



**AUSTRALIAN DENTAL
ASSOCIATION INC.**

Incorporated in the ACT ARBN 131 755 989

14-16 Chandos Street St Leonards NSW 2065

All Correspondence to:
PO Box 520 St Leonards NSW 1590

FILE No:
DOC:
MARS/PRISM:

3 April 2012

The FOI Team
Australian Competition and Consumer Commission
Canberra, ACT. 2601

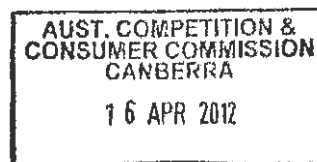
Dear Ms Ross

Re: Request for access under the Freedom of Information Act 1982

Thank you for letter dated 30 March 2012 seeking approval from the Australian Dental Association Inc. (ADA) to release copies of relevant documents between the ADA and other parties relating to the provision of tooth whitening products by non-dental practitioners.

The ADA has considered your request and finds no reason to object to the release of said documents should you feel it appropriate to do so in this case.

Yours sincerely,



Our Ref: #48193
Contact Officer: William Herron
Contact Phone: (02) 6243 1244
Contact fax: (02) 6243 1210
Email: foi@acc.gov.au



**Australian
Competition &
Consumer
Commission**

GPO Box 3131
Canberra ACT 2601

23 Marcus Clarke Street
Canberra ACT 2601

tel: (02) 6243 1111
fax: (02) 6243 1199

www.accc.gov.au

30 March 2012



Australian Dental Association Inc.
14-16 Chandos Street
ST LEONARDS NSW 2065

Via email to: [Redacted]

Dear [Redacted]

Request for access under the *Freedom of Information Act 1982*

The Australian Competition and Consumer Commission (ACCC) has received a request under the *Freedom of Information Act 1982* (FOI Act) seeking access to documents relating to the recall of Pro Teeth Whitening products.

The ACCC has identified the enclosed documents in its possession as falling within the scope of the request. These documents may relate to the business affairs of yourself or your organisation.

Consultation

Consistent with the FOI Act, the ACCC is consulting with you as to whether you have any objections to the release of copies of these documents. I have not made any decision to release these documents at this time.

Your comments are being sought to assist me in deciding whether to grant or to refuse access to the documents under the FOI Act. I ask you to please consider whether there would be any real harm in the release of the material, in light of the age, content etc of the documents.

If you object to the release of the information, you will need to justify your claims, preferably by identifying the relevant exemption provision of the FOI Act, and how you believe that provision is satisfied. The mere assertion that release of the documents would be an unreasonable disclosure of your business or personal information would generally be insufficient to sustain an exemption under the FOI Act. Guidelines regarding FOI Act, the exemption provisions and their application are available from the website of the Office of the Australian Information Commissioner at <http://www.oaic.gov.au/publications/guidelines.html>.

D12/48693

Section 22 of the FOI Act allows information to be deleted from documents where it is exempt from release or outside the scope of the request. Please consider whether deletion of any specific information would eliminate or substantially reduce any objections you might have to the release of the documents, and if so advise what deletions you seek.

Note that if the FOI request proceeds to the Office of the Australian Information Commissioner (OAIC) or the Administrative Appeals Tribunal (AAT) for review of the ACCC's decision, your response to this consultation may form part of the OAIC or Tribunal documents, and become available to the FOI applicant. Therefore, you may wish to frame your response accordingly. Please also note that you may be asked to give evidence at the AAT in relation to your claims. If you have concerns relating to the possible disclosure of your response to this letter, please contact us to discuss.

Publication of released material

In accordance with recent changes to the FOI Act, the ACCC is now required to publish on its website (foi.accc.gov.au) any material released in response to an FOI request. Where the ACCC considers that it would be unreasonable to publish particular information, the ACCC can delete personal and business information from such documents before they are published.

Accordingly, please note that if the attached material is released, it will most likely be published on a public website, and available for download without restriction.

When making my decision in relation to these documents I am only able to refuse access if an exemption applies in relation to that document. Most exemptions are subject to a public interest test that is weighted in favour of release, and therefore I must believe that release of the document would be contrary to the public interest. Whilst assessing the material for release, I will also decide whether it would be unreasonable to publish the material on our website as outlined above.

When preparing your response to this letter, I ask that you provide comments to assist me in making my access decision under the FOI Act, and also comments to assist me in making a decision in relation to the publication of any released material.

Particularly, you will need to clearly identify documents, or part thereof, which you do not wish to be published and why it would be unreasonable for that information to be published.

Although I am not bound by the comments you will make they will be given careful consideration. Should your comments not be accepted you will be contact again concerning your review rights.

