulation, the provision and use of teeth whitening products by untrained personnel upon third parties falls within "the practice of dentistry". As such it is unlawful for such unqualified personnel to provide such a service. Only registered dental practitioners with education, training and competence in teeth whitening/bleaching are permitted to conduct this activity. The imposition of such regulation was not done until after detailed evaluation of the safety aspects of tooth whitening was conducted by the DBA. The DBA recognised the dangers and acted in accordance with its charter to ensure that dental services are only provided in a fashion that is in the interests of public health and safety.

Teeth whitening/bleaching is an irreversible procedure on the human teeth. In untrained hands it has the potential to cause significant damage to teeth. It needs to be closely monitored to ensure no long-term damage is sustained by users. A restriction is required to protect the public from exposure to concentrations of hydrogen peroxide or carbamide peroxide that carry the real risk of injury to teeth and/or the soft tissues of the mouth and throat.

In light of the recognition of the dangers to the public associated with teeth whitening by the DBA, the delegates should ensure the same protections are afforded to the public. To not draw an adequate regulatory boundary which requires persons who access teeth whiteners (that will be administered to others) to have appropriate health qualifications and to be registered by the relevant authority is to effectively endorse the practice of dentistry by inadequately qualified/registered persons.

The ADA has seen a significant growth in the use of tooth whitening products, no doubt brought on by peer pressure and targeted marketing about the purported benefits of having 'quick', 'fast acting' and 'cheap' whiter teeth. It has become so prevalent that many consumers are bleaching their teeth into oblivion. Dentists call this addiction to whitening "bleachorexia",<sup>1</sup> which describes those that continually bleach their teeth "bleach junkies". There is discussion internationally about the real risks of overuse of OTC teeth whitening products:<sup>2</sup>

*As to the US government position ... the FDA points out the risk for potential abusive use of these OTC bleaching products, which are used by one in each four American teenagers ...*

*The ADF (Association Dentaire Française), in a comprehensive literature review concerning bleaching procedures, emphasized that OTC products should be classified as medical devices, instead of cosmetics, especially due to the crescent overuse.*

*The ADF committee concluded that when bleaching agents are repetitively used without supervision and without real motivations, this must be considered a public health problem ... Safety concerns emerge in relation to the abusive use of OTC products, taking into account that nowadays younger patients are looking for bleaching procedures.*

When these patients (untrained in the use of teeth whitening products) use home bleaching agents, the results are often eroded teeth that are prone to sensitivity. These results occur while achieving pearly white exteriors. Dentists know that whitening agents can irritate the gums, causing them to recede, as well as making the teeth brittle, chalky and so thin as to be translucent at the edges. The provision of appropriate scheduling of these products is the only way to prevent these outcomes from occurring.

The ADA has already provided evidence of action taken by an Australian Government agency, the Australian Competition and Consumer Commission (ACCC), and a Minister of Crown, the then Parliamentary Secretary to the Treasurer, the Hon. David Bradbury, on this issue of inappropriately supplied and administered teeth whiteners. The ADA has previously provided material concerning the ACCC's negotiated voluntary recall of OTC teeth whiteners, and the Parliamentary Secretary's compulsory recall of some of these products in the interests of ensuring the safety of the public. Such actions demonstrate the Australian Government's recognition of the dangers that confront Australians in the inappropriate use of tooth whitening products. It is reasonable to expect that the delegates would reconsider the scheduling classifications of teeth whiteners accordingly.

The ADA outlined in its letter of 28 May 2012, that:

*... it is agnostic as to which scheduling classifications the ACCS/ACMS should adopt, **provided that the end result gives effect** to the intentions stated in its ... application. Naturally the option that is ideal would be one that would not have to result in as much regulatory/administrative change yet be able to strike the correct balance between the safety of the public and the appropriate development, access, use, and distribution of teeth whitening products that contain levels of hydrogen peroxide/carbamide peroxide within the thresholds outlined above. It is for this reason that the ADA's ... application leaves it to the Committees to determine the final form of the scheduling arrangements for teeth whitening products containing the outlined levels of hydrogen peroxide/carbamide peroxide it would like to recommend to the Delegate. (ADA original bolding)*

<sup>1</sup> Demarco F. F.; Meireles S. S.; Masotti A. S.; 'Over-the-counter whitening agents: a concise review', in *Braz Oral Res* 2009; 23 (Spec Iss 1): 64-70

<sup>2</sup> As above.

