

Petreski, Sonya

From: Wallner, Peter
Sent: Monday, 2 April 2012 2:52 PM
To: Jamieson, John; Mackay, Ruth; Wright, Dean; Resurreccion, Dixie; Hutchison, Paul
Subject: FW: Australian Dental Association reply to 16 March 2012 ACCC letter re dentists issuing teeth whiteners [SEC=IN-CONFIDENCE]
Attachments: Attachment A - Letter to ACCS.pdf; ACCS attachments.zip; ADA Letter to S Hutchinson re dentists' teeth whitener supply.pdf
Follow Up Flag: Follow up
Flag Status: Flagged

FYI

Peter Wallner
Director - Chemical Assessment & Information Standards
Product Safety Branch
Australian Competition & Consumer Commission
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From: [REDACTED]
Sent: Monday, 2 April 2012 2:35 PM
To: Hutchison, Steve
Cc: Wallner, Peter
Subject: Australian Dental Association reply to 16 March 2012 ACCC letter re dentists issuing teeth whiteners

Dear Steve,

Find attached the Australian Dental Association's response to the 16 March 2012 letter you wrote on behalf of the ACCC to our association.

Note that the zip file contains attachments that originally accompanied the letter to the Advisory Committee on Chemicals Scheduling which we have attached for your convenience.

We have also sent through postal mail hard copies of the ADA's response.

We look forward to the ACCC's urgent consideration of this matter.

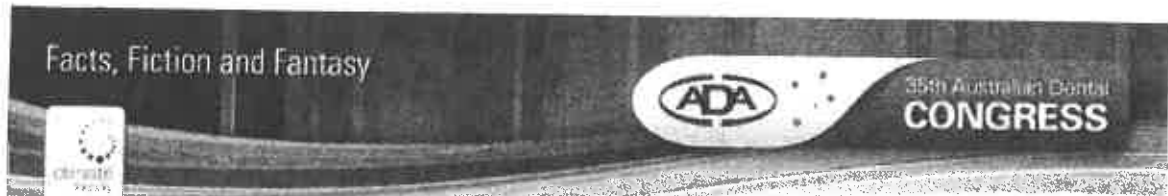
Regards



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14 February 2012

Warren Hough
Scheduling Secretariat
DoHA Office of Chemical Safety and Environmental health
smp@health.gov.au
Phone: +61 2 6289 1359
Fax: +61 2 6289 2650

Sent by email

Dear Mr Hough

This letter outlines the Australian Dental Association Inc. (ADA)'s submission to the Advisory Committee on Chemical Scheduling (ACCS) for them to consider at the next available meeting (July 2012).

Recommendation: That the ACCS recommend to the Secretary of the Department of Health and Ageing (DoHA) that over the counter teeth whitening products (that contain hydrogen peroxide or carbamide peroxide) be classed as Schedule 4 products under the Poisons Standard

Moving over the counter (OTC) teeth whitening products (that contain hydrogen peroxide or carbamide peroxide) to Schedule 4 of the Poisons Standard will remove any confusion around whether such products can be supplied directly to the public. It would provide the necessary restriction to protect the public from exposure to concentrations of hydrogen peroxide or carbamide peroxide that carry the real risk of injury to the soft tissues of the mouth and face while at the same time allow for suitably qualified persons to access and use them in procedures. Teeth whitening/bleaching is an irreversible procedure on the human teeth which therefore needs to be closely monitored to ensure no long-term damage is sustained. By regulation such activity falls within "the practice of dentistry". The use of teeth whitening procedures involving products with high levels of hydrogen peroxide or carbamide peroxide should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching.

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.

ADA's Policy Statement

The ADA's Policy Statement on Teeth Whiteners 2.2.8 (see **Attachment A**) states that:

"3.1 Only dentists should use tooth whitening (bleaching) agents incorporating hydrogen peroxide at concentrations exceeding 3% or carbamide peroxide exceeding 9%.

3.2 Dental Boards, the Therapeutic Goods Administration and other health authorities must take appropriate steps to protect consumers from the risks of unregistered and untrained providers of tooth whitening (bleaching).

3.3 The TGA should recognize that any dental bleaching agent with a hydrogen peroxide concentration exceeding 3% or a carbamide peroxide concentration exceeding 9% should be classified as a dental therapeutic agent."