Please forward your response as requested above to:

The FOI Team
Australian Competition & Consumer Commission
GPO Box 3131
Canberra ACT 2601

It would assist the ACCC to meet its obligations under the FOI Act if a reply could be provided by **6 April 2012**. It would help to avoid any misunderstandings if the document number in the attached schedule is referred to when providing your response. **If a response is not received by the above date, the ACCC will assume you have no objections to the release of the information.**

Should you have any inquiries concerning this matter, or prefer to provide a response via telephone, please do not hesitate to contact me on 02 6243 1244.

Yours sincerely



Nicole Ross
FOI Delegate
ACCC Legal Group

D12/48693

Email correspondence – Australian Dental Association

-----Original Message-----

From: [REDACTED]
 Sent: Thursday, 15 September 2011 8:26 AM
 To: Wallner, Peter
 Subject: Teeth Whitening Products

Mr Peter Wallner
 Australian Competition & Consumer Commission
 Product Safety Area

Dear Peter,

Re : Australians at risk of injury from teeth whitening

Thankyou for the opportunity to discuss over the counter (OTC) teeth whitening products on the phone on Monday. I was reassured to learn that your department has identified the potential for misuse and damage by inappropriate teeth whitening kits. I was particularly alarmed by your discovery that some of the products you investigated contained concentrations of carbamide peroxide as high as 22% and 36%. I can confirm that these concentrations are much higher than dentists would usually prescribe for their patients.

The Australian Dental Association (ADA) shares your concerns and in May 2011 launched a dedicated website www.teethwhiteningfacts.com.au to help the public understand the alternatives available for teeth whitening. It also highlights the dangers of teeth whitening performed without a dentist's diagnosis and treatment prescription (ie OTC products and services provided by beauticians and hairdressers). The ADA also launched a public awareness campaign and received considerable media coverage over the following 3 months. Hopefully the message is starting to penetrate the community that teeth whitening can be perilous if not prescribed by a registered dental practitioner.

You may be aware that in May the CHOICE consumer group also, coincidentally, issued a media release entitled "Whiter Teeth Craze Thrives With No Rules". There was also an article in the June edition of CHOICE magazine.

In our discussion you requested injury data relating to teeth whitening. Unfortunately the ADA is in a similar position to the ACCC in that it has only anecdotal evidence of damage from teeth whitening. When members of the public are damaged by teeth whitening OTC kits or by bleaching applied by a beautician or hairdresser, they will usually present to their dentist (somewhat embarrassed) after the event. I have attached a photograph of a lady whose gums were severely burned by application of a bleaching agent by a beautician. This lady provided this evidence to the ADA in response to a story she saw on television, hoping she could help other un-suspecting people to avoid similar injury. The same injury could occur from an OTC product because the bleaching gel is not confined to the tooth surface and because the concentration of the peroxide could be too high.

The kinds of injuries we see from inappropriate teeth whitening include:

- alteration to the surface enamel of the teeth
- reduced strength of dental filling materials
- damaged and inflamed gums
- chemical burns to the gums and oral soft tissues
- blistering of gums and oral tissues
- severe tooth sensitivity
- multi-coloured teeth, as a result of fillings, crowns and veneers not

changing colour.


I am told that in South Africa there has recently been a ban placed on teeth whitening outside of a dental practitioner's prescription. The General Dental Council in the UK are currently investigating a number of complaints against non-dental personnel (ie beauticians and hairdressers) who have caused harm to their customers by teeth whitening.

In Australia, the Dental Board of Australia states "Teeth whitening/bleaching is an irreversible procedure on 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."

Worksafe Australia's current guidelines list hydrogen peroxide at concentrations above 5% as a hazardous substance.

The ADA welcomes any action which progresses the safety of the public and protects them from injury by inappropriate use of OTC kits and administration of teeth whitening by non-dental personnel. Please let me know if the ADA can assist your department any further.

Kind regards,


Australian Dental Association.

Wright, Dean

From: [REDACTED]
Sent: Friday, 2 December 2011 11:46 AM
To: Wallner, Peter
Subject: Tooth Whitening
Attachments: DoHA CORRESPONDENCE TEETH WHITENING.PDF; HALTON TEETH WHITENING.PDF; 20111019 DOHA ROXON CORRESPONDENCE.PDF

Dear Peter,

Thanks for the chat this morning.

I attach copies of an exchange of correspondence with Minister Roxon and Jane Halton. A similar letter was sent to the Dental Board but no response has been received.

As I mentioned I shall be seeking the assistance of someone from within the ADA to assist with a possible submission to Warren Hough-if you could supply his contact details and anything else that you think may be of assistance, please send it through. I shall keep in touch.