The ADA has been aware of cases of injury from the inappropriate use of teeth whiteners containing levels of hydrogen peroxide/carbamide peroxide by unregistered, unqualified persons. It is for this reason that the ADA, in the interests of public safety, has raised this issue with the Committees and makes this further plea for further review and to take these considerations into account. The ADA have made points (that will be raised in this response) previously, in particular when asked to comment on the evaluation report (which the delegates have subsequently considered in making its interim decision amongst other factors – herein referred to as the “ER”). An appropriate scheduling decision is required to ensure that access to these teeth whitening products is underpinned by adequate checks, supervision and clinical management. A scheduling decision needs to be framed in a way that ensures that cases of injury are eliminated altogether. The ADA does not suggest a specific form of scheduling, but requests that such a decision on scheduling give effect to the principles outlined in its proposal.

The ADA would like to point out that its proposal, including subsequent correspondence provided to the Committees, has been based upon sound advice from Australian dental experts. These submissions were not made in any haphazard way, and were designed to educate the Committees upon the impact of teeth whitening products. The advice provided was designed to provide the Committees with facts about dental health, dental care and in particular the dangers of the use of various tooth whitening products upon teeth.

While the ADA understands that the ER is not publically available, the ADA’s response would like to state as a matter of public record the concerns it has with respect to the recommendations and views expressed in it.

#### **Limitations of the evaluation report**

For the ER to have seemingly reviewed the advice of dental experts but to then largely ignore it seems reckless. The ADA warns the delegates to seriously question the ER’s assessment of the ADA’s application and the suggestions the ER subsequently made. To choose to not do so would amount to what the ADA sees as a dereliction of the delegates and the Office of Chemical Safety’s (OCS) role and duty – to ensure the protection and safety of the public.

#### The ER’s assessment of ADA sources

The ER stated that:

*Beyond reference to the actions of the ACCC apparently targeted at products containing more than 18% carbamide peroxide, the application does not include any detailed records of Australian cases of injury from dental bleaches and whiteners that identify the causative agent or its concentration.*

This is not correct. The ADA has referred to a case which the ER not only considered, but inappropriately dismissed. This case is the *Victorian Dental Practice Board of Victoria v Suong Van Thi (2009)*. This case concerned a beautician who caused serious burns to oral soft tissues of the mouth and throat from doing a bleaching procedure in a shopping centre booth.

Dental practice is restricted under the *Health Practitioner Regulation National Law Act 2009* (National Law). The National Law provides for the regulation of practitioners by the Dental Board of Australia (DBA). The National Law states that restricted dental acts include, “performing any irreversible procedure on the human teeth or jaw or associated structure” and must not be carried out by anyone other than people registered in the dental or medical profession. The National Law indicates that the penalty for unregistered people found to be performing a restricted dental act will be up to \$30,000.

This case provides an example of how the current scheduling arrangements are not adequate to ensure the safety of the public from the inappropriate use and supply of such products. Similarly, while the DBA and the Australian Health Practitioner Regulation Agency are in a position to bring to the attention of the police

individuals who are not registered but who are providing tooth whitening services on the basis that such services are restricted to the practice of dentistry, there is a legitimate and justified need for a serious reconsideration of the existing scheduling arrangements for teeth whitening products.

What is of great concern is the ER's incorrect assessment of the significance of this Dental Practice Board case. The ER stated:

*"[a]s with the first case report, there are no details of the substance or the concentration of the substance said to have caused the injuries."*

That is not correct. This case outlined that 6% peroxide was used in the procedure that resulted in the injury. As such, this case is a specific example of how injury has resulted from teeth whitening using specific concentrations of peroxide. The ADA has reattached this case for your consideration (**Attachment A**). Seeing that an external evaluation of the ADA's application was requested, presumably to seek further independent analysis, the ADA questions the rigour in which this evaluation has been conducted. It puts into question the extent to which the ER itself fairly considered the scientific evidence provided by the ADA, and the extent to which the ER appreciates the real risks to public safety that will continue to exist if the current supply arrangements for teeth whiteners are not adequately revised.