Negotiated recalls followed by compulsory recalls of DIY teeth whitening kits

The ADA notes that the Australian Competition and Consumer Commission (ACCC) took action to stop the supply of do-it-yourself (DIY) teeth-whiteners containing unsafe concentrations of peroxide December 2011. The ACCC media release is attached for your convenience (see **Attachment B**).

The ACCC have notified all known suppliers of DIY teeth whitening kits that products contain concentrations of more than 6% hydrogen peroxide or more than 18% carbamide peroxide are unsafe and should not be supplied to consumers.

In forming its decision the ACCC also undertook a market survey of DIY teeth-whitening kits after receiving reports of injuries associated with these products.

While the ACCC's actions have spurred the removal of these unsafe goods from the market, the ADA seeks there to be a permanent resolution to classifying these products.

Further to this, the Parliamentary Secretary to the Treasurer, the Hon. David Bradbury, has taken swift action to protect the public by issuing a compulsory recall of do-it-yourself teeth-whiteners that have unsafe concentrations of hydrogen peroxide or carbamide peroxide. The media release announcing this action is attached for your convenience (**Attachment C**).

Dental Board of Australia's Interim Policy

The Dental Board of Australia released its interim policy on teeth whitening/bleaching dated on 12 November 2010. It states:

"Teeth whitening/bleaching, is an irreversible procedure on the human teeth and any tooth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent, should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching."

While the ACCC and the DBA's prescribed levels of concentrations of hydrogen peroxide or carbamide peroxide that warrant restriction is different from the ADA's Policy Statement, the ADA urges the ACCS to recommend to the Secretary to move to Schedule 4 of the Poisons Standard those OTC teeth whitening kits that contain concentrations of hydrogen peroxide or carbamide peroxide. Adding OTC DIY teeth whitening products with these substances to Schedule 4 would best ensure the safety of those consumers exposed to these products while at the same time allowing only those with appropriate accreditation and qualifications to access them.

The position in the United Kingdom

The ADA submits that increasing the threshold to restrict public access to OTC teeth whitener products with concentrations of hydrogen peroxide/carbamide peroxide to Schedule 4 is a reasonable response. The policy positions outlined above as to the particular concentrations of hydrogen peroxide/carbamide peroxide in teeth whitener products that warrant restriction is not as strict as in other comparable countries such as the United Kingdom. The General Dental Council (UK) states that:

Under the terms of the Cosmetic Products (Safety) Regulations it is illegal for tooth whitening products to be supplied which contain more than 0.1% hydrogen peroxide or for any associated products which release greater than 0.1% hydrogen peroxide to be supplied.

The UK's regulations of teeth whitening concentrations at the levels above are based on the fact that tooth whiteners are generally regarded in Europe as cosmetic products. According to the cosmetic regulation, the maximum authorized content or release of hydrogen peroxide in such oral hygiene products is 0.1%. Tooth-whitening products can also be claimed to be medical devices, and evaluated according to the medical device regulation.

The ADA would refer to the ACCS a study which shows that hydrogen peroxide can be cytotoxic above 1.7%, and, without adequate gingival protection, severe mucosal damage can occur (*Li Y. Safety controversies in tooth bleaching, Dent Clin North Am. 2011 55(2):255-63*).

While not advocating that the ACCS recommend to the delegate that they adopt the UK position, the ADA believes the case for further restriction is justified, in the interests of public safety.

ADA previous correspondence on this issue

The ADA has previously written to the then Health Minister Nicola Roxon and Department of Health and Ageing Secretary Jane Halton on this issue.

The Minister's response, dated 13 October 2011 (see **Attachment D**) and the Secretary's response on 30 September 2011 (see **Attachment E**) both state that at the February and June 2005 meetings the National Drugs and Poisons Scheduling Committee (NDPSC) agreed that tooth whiteners containing more than 6% hydrogen peroxide or 18% carbamide peroxide had sufficient potential to cause harm to justify capture in Schedule 6 of the Poisons Standard and should be restricted through scheduling packing and labelling requirements. The mandatory labelling requirements arising from listing in Schedule 6 include a 'POISON' signal word, strong warnings and safety direction on the label.

At the time the NDPSC members generally considered that those requirements, in combination with general trade practices requirements for supply of safe products, would limit the legitimate availability of such high strength tooth whiteners to dental professionals. Such restrictions did not actually occur, and such products continued to be available and were marketed actively, leading to instances of damage being sustained by members of the public because of procedures undertaken by persons other than dental professionals.