In the meantime I shall place onto the website and into an email newsletter a call for members to send info relating to cases of injury relating to tooth whitening by persons other than dental practitioners.

Regards,



AUSTRALIAN DENTAL
ASSOCIATION INC.

Australian Dental Association Inc.

14-16 Chandos Street St Leonards NSW 2065
PO Box 520 St Leonards NSW 1590

T: 02 9906 4412
F: 02 9906 4917
E: [REDACTED]
W: www.ada.org.au

PRIVATE & CONFIDENTIAL

This e-mail may contain privileged or confidential information which is intended for the use of the addressee only. If you receive this e-mail in error please delete it from your system immediately and notify us at either the above e-mail address or on 02 9906 4412. The ADA respects your privacy. When using email to communicate with the ADA, please be aware that all the information contained in your email is stored on our server. Access to that information by ADA personnel is strictly limited and controlled.

27/02/2012



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.

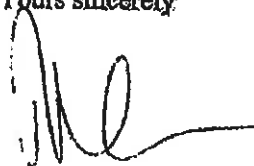
The NDPSC members generally considered that these requirements, in combination with general trade practices requirements for supply of safe products, would limit the legitimate availability of such high strength tooth whiteners to dental professionals. The Record-of-Reasons for these considerations are 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(B) 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 DENTAL
ASSOCIATION INC
INCORPORATED IN THE ACT UNDER THE ACT 155 987

14-16 Chandos Street St Leonards NSW 2055

All Correspondence to:
PO Box 520 St Leonards NSW 1590

1 September 2011

Ms Jane Halton
Secretary
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Dear Ms Halton

The Australian Dental Association (ADA) wishes to express its concern over the widespread practice of teeth whitening by non-Dentists including hairdressers, beauticians and "bleaching booths" in shopping centres. These individuals are placing the public at risk of serious damage due to inappropriate application of peroxide bleaching agents. There are numerous side effects associated with using chemicals to whiten teeth, and some can be irreversible. Damage can include alteration to the enamel surface of teeth, reduced strength of resin fillings, damaged and inflamed gums, chemical burns, blistering of mouth and gum tissues and severe tooth sensitivity and pain. Inappropriate teeth whitening and failure of proper diagnosis can also result in the appearance of multi-coloured teeth. The ADA maintains that only dentists are qualified to diagnose whether individual patients are suitable candidates for teeth whitening. In order to help educate the public about the risks of injury from tooth whitening, the ADA has established a website www.teethwhiteningfacts.com.au

The ADA's concerns for public safety are supported by the case which occurred in Victoria in 2009, where a beauty therapist was found guilty of illegally practicing dentistry, as a result of a complaint from a member of the public. This was the first time that the legality of teeth whitening was considered by an Australian Court. The state legislation under which this prosecution occurred has been made redundant by National Law which created the Dental Board of Australia (DBA) in July 2010.

The DBA Interim policy on Tooth Whitening/Bleaching states that "Tooth whitening/bleaching is an irreversible procedure on 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." The ADA believes the appropriate practitioner is a Dentist. The Health Practitioners Regulation National Law Act 2009 clearly states under S.121: Restricted dental acts (2)(a) that a "restricted dental act" means performing any irreversible procedure on the human teeth or jaw or associated structures" In light of this, the ADA calls upon Health Ministers, Departments of Health and the Dental Board of Australia to focus upon public safety and enforce a ban on tooth whitening by non-dentists.

AUSTRALIAN DENTAL
ASSOCIATION INC.

Worksafe Australia's current guidelines list hydrogen peroxide at concentrations above 5% as a hazardous substance. Inappropriate exposure can lead to permanent damage. Direct exposure to skin and eyes can cause severe irritation or burns, while ingestion may cause irritation to the esophagus and stomach, resulting in bleeding.

Notwithstanding these recommendations, the ADA believes that concentrations far greater than 6% are being used by non-dentists to whiten the teeth of unsuspecting members of the public. The ADA maintains that no concentration of peroxide can be safely used for tooth whitening by unqualified personnel.

It appears that the ADA is not the only body concerned about public safety from inappropriate tooth whitening by non-registered persons. The ADA is encouraged by recent warnings from the CHOICE consumer group about tooth whitening in their media release dated 31 May 2011 and an article in the Choice magazine, June 2011.

The ADA requests that you consider this issue as a matter of urgency and take the appropriate steps to protect the public.

Yours sincerely

A large black rectangular redaction box covering the signature area.



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.

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

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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 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


Janie Hallon PSM
Secretary

20 September 2011