One other example of injury by teeth whitening provided by inadequately qualified and registered persons was reported in Adelaide, <http://www.adelaidenow.com.au/news/breaking-news/beware-of-dodgy-teeth-whiteners-dentists/story-e6frea73-1226062787615> . The ADA has also received advice that in Victoria alone in 2012 approximately ten complaints about the provision of teeth whitening services by unregistered providers were lodged with authorities.

The ADA's concerns are further confirmed by how the ER reviewed the scientific research. The ADA represents the vast majority of the dental profession in Australia, and is familiar with the local and international research about the safety risks of teeth whitening products. Not only is the ADA familiar with the research on the safety risks of teeth whitening products, but more importantly, it understands intimately that qualified dental supervision is essential to ensure that whitening is performed safely. Previous ADA correspondence, namely contained in its 28 May 2012 letter referred to the following scientific articles that illustrate the basis for which the ADA seeks restriction of access of teeth whiteners as described by paragraphs (b) and (c) in this response. The ER appears to have attempted to suggest that the evidence does not support the concerns outlined in the application. Please note the ADA sections in bold.

- "A clinical evaluation of 10 percent vs. 15 percent carbamide peroxide tooth-whitening agents", Kihn PW, Barnes DM, Romberg E, Peterson K. J, *Am Dent Assoc.*, 2000 Oct; 131(10): 1478-84

*"If performed under the careful guidance of a dentist, at-home whitening is an effective treatment, regardless of whether 10 percent CP or 15 percent CP is used. There may be added colour change and varying sensitivity with the use of 15 percent CP."*

- "Considerations for Vital Nightguard Tooth Bleaching with 10% Carbamide Peroxide After Nearly 20 Years of Proven Use", Hayward VB, *Inside Dentistry*, 2006; September: 2-5

*"When properly supervised and dentist monitored, vital nightguard tooth whitening with 10% carbamide peroxide is safe and effective, with no long-term posttreatment side effects (e.g., no external cervical resorption, gingival index and tooth vitality findings within normal range, no restorations or root canal therapy required as a result of whitening) reported at approximately 10 years posttreatment."*

*"Whitening is best performed in a professionally supervised manner following a thorough examination and proper diagnosis. It is this author's opinion after reviewing the current research that 10% carbamide peroxide in a custom-fitted soft tray is the most ideal whitening treatment."*

- “Tooth Bleaching--a Critical Review of the Biological Aspects”, Dahl JE, Pallesen U., *Critical Reviews in Oral Biology & Medicine*, 2003; 14(4): 292-304

*“The recommendation is to avoid using concentrations higher than 10% carbamide peroxide when one performs external bleaching. We advocate a selective use of external tooth bleaching based on high ethical standards and professional judgment.”*

- “Hydrogen peroxide tooth-whitening (bleaching) products: Review of adverse effects and safety issues”, Tredwin CJ, Naik S, Lewis NJ and Scully C., *British Dental Journal*, 2006; 200(7): 371-6

*“For nightguard vital bleaching, minimal amounts of low dose H<sub>2</sub>O<sub>2</sub> (10% carbamide peroxide) is preferred, avoiding prolonged and long term use. Patients undergoing nightguard vital beaching should be regularly reviewed and monitored.”*

The ER acknowledged that these sources provided by the ADA illustrated the importance of supervision and guidance by a dentist for 10 or 15% carbamide peroxide (and its hydrogen peroxide equivalent) in teeth whitening. That notwithstanding, the ADA is disturbed by the ER's comment and overall view of the scientific evidence, that:

*“There is support in the submitted paper of Li and the report of the [European Commission Scientific Committee on Consumer Products] for the view that the use of tooth whitening products should only be undertaken following dental assessment and advice. That is something different to requiring the lawful supply of some products to be only on a valid prescription or that only dentists should use products with concentrations exceeding a particular strength.”*

While policy and legislative/regulatory parameters need to be defined to determine what constitutes lawful supply of these products, the public expects that these decisions are informed by scientific evidence from the health sector. The ADA's 28 May 2012 letter and this response provide the scientific evidence. The ER nonetheless attempted to draw distinctions to explain how this evidence was not applicable, contrary to the duties and principles that the OCS and Committees are meant to serve.