Cases of injury

Unfortunately since 2005 when the NDPSC decision occurred, the ADA has been informed of cases of injury through use of these over the counter tooth whitening products, suggesting that a Schedule 4 classification rather than the current Schedule 6 classifications is the more appropriate response in the interests of safety of the public.

In 2009 there was a case in Victoria (*Dental Practice Board of Victoria v Suong Van Thi, Wednesday 30 September 2009, Magistrates' Court*) that concerned a beautician who caused serious burns to oral soft tissues and the soft tissues of the throat from doing a bleaching procedure in a shopping centre booth.

In response to a request for feedback from our members, we also received one case study example of an occasion where there was damage done by a beautician's administration of tooth whiteners also in Victoria. The oral and throat burns (due to the use of these whiteners by the beautician) occurred to the patient during the actual procedure. When the patient complained the beautician offered her free eyelash extensions. She developed infections in both eyes that had to be treated with antibiotics.

Further restrictions required

Both the then Minister and Secretary have suggested that if the ADA wished to pursue this matter further it should write to the Scheduling Secretariat.

Teeth whitening procedures have irreversible impacts on the teeth and therefore the ADA urges the ACCS to recommend to the Secretary that OTC teeth whitening products that have concentrations of hydrogen peroxide or carbamide peroxide be classified under Schedule 4 of the Poisons Standard. This is to remove all together the ability for these products to be bought over the counter, adding a layer of protection to the public, while at the same time allowing professional health practitioners access to it where appropriate.

We welcome the Advisory Committee on Chemical Scheduling's urgent consideration of this matter.

Yours sincerely,



COMMUNITY ORAL HEALTH PROMOTION: TOOTH WHITENING (BLEACHING) BY PERSONS OTHER THAN DENTAL CARE PROVIDERS

1 Introduction

- 1.1 The use of bleaching agents to lighten the colour of vital teeth has become a common part of general dental practice. However, the procedures involved can be potentially hazardous to the patient, and the process of bleaching involves irreversible chemical changes.
- 1.2 Hydrogen peroxide is the active bleaching agent in professionally applied dental bleaching products. The effective concentration of hydrogen peroxide varies greatly from concentrations as low as 3% for *whitening toothpastes* to 35% in some *office-based* bleaching products. Many bleaching products available contain carbamide (urea) peroxide which is more stable than hydrogen peroxide but generates hydrogen peroxide as the active bleaching agent. The application of energy to the hydrogen peroxide in the form of heat, high intensity visible light, laser light or other energy forms accelerates the action of hydrogen peroxide.
- 1.3 While weak solutions of hydrogen peroxide have been used in the oral cavity for many years with few problems, when used in higher concentrations the potential for adverse effects on the oral tissues is high.
- 1.4 WorkSafe Australia's current guidelines designate hydrogen peroxide at concentrations above 5% as a hazardous substance. Direct exposure of the skin, eyes and mucous membranes to hydrogen peroxide may cause severe irritation or burns, while ingestion may cause irritation to the oesophagus and stomach resulting in bleeding or sudden distension. Percolation of hydrogen peroxide into the pulpal tissues via exposed dentine and enamel fractures can lead to pulpal inflammation. For these reasons it is necessary to take great care when handling and using hydrogen peroxide bleaching agents especially in the higher concentrations.
- 1.5 The Poison Standard 2008 recognizes hydrogen peroxide 3–6% as a Schedule 5 substance (Caution) and greater than 6% as a Schedule 6 (Poison). For carbamide peroxide 9–18% is classified as Schedule 5 and greater than 18% as Schedule 6.
- 1.6 The application of heat and other forms of energy such as light from a plasma arc lamp or laser accelerates the action of hydrogen peroxide, but the incorrect application of these forms of energy may also cause pulpal damage to the tooth and burns to adjacent soft tissues.
- 1.7 **Definitions**
 - 1.7.1 BOARD is a Federal, State or Territory dental registration board.
 - 1.7.2 DENTAL ACT is any Federal, State or Territory Act that has a primary purpose to regulate the practice of dentistry.
 - 1.7.3 DENTAL CARE PROVIDER is a person registered by a Board to provide dental care.

2 Principles

- 2.1 Any irreversible procedure performed in the oral cavity is the practice of dentistry.
- 2.2 Any bleaching procedure which causes an irreversible change in the teeth is the practice of dentistry.
- 2.3 Dental Acts prohibit the practice of dentistry by persons who are not registered as dental care providers.
- 2.4 Any bleaching agent for use on teeth that can cause irreversible changes should be regulated as a therapeutic agent.
- 2.5 A number of high power (Class 4) lasers are used for accelerating the whitening of teeth. Under the Radiation Safety legislation only dentists can use Class 4 lasers in patient care for "dental hard and soft tissue procedures". The Radiation Safety legislation specifically excludes dental registrants other than dentists and dental specialists from undertaking dental procedures with a Class 4 laser.

3 Policy

- 3.1 Only dentists should use tooth whitening (bleaching) agents incorporating hydrogen peroxide at concentrations exceeding 3% or carbamide peroxide exceeding 9%.
- 3.2 Dental Boards, the Therapeutic Goods Administration and other health authorities must take appropriate steps to protect consumers from the risks of unregistered and untrained providers of tooth whitening (bleaching).
- 3.3 The TGA should recognize that any dental bleaching agent with a hydrogen peroxide concentration exceeding 3% or a carbamide peroxide concentration exceeding 9% should be classified as a dental therapeutic agent.

Policy Statement 2.2.8

Adopted by ADA Federal Council, April 10/11, 2008.
Amended by ADA Federal Council, April 16/17, 2009.



Australian
Competition &
Consumer
Commission

NEWS RELEASE

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www.accc.gov.au

ACCC TAKES ACTION ON UNSAFE TEETH-WHITENERS

The Australian Competition and Consumer Commission has acted to stop the supply of do-it-yourself (DIY) teeth-whiteners containing unsafe concentrations of peroxide.

"The ACCC is concerned that high concentrations of peroxides used in these products has resulted in injuries such as chemical burns to gums and the mouth," ACCC Commissioner Sarah Court said.

"The ACCC has identified a number of products which exceed safe peroxide limits, and has negotiated recalls to remove these products from the marketplace."

To date, the ACCC has negotiated recalls of nine home use teeth-whitening products available nationally.

Three products supplied by White My Bite have been recalled including:

- "White My Bite" Sensitive
- "White My Bite" Professional, and
- "White My Bite" Advanced kits

Four products supplied by WhiteSmile Pty Ltd have been recalled including:

- DayWhite Teeth Whitening Gel
- NiteWhite Teeth Whitening Gel
- Sunshine Health Teeth Whitening Gel, and
- Crest Teeth Whitening Strips

Two products supplied by DaVinci Elite Pty Ltd have been recalled including:

- DaVinci Elite tooth whitening pen
- DaVinci Elite take-home teeth whitening kit.

Further recalls are likely.

The ACCC recently notified all known suppliers of DIY teeth whitening kits that products containing concentrations of more than 6 per cent hydrogen peroxide or more than 18 per cent carbamide peroxide are unsafe and should not be supplied to consumers.

The ACCC undertook a market survey of DIY teeth-whitening kits after receiving reports of injuries associated with these products.

"In addition to chemical burns to gums and the mouth, other reported injuries have included blistering or ulceration of the mouth and throat, tooth sensitivity, marbled or unnaturally coloured teeth, tissue tingling and headaches," Ms Court said.

"Consumers should be extremely cautious before undertaking any DIY teeth whitening treatment and should not use kits that contain more than 6 per cent hydrogen peroxide and/or more than 18 per cent carbamide peroxide."

"If the concentration of the bleaching agents is not clearly labelled, consumers are advised not to use the product."

Safe limits for these active bleaching agents are based on the requirements of the Poisons Standard 2011, expert clinical advice published by the Australian Dental Association and a scientific risk assessment published by the European Union's Scientific Committee on Consumer Products.

For more information on product safety generally, visit www.productsafety.gov.au, call the ACCC Infocentre on 1300 302 502 or follow us on Twitter @ProductSafetyAU.

Media inquiries

Mr Duncan Harrod, media unit, (02) 6243 1108 or 0408 995 408

General inquiries

Infocentre: 1300 302 502

NR 237/11

9 December 2011

**ATTACHMENT C – MEDIA RELEASE FROM THE
PARLIAMENTARY SECRETARY TO THE TREASURER, THE HON
DAVID BRADBURY**

**HTTP://PARLSEC.TREASURER.GOV.AU/DISPLAYDOCS.ASPX?
DOC=PRESSRELEASES/2012/002.HTM&PAGEID=003&MIN=
DJB&YEAR=&DOCTYPE=0**

**COMPULSORY RECALL OF DO-IT-YOURSELF TEETH
WHITENERS**

The Parliamentary Secretary to the Treasurer, David Bradbury has today signed a Consumer Protection Notice ordering a company to recall two do-it-yourself (DIY) teeth whitening kits to protect consumers from high concentrations of hydrogen peroxide that may cause chemical burns to a user's mouth and gums.