The ER stated that there was no information on the safety risks that existed for teeth whitening products containing concentrations beyond those thresholds outlined in the ADA's Policy Statement 2.2.8 (that is reflected in point (b) of our proposal. The ADA's 28 May 2012 letter had already provided a response to this concern:

*[The ADA] understands that these cases of injury arose from the administration of OTC teeth whitening products by unqualified persons, and on this basis has accordingly applied to have adequate measures put in place to appropriately restrict access and provision of such products. Naturally the ADA has referred to its Policy Statement 2.2.8 (previously provided) to further detail its view of the particular percentage thresholds that teeth whitening products containing hydrogen peroxide and/or carbamide peroxide could be safely administered by dental practitioners.*

The ADA has already outlined to the Secretariat that ADA Policy Statements are developed by ADA Committees whose membership comprise of clinical experts familiar with the latest research on oral health issues. Professional clinical determinations have been made in the Policy Statement about the level of concentration of peroxide for teeth whiteners that would be able to be safely applied, provided that qualified practitioners are supervising the practice of teeth whitening.

#### **Scheduling options suggested by the ER**

While the ADA has stated that it has an agnostic approach to which schedule should be adopted per se, it previously outlined the following concerns about the ER's suggested scheduling arrangements.

For the purposes of this response, the ADA will only reiterate its commentary with respect to the ER's views of the options for Schedules 5 and 6 (the status quo, which is implicitly endorsed by the interim decision).

Schedule 5 warning statements for teeth whitening products containing >3-6% hydrogen peroxide / >9-18% carbamide peroxide

The ER discussed the option of:

*"an additional warning statement ... for products containing between 3% and 6% hydrogen peroxide and 9% and 18% carbamide peroxide ... There would be merit in requiring that [these] products in Schedule 5 ... for dental bleaching or whitening carry a specific warning statement, which would need to be added to Appendix F, Part 1. "Seek advice of a dental care provider before using is suggested for consideration.*

The ADA's 28 May 2012 letter outlined concerns about the efficacy of these warning statements. The existing Schedule 5 and 6 classifications have seen cases of injury following the issuing of these products by unqualified persons (such as through the Poisons Information Centre and from anecdotal cases provided to the ADA). The ADA seriously questions whether warning statements, especially in light of possible supply arrangements outlined above (that a non-qualified person can procure the product on behalf of their customers), could minimise cases of injury.

The product remains accessible for use in untrained hands and as such this scheduling option suggested by the ER does not provide adequate protection to the public.

Schedule 4 for teeth whitening products containing >3-6% hydrogen peroxide/ >9-18% carbamide peroxide

The ER formed the view that:

*"Inclusion of such a warning [for Schedule 5 to apply to teeth whitening products containing 3-6% hydrogen peroxide and/or 9-18% carbamide peroxide) would not go as far as requested by the Australian Dental Association, which has sought that products containing more than 3% hydrogen peroxide or more than 9% carbamide peroxide and up to 6% hydrogen peroxide and 18% carbamide peroxide be only accessible (able to be prescribed) by registered health (dental) practitioners and that patients only be able to use them after consultation. That would require such products to be included in Schedule 4. Such scheduling is not justified by the submitted information."*

The ADA has outlined it seeks any scheduling decision that ensures **that the end result gives effect** to the intentions stated in the 28 May 2012 letter.

Our response has again outlined concerns that the ER has inappropriately formed the view that the scientific evidence provided by the dental profession does not provide guidance for how to re-schedule teeth whitening products in a manner which protects the public.

The ADA urges the delegates to seriously question the ER's assessment of the ADA's application and the suggestions it made.

**Section 52E(1) of the Therapeutic Goods Act 1989**

The relevant matters the delegates are required to consider under section 52E (1) of the *Therapeutic Goods Act 1989* (TGA Act) in making their decision include:

- (a) The risks and benefits;
- (b) The purpose for and the extent of use;
- (c) The toxicity;

- (d) The dosage, formulation, labelling, packaging and presentation;
- (e) The potential for abuse; and
- (f) Any other matters considers necessary to protect public health.