The products recalled are 'Bright White Express – Advanced Teeth Whitening Kit' and 'Proteethwhitening – Professional Teeth Whitening Pen', both supplied by Pro Teeth Whitening (Aust) Pty Limited.

"These products contain the bleaching agent hydrogen peroxide in higher concentrations than the recognised safe limits as set out in the *Poisons Standard 2011* and are unsafe for DIY teeth whitening," said Mr Bradbury.

"Following negotiations with the Australian Competition and Consumer Commission (ACCC), 22 teeth whitening products with unsafe levels of hydrogen peroxide or carbamide peroxide have already been voluntarily recalled by 8 other suppliers since December 2011.

"Consumers are advised to cease using these products immediately and visit the Recalls Australia website www.recalls.gov.au for more information on returning the goods for replacement or refund."

Pro Teeth Whitening (Aust) Pty Limited has 3 days to comply with the compulsory recall order. Consumers can keep up to date by checking progress on the Recalls Australia website.

"DIY teeth whitening kits have grown in popularity, but kits with high concentrations of hydrogen peroxide or carbamide peroxide may cause painful injuries to a user's mouth and gums, including sensitive teeth and chemical burns," said Mr Bradbury.

"The Australian Dental Association has also reported that dentists are seeing an increasing number of patients presenting with mouth injuries

attributed to home teeth bleaching. Some cases have also been treated in emergency departments of hospitals.

"Poisons Information Centres in Queensland, New South Wales and Victoria have received a combined total of at least 58 reports of injuries involving teeth whiteners since 2004."

If you experience any adverse symptoms after using a DIY teeth whitening kit you should seek medical treatment.

27 January 2012



THE HON NICOLA ROXON MP
MINISTER FOR HEALTH AND AGEING

[REDACTED]
Australian Dental Association Inc
PO Box 520
ST LEONARDS NSW 1590

Dear [REDACTED]

Thank you for your letter of 1 September 2011 regarding the practice of teeth whitening by non-dentists. I note that you have also written to the Secretary of the Department of Health and Ageing regarding this issue.

As you are aware, the National Registration and Accreditation Scheme (NRAS) for health professions commenced on 1 July 2010. The NRAS is a national scheme, and operates independently of the Commonwealth under the *Health Practitioner Regulation National Law Act 2009*, known as the National Law.

Under the NRAS the state and territory registration boards for dental practitioners have been replaced by a national board, the Dental Board of Australia (DBA). The DBA's responsibilities include developing standards, codes, guidelines and accreditation of training for the dental profession and handling notifications and complaints and investigations in respect of individual dental practitioners.

As you have noted, the DBA issued an interim policy on 12 November 2010 on teeth whitening/bleaching. This policy has been developed by the DBA under section 39 of the National Law as an interim measure whilst it continues to examine the issues within the context of public protection.

The DBA is only responsible for regulating the practice of registered dental practitioners and cannot legally direct practices of unregulated or unqualified service providers outside the dental profession.

Similarly, I understand that the restricted dental acts provisions of the National Law do not prevent members of the general public or other health professionals from advertising, promoting and selling teeth whitening and bleaching agents (of any concentration) or advising members of the public how to apply the agents of any concentration. The DBA therefore only has a limited scope of regulatory influence regarding the regulation of teeth whitening and bleaching agents in the general public domain.

However, you may be interested in the work that is currently being undertaken on behalf of the Australian Health Ministers' Advisory Council (AHMAC) regarding the unregulated provision of health care services by unregistered or unqualified practitioners. In November 2010, Australian Health Ministers agreed to a national consultation exercise seeking stakeholders' views on whether there is a need for strengthened regulatory protection for consumers in relation to unregistered health professions.

Public consultation commenced on 28 February 2011 with the release of a consultation paper. Written submissions to the paper closed on 15 April 2011. I understand the Western Australian Branch of the ADA provided a submission. The consultation paper is available under the 'Related Links' menu on the home page of the AHMAC website at www.ahmac.gov.au/site/home.aspx. Further information will be available in due course.

You may also be interested to know that under the *Therapeutic Goods Act 1989* (the Act), scheduling decisions in relation to the circumstances under which medicines and chemicals are accessible to consumers are now made by delegated officers in my Department, independent of Ministerial involvement. These decisions act as recommendations to state and territory governments for implementation through specific jurisdictional legislation. As such, implementation of controls on scheduled substances is done at a state or territory level.

Prior to July 2010, scheduling decisions were made by the National Drugs and Poisons Scheduling Committee (NDPSC), an independent expert committee. The most recent consideration of access restrictions on hydrogen peroxide or carbamide peroxide (which are generally contained in teeth whitening products) occurred at the February and June 2005 NDPSC meetings.

The NDPSC Members agreed that tooth whiteners containing more than 6% hydrogen peroxide (18% carbamide peroxide) had sufficient potential for causing harm to justify capture in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons and should be restricted through scheduling packaging and labelling requirements. Mandatory labelling requirements arising from listing in Schedule 6 including a 'POISON' signal word, strong warnings and safety directions on the label.

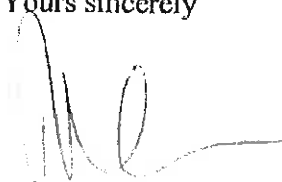
The NDPSC members generally considered that these requirements, in combination with general trade practices requirements for supply of safe products, would limit the legitimate availability of such high strength tooth whiteners to dental professionals. The Record-of-Reasons for these considerations are publicly available at www.tga.gov.au/archive/committees-ndpsc-record.htm

However, should you consider the current scheduling approach is not sufficiently mitigating the risks from tooth whitening products a rescheduling application can be submitted to my Department. The decision-maker is required to consider legislatively stipulated matters (set out under Section 52(E) of the Act) in making any scheduling decision. The ability to reach a decision regarding an application will therefore be dependent upon the data provided for each of these matters, as outlined in the application form. Information on the pathways to scheduling decisions, including the electronic application template, is available at www.tga.gov.au/industry/scheduling-basics.htm

Please contact the Medicines and Poisons Scheduling Secretariat via email to smp@health.gov.au or by contacting (02) 6289 1359 if you have any further queries regarding scheduling.

I trust that the above information is of assistance.

Yours sincerely



NICOLA ROXON

13 OCT 2011



Australian Government
Department of Health and Ageing

SECRETARY

[REDACTED]
Australian Dental Association Inc
PO Box 520
St Leonards NSW 1590

Dear [REDACTED]

Thank you for your letter of 1 September 2011 concerning the practice of teeth whitening by non-dentists.

As you are aware, the National Registration and Accreditation Scheme (NRAS) for health professions commenced on 1 July 2010. The NRAS is a national scheme, and operates independently of the Commonwealth under the *Health Practitioner Regulation National Law Act 2009*, known as the National Law.

Under the NRAS the state and territory registration boards for dental practitioners have been replaced by a national board, the Dental Board of Australia (DBA). The DBA's responsibilities include developing standards, codes, guidelines and accreditation of training for the dental profession and handling notifications and complaints, investigations in respect of individual dental practitioners.

As you have noted, the DBA issued an interim policy on 12 November 2010 on Teeth Whitening/Bleaching. This policy has been developed by the DBA under section 39 of the National Law as an interim measure whilst it continues to examine the issues within the context of public protection.

The DBA is only responsible for regulating the practice of registered dental practitioners and cannot legally direct practices of unregulated or unqualified service providers outside the dental profession.

Similarly, I understand that the *restricted dental acts* provisions of the National Law do not prevent members of the general public or other health professionals from advertising, promoting and selling teeth whitening and bleaching agents (of any concentration) or advising members of the public how to apply the agents of any concentration. The DBA therefore only has a limited scope of regulatory influence regarding the regulation of teeth whitening and bleaching agents in the general public domain.

However, you may be interested in the work that is currently being undertaken on behalf of the Australian Health Ministers' Advisory Council (AHMAC) regarding the unregulated provision of health care services by unregistered or unqualified practitioners. In November 2010, Australian Health Ministers agreed to a national consultation exercise seeking stakeholders'

views on whether there is a need for strengthened regulatory protection for consumers in relation to unregistered health professions.