The ADA's proposal details how injury will continue to occur if the existing scheduling classifications for teeth whitening products are not changed to also be in alignment with the proposal's points (b) and (c). Not only has the academic research literature suggested that concentrations of hydrogen peroxide/carbamide peroxide below the existing respective 6%/18% levels pose significant risks, especially if administered by not appropriately qualified and registered health professionals, but also cases of injuries already suggest that public safety has been impacted under the current scheduling arrangements. The ADA's response has also referred to sources that suggest there is a considerable risk of abuse of teeth whitening products by consumers and also by inadequately trained and qualified persons.

While the delegates are required to consider section 52E(1) of the TGA Act alongside the factors outlined in the Notice, the ADA also refers the delegates to key goals of the OCS and the Scheduling Secretariat (Secretariat) that sits within that office. All references can be found in the Australian Government Department of Health and Ageing website. The role of the OCS and Scheduling Secretariat itself further suggests that a more proactive and considered decision needs to be made.

#### The role of the Office of Chemical Safety and the Scheduling Secretariat

*The Office of Chemical Safety (OCS) ...*

*The OCS is responsible for:*

- **Using robust science** to monitor developments, provide policy advice and regulate to **address threats to human health** posed by chemical and biological health risks;
- **... support ... the regime of scheduling medicines and poisons**, which ensures a uniform system for the classification of medicines ... and other chemicals, **in the interests of public health and safety;**
- **... liaising with the Standing Committee on Chemicals on chemical regulation.**

*Scheduling Secretariat*

**Scheduling is designed to prevent or minimise the potential for harm to the community from exposure to chemicals and medicines by regulating the supply of and access to these substances.**

...

*The OCS provides the Secretariat for the scheduling function. The Secretariat provides technical and administrative support to the scheduling delegates, the ACCS and the ACMS, and maintains the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).*

*Medicines and chemicals are classified according to the Schedules in which they are included. A number of factors are considered in the scheduling of substances, including:*

- **Potential for abuse;**
- **Safety in use;**
- *Legitimate need for the substance; and*
- *The extent and pattern of use of the substance. (emphasis added)*

#### **Other public submissions**

The ADA notes that overall the public submissions lodged have been supportive of our proposal. While all stakeholders' input should be considered (industry, consumers and the health practitioners), we urge the delegates to consider that the ADA has made its proposal in response to grave concerns it has with the level of risk to public safety that exists under the current scheduling arrangements. The proposal has been made in response to not only research outlining the real risks of teeth whiteners that have particular levels of hydrogen peroxide/carbamide peroxide, especially when administered by inadequately qualified persons, but also to address actual cases of injury and in light of action already taken by the Australian Government.

Measures to increase the safety of the public, supported and informed by evidence provided by the healthcare sector should always be implemented.

The ADA would like to thank the delegates and the Secretariat for the opportunity to comment on this urgent matter.

If you have any further questions, please contact [ceo@ada.org.au](mailto:ceo@ada.org.au) or 02 9906 4412.

Yours sincerely,



Dr Karin Alexander  
President

Enc.



Ref: 4.8.5M — 18 January 2013

The Secretary  
Medicines and Poisons Scheduling Secretariat  
Department of Health & Ageing  
PO Box 9848 (MDP 88)  
CANBERRA ACT 2601

Dear Sir / Madam

**RE: Interim Decision – Scheduling of hydrogen peroxide and carbamide peroxide**

The Australian Dental Industry Association (ADIA) refers to the notice published on 7 January 2013, specifically the interim decisions made pursuant to subsection 42ZCZP of the *Therapeutic Goods Regulations (Cth) 1990* to amend the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*. ADIA takes this opportunity to tender further comment with regard to concerning proposed amendments to the entries for hydrogen peroxide and carbamide peroxide used in teeth whitening products.

ADIA supports the decision that the current SUSMP Schedule 5 and Schedule 6 entries for carbamide peroxide and hydrogen peroxide as these remain appropriate and therefore do not require amendment.