Public consultation commenced on 28 February 2011 with the release of a consultation paper and written submissions to the paper closed on 15 April 2011. I understand the WA Branch of the ADA provided a submission. The consultation paper is available under the 'Related Links' menu on the home page of the AHMAC website at www.ahmac.gov.au/site/home.aspx. Further information will be available in due course.

You may also be interested to know that under the *Therapeutic Goods Act 1989*, scheduling decisions in relation to the circumstances under which medicines and chemicals are accessible to consumers are now made by delegated officers in the Department of Health and Ageing. These decisions act as recommendations to State and Territory governments for implementation through specific jurisdictional legislation. As such, implementation of controls on scheduled substances is done at a State or Territory level.

Prior to July 2010, scheduling decisions were made by the National Drugs and Poisons Scheduling Committee (NDPSC), an independent expert committee. The most recent consideration of access restrictions on hydrogen peroxide or carbamide peroxide (which are generally contained in teeth whitening products) occurred at the February and June 2005 NDPSC meetings.

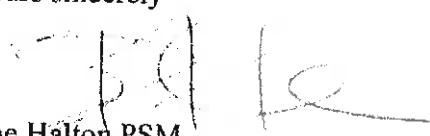
The NDPSC Members agreed that tooth whiteners containing more than 6% hydrogen peroxide (18% carbamide peroxide) had sufficient potential for causing harm to justify capture in Schedule 6 of the *Standard for the Uniform Scheduling of Medicines and Poisons* and should be restricted through scheduling packaging and labelling requirements. Mandatory labelling requirements arising from listing in Schedule 6 including a "POISON" signal word and strong warnings and safety directions on the label.

NDPSC members generally considered that these requirements, in combination with general trade practices requirements for supply of safe products, would limit the legitimate availability of such high strength tooth whiteners to dental professionals. The Record-of-Reasons for these considerations are publicly available at [ww.tga.gov.au/archive/committees-ndpsc-record.htm](http://www.tga.gov.au/archive/committees-ndpsc-record.htm).

However, should you consider the current scheduling approach is not sufficiently mitigating the risks from tooth whitening products a rescheduling application can be submitted to the Department. The decision-maker is required to consider legislatively stipulated matters (set out under Section 52(E) of the *Therapeutic Goods Act 1989*) in making any scheduling decision. The ability to reach a decision regarding an application will therefore be dependent upon the data provided for each of these matters, as outlined in the application form. Information on the pathways to scheduling decisions, including the electronic application template, is available at www.tga.gov.au/industry/scheduling-basics.htm

Please contact the Medicines and Poisons Scheduling Secretariat (email: smp@health.gov.au or phone: 02 6289 1359) if you have any further queries regarding scheduling.

Yours sincerely


Jane Halton PSM
Secretary

September 2011



**AUSTRALIAN DENTAL
ASSOCIATION INC.**

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14-16 Chandos Street St Leonards NSW 2065

All Correspondence to:
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2 April 2012

Steve Hutchison
Acting General Manager
Product Safety Branch
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Phone: +61 2 6243 4972
Fax: +61 2 6243 1073

Cc: Peter Wallner
Director Chemical Assessment & Information Standards
Product Safety Hazard Response Branch
ACCC

Sent by email and postal letter

Dear Mr Hutchison

Thank you for your letter dated 16 March 2012 ("letter") outlining the actions recently undertaken by the Australian Competition and Consumer Commission (the Commission) in relation to do-it-yourself teeth whiteners supplied directly to consumers.

The Australian Dental Association Inc. (ADA) supports the moves taken by the Commission to reduce the risk to consumers of hazardous concentrations of hydrogen/carbamide peroxide by restricting the sale of such items. However, the ADA is concerned about the limitations on dental practitioners' ability to issue such products as outlined by the Commission's letter.

The Commission's letter sought the ADA's assistance in ensuring its members have a clear understanding of their obligations in relation to the supply of safe consumer goods under the *Competition and Consumer Act 2010* (CCA).

In particular, the Commission stated:

"It is the position of the ACCC that DIY teeth whitening products containing concentrations of more than 6% hydrogen peroxide and/or more than 18% carbamide peroxide are inherently unsafe for self-administered home use and that they do not comply with the existing provisions of the Poisons Standard for a preparation intended to be taken into the mouth..."

The ACCC position does not apply to the supply of teeth whitening products (of any concentration) to dental practices and the clinical use of these products by registered dental practitioners on patients under their direct care and supervision in their surgery/office."

While the ADA's recent advocacy and submission to the Advisory Committee on Chemicals Scheduling (ACCC) is largely consistent with the Commission's view as stated above (see **Attachment A**), the ADA

believes the Commission's position with respect to the applicability of the CCA excessively restricts dentists' ability to practise and issue teeth whitening products as part of their patients' course of treatment.

In particular the Commission's letter stated:

"However, the ACCC has reason to believe that some dentists may not be aware that this ceases to be the case if teeth whitening kits are supplied by dental suppliers or dentists (with or without education, training and competence in teeth whitening/bleaching) for use by consumers at home.

The supply of any DIY teeth whitening product to a consumer for use at home constitutes the supply of a consumer good under the CCA, whether supplied by cosmetic retailers, online traders, registered dentists, pharmacists or beauty salons".

As the peak national professional body representing more than 13,000 dentists and dental students across both the public and private sectors, the ADA requests that the Commission reconsider this view.

To understand the basis for the view outlined in the letter, the ADA requests the Commission outline:

- The specific evidence it has of patients who were injured from self-administering teeth whiteners at home – who had these teeth whiteners issued by dentists who also gave instructions about how patients should use of these products; and
- Those parties that the Commission consulted in forming its view outlined in the letter.

The ADA is greatly concerned and disappointed that the Commission has not consulted with the dental profession in forming this view, notwithstanding that we have always made ourselves available.

Whether or not teeth whiteners (of any concentration) are administered under the dentists' direct supervision within a practice, or whether such courses of treatment are subsequently prescribed to that patient for their self-administered use in the home by their dentist – the ADA's view is that the dental profession has the appropriate qualifications and expertise to not only apply such substances in surgery, but to also give directions to patients on their own (self) use outside of the dental practice.

Registered dentists, the leaders of the dental team of dental practitioners, through their extensive training and requirements to participate in continuing professional development, are highly skilled in the practise of dentistry and as such have more than adequate skills and knowledge in the provision of teeth whitening advice and treatment.

The ADA's view however is that the Commission's letter does not sufficiently recognise the skills and expertise of the dentist. They are the health professional with the greatest level of expertise to provide advice on teeth whitening and this must be recognised.

The ADA contends that if dentists deem that self-administration from home of teeth whitening products is to occur, they will have provided adequate instruction to the patient to facilitate the safe self-administration by the patient of the teeth whitening kit's contents. Dentists should not be unjustifiably restricted from this practice.

To restrict this practice would be akin to preventing medical practitioners from prescribing drugs for home consumption on the basis that the patient may overdose and thus consumption of the prescribed drug must be in the medical surgery. This practice of home consumption of the drug is permitted as authorities recognise that accompanying the prescription of the drug was the provision of advice from the medical practitioner/pharmacist as to how to administer the drug. The same situation applies to the provision of teeth whitening substances to patients. Dentists will have provided instructions and advice to the patient - just as was the case for the drug prescription provided by medical practitioners.

No law or regulation can be made to guarantee patients' compliance with instructions (and therefore guarantee the safe use of any issued products, medical or otherwise). That said, the risk of patient non-compliance - which is an ongoing risk across all aspects of healthcare - should not be used as the basis to

restrict dentists from issuing or prescribing teeth whitening products for patients to self-administer outside of the dental practice, if dentists make the professional judgement that such action is required as part of the course of treatment and have given appropriate instruction about their safe use.

The fact that cases of injury have occurred through the use of OTC teeth whitening kits provided by unqualified persons, notwithstanding the existing Schedule 5 and 6 classification of the teeth whitening products in question, has given rise to the ADA's submission to the ACCS to consider adopting a Schedule 4 (Prescription only Medicine) classification. A Schedule 4 classification would appropriately provide the level of protection required for the public while at the same time permitting the use/prescription of these products by suitably qualified persons.

To extend the application of the CCA's supply of consumer goods restrictions by unqualified persons (such as beauticians or cosmetic retailers) to also include dentists is regulatory overreach that unnecessarily prevents dentists from performing valuable, safe and effective treatment they are qualified to do, and denies patients from receiving and participating in the full course of care.

We welcome the ACCC's urgent consideration of this matter.

If you seek any further information, please contact ceo@ada.org.au or 02 9906 4412.

Yours sincerely,