With respect to the proposed new SUSMP Appendix C entries, consistent with our earlier representations on this matter this approach is endorsed although there are concerns with the proposed text, this being:

*HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.*

*CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.*

The entries for both hydrogen peroxide and carbamide peroxide vary from that initially proposed by ADIA and other stakeholders insofar as includes the qualification that the products are “supplied solely for direct in-clinic use by registered dental practitioners”. ADIA respectfully advises that this qualification is unclear and problematic thus requires amendment. The basis for this conclusion is set out below:

Australian Dental Industry Association Incorporated  
ABN 32 003 314 396

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Government Affairs: GPO Box 1, Canberra, ACT, 2601

e: [national.office@adia.org.au](mailto:national.office@adia.org.au) twitter: @AusDental  
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**Representing Dental Industry Excellence**

ADIA Facebook Page:  
[www.facebook.com/dentalindustry](http://www.facebook.com/dentalindustry) 

- The proposed text refers to “in-clinic” use. The term “clinic” is not defined by some state / territory jurisdictions and is contradictory where it is defined by others. In this context, the current proposed text will lead to confusion amongst suppliers, dentists and allied oral healthcare professionals. Further, given the definitional issues, regulatory enforcement activities become problematic. Such problems were considered and were overcome by the solution initially tendered for consideration by ADIA (and as set out below).
- The text is also subject to misinterpretation insofar as some may believe that the intent is that a registered dental practitioner can dispense the teeth whitening products, with appropriate use directions and warnings, at the clinic as part of their dental practice. Although ADIA is supportive of this outcome, it is understood that the proposal intended to prohibit such practice.

ADIA believes that the proposed decision is inconsistent with both the Reasons for Decisions and what is understood were discussions within the joint meeting of the Advisory Committee on Chemicals Scheduling (ACCS) / Advisory Committee on Medicines Scheduling (ACMS) held on 12 October 2012. If ADIA has misinterpreted the statement and deliberations please accept our apologies.

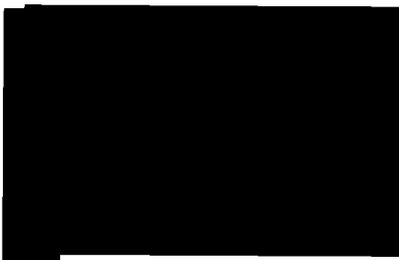
Based upon ADIA’s earlier advice to the joint ACCS / ACMS meeting, and the published reasons for decision, the following new SUSMP Appendix C entries are proposed.

*HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide except in preparations manufactured for and supplied solely through registered dental practitioners as part of their dental practice.*

*CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide except in preparations manufactured for and supplied solely through registered dental practitioners as part of their dental practice.*

As stated earlier, ADIA strongly supports the decision that the current SUSMP Schedule 5 and Schedule 6 entries for carbamide peroxide and hydrogen peroxide remained appropriate and therefore do not require amendment.

If you require further information or clarification of the issues raised in this correspondence please contact me at your convenience.



Medicines and Poisons Scheduling Secretariat (MDP88)  
PO Box 9848  
Canberra ACT 2601  
Email: SMP@health.gov.au

**Re: Rescheduling Vitamin D and Decision on Appendix H entry**

Dear Sir/Madam,

[REDACTED] Schedule 3 entry for Vitamin D to allow a weekly dose up to 175micrograms (7000IU) per recommended dose and the request to include Vitamin D in Appendix H, we are writing to provide comment on the interim decision '*not to include Vitamin D in Appendix H*' as per the minutes of the ACMS meeting, October 2012.

We have taken note of the evaluation report and the fact that the TGA Medical Advisor recommended acceptance of the proposal to include the advertising as an OTC vitamin supplement (ie: inclusion in Appendix H).

A review of the 'record of reasons' for the decision, does not disclose any serious argument against the position taken by the Medical Advisor. Two points were raised and neither carries weight:

- a) Off label use could occur.

This is true of any and every medicine. It is less likely, not more likely, to be true in a case like this, where there is a mandated role for advice from a pharmacist, and high level regulation of the advertising.

- b) ...could be inadvertently promoted

We fail to see how this could occur given the safeguards built in by the scheduling and by advertising controls, where ASMI review is required.

All broadcast and mainstream advertisements to the public for OTC S3 products must go through ASMI and therefore the possibility of inappropriate advertising for the weekly dose product is unlikely to occur. Additionally, we note the *Therapeutic Goods Act 1989* (the Act) and Regulations only allow a product to be promoted for the indications that appear on the ARTG, including advertising to healthcare professionals; as such, inadvertent promotion for 'off label' use should not occur.

The proposed product will be clearly differentiated from the current daily dose products of 1000 IU per daily dose by labelling and product name. We suggest the risk with an S3 vitamin D product is less, rather than more than, with the currently available 1000IU products available for self selection at the pharmacy and supermarket.

The application specifically requested an S3 entry rather than an S2 entry to ensure pharmacist advice was received by the consumer at the point of purchase to clarify that the product was a weekly dose.

We request the committee re-consider the decision not to include Vitamin D in Appendix H.

Yours sincerely,

A large black rectangular redaction box covering the signature area.

21 January 2013



The Secretary  
Scheduling Secretariat  
GPO Box 9848  
CANBERRA ACT 2601

Email: [SMP@health.gov.au](mailto:SMP@health.gov.au)

Dear Sir/Madam

**Public Comment Submission to the Delegate's Interim Decision  
under subsection 42ZCZP of the Therapeutic Goods Regulations 1990**

We refer to the notice published on 7 January 2013 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 provided comments on **thymol** for consideration at the meeting of the ACCS and **hydrogen peroxide/carbamide peroxide** at the joint meeting of the ACMS and ACCS held in October 2012.

Accord has reviewed the Interim Decisions & Reasons for Decisions by the Delegate of the Secretary to the Department of Health and Ageing.

Accord supports the Interim Decision on thymol by the Delegate. We seek further clarification on the Interim Decision on hydrogen peroxide/carbamide peroxide. Please see attached submission for details.

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

Yours sincerely

Catherine Oh  
**Manager, Regulatory and Technical**

18 January 2013

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*Products for healthy living and a quality lifestyle*

## Delegate's Interim Decision - ACCS/ACMS Joint-meeting: October 2012

### Hydrogen peroxide and carbamide peroxide

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As highlighted to our pre-meeting submission, Accord does not believe there is any new evidence to support a change to the current Schedule 5 and Schedule 6 entries for hydrogen peroxide and carbamide peroxide. We therefore strongly support the Delegate's Interim Decision to maintain the current Schedule 5 and Schedule 6 hydrogen peroxide/carbamide peroxide scheduling.

Accord seeks clarification on the wording of the new Appendix C entries for hydrogen peroxide and carbamide peroxide. While we support the creation of Appendix C entries for hydrogen peroxide and carbamide peroxide, we believe that the wording proposed has the potential to be interpreted in at least two ways.

The Appendix C entries proposed by the Delegate are reproduced below:

#### *Appendix C - New entry*

CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except** in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations manufactured and supplied solely for direct in-clinic use by registered dental practitioners as part of their dental practice.

We note that the intent of this phrase "direct in-clinic use" (underlined above) is currently unclear.

Firstly, we understand that the word "clinic" is defined in some States and Territories but not others. Even those States that provide a definition, contradictions exist between the States.

Secondly, the phrase "direct in-clinic use" could be interpreted conservatively as meaning that these products can only be used for in-chair treatment within the clinic. A broader interpretation could be that the registered dental practitioner can dispense the teeth whitening products, with appropriate use directions and warnings, at the clinic as part of their dental practice.

Of the two possible interpretations highlighted above, Accord supports the broader interpretation. A registered dental practitioner, as part of their dental practice, should be able to appropriately judge whether a patient can take home a teeth whitening kit.

This interpretation would also ensure that a range of options continue to be available to registered dental practitioners for their patients. We understand that generally, take home teeth whitening kits contain lower levels of hydrogen peroxide/carbamide peroxide than products intended for in-chair treatments. This is due to the longer contact time available for take home kits that can be worn for a few hours per day over several days. In-chair treatments tend to be performed over one or two visits, usually with approximately half an hour contact time.

Having read through the Reasons for Decisions, we believe that the broader interpretation also reflects the discussion of the ACCS/ACMS and the intent of the Delegate. If this is not the case, we apologise in advance for making such an assumption and respectfully seek further clarification and information.

However, if our assumption is correct, in order to ensure that the intent is clear we suggest the following wordings. The amended words/added words are underlined.

*Appendix C - New entry*

CARBAMIDE PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except** in preparations manufactured for and supplied solely via registered dental practitioners as part of their dental practice.

HYDROGEN PEROXIDE (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations manufactured for and supplied solely via registered dental practitioners as part of their dental practice.