

Our Ref: D12/33403
Your Ref:
Contact Officer: Peter Wallner
Contact Phone: 02 6243 4972

15 March 2012

Mr Troy Williams
Chief Executive Officer
Australian Dental Industry Association
Government Affairs
GPO Box 1
CANBERRA ACT 2601

Dear Mr Williams

Re: Supply of do-it-yourself teeth whitening kits for use by consumers at home

I am writing to inform you of actions recently undertaken by the Australian Competition and Consumer Commission (ACCC) in relation to do-it-yourself (DIY) teeth whiteners supplied directly to consumers which contain hazardous concentrations of hydrogen/carbamide peroxide and appear to be in breach of the limits set through the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard).

I am also seeking your assistance in ensuring the dental industry has a clear understanding of their obligations in relation to the supply of safe consumer goods under the *Competition and Consumer Act 2010 (CCA)*.

In late 2011, the ACCC became aware of various media reports citing injuries associated with DIY teeth bleaching agents. The Australian Dental Association also reported that dentists were seeing an increasing number of patients presenting mouth injuries attributed to at-home teeth bleaching attempts. The ACCC since identified further injury cases which had been treated in emergency departments of hospitals within Australia; and that since 2005, the Australian Poisons Information Centres had received at least 63 reports of injuries involving teeth whiteners.

In early December 2011, the ACCC contacted known suppliers of DIY teeth whiteners and commenced negotiations for voluntary recalls of DIY teeth whitening products containing concentrations of more than 6% hydrogen peroxide and/or more than 18% carbamide peroxide. The ACCC also issued a media release on the initial series of voluntary recalls which helped alert consumers as well as suppliers to the problem of excessive peroxide concentrations in some teeth whitening products.

To date the ACCC has successfully negotiated the voluntary recall of 22 DIY teeth whitening products, from eight different suppliers, that contained concentrations of peroxide bleaching agents that are unsafe for a DIY product.

On Monday, 6 February 2012, the Parliamentary Secretary to the Treasurer, the Hon. David Bradbury MP also ordered a compulsory recall of two further DIY teeth whiteners containing unsafe levels of hydrogen peroxide, as the Queensland based supplier of those products had not voluntarily removed their products from the market. Details of all the recalled products can be accessed at <http://www.recalls.gov.au>.

These recent efforts appear to have impacted on what had been an increasingly widespread supply of unsafe DIY teeth whitening products, as the major suppliers known to the ACCC seem to now be supplying products below 6% hydrogen peroxide/18% carbamide peroxide. Nonetheless, should the ACCC identify other unsafe DIY teeth whiteners in the marketplace we will take consistent action to ensure compliance with the recognised safe limits.

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 Poisons Standard provides a statutory basis to restrict DIY teeth whiteners to the concentration limits set out in Schedule 5, irrespective of whether the signal word "Poison" appears on the packaging. Classification into Schedule 6, along with the prohibitions set out in paragraph 18 should not allow the label of a Poison to include messages, either directly or by implication, that contradict those messages required by the Standard such as instructing the Poison; 'be taken directly into the mouth', 'come into direct contact with the skin', 'that it is safe/harmless on gums or if ingested' or 'has a cool minty flavour' etc.

The ACCC's position reflects the Scheduling Committee Record-of-Reasons (see February and June 2005: <http://www.tga.gov.au/archive/committees-ndpsc-record.htm>) and the positions of the Australian Dental Association (see <http://www.ada.org.au/about/policies.aspx>), and the European Union's Scientific Committee on Consumer Products 2007 "*Opinion on Hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products*", which concluded that the use of tooth whitening products containing more than 6% hydrogen peroxide is not considered safe for use by consumers

We also note the Dental Board of Australia's interim policy made under section 39 of the *Health Practitioner Regulation National Law Act* states;

"[that] ... 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. (see <http://www.dentalboard.gov.au/Codes-Guidelines/Policies-Codes-Guidelines.aspx>)

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. 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. **Attachment A** provides some additional information about the obligations of suppliers of teeth-whitening kits under the CCA.

We would appreciate your assistance in generally communicating the potential hazards associated with teeth whitening to the public and in helping to ensure the current regulatory requirements for teeth whiteners are adhered to by your members. We would also appreciate being advised of any action being taken by the Australian Dental Industry Association to address the possible supply of over-strength bleaching agents to unregistered teeth bleaching practitioners, registered dental practitioners without education, training and competence in teeth whitening/bleaching) or to consumers for home use.

Should the Australian Dental Industry Association be intending to seek changes to the current regulatory arrangements around teeth whitening we would appreciate being appraised of the details of such plans.

Regards

Steve Hutchison
Acting General Manager
Product Safety Branch

ATTACHMENT A

Obligations for suppliers of do-it-yourself teeth-whitening kits in Australia under the *Competition and Consumer Act 2010*

Do-it-yourself (DIY) Teeth-whitening kits are consumer goods and are therefore subject to statutory consumer guarantees that require suppliers to remedy consumers if goods are unfit for purpose or of unacceptable quality, including if they are unsafe. The *Competition and Consumer Act 2010* (CCA) also requires that all representations or claims made in relation to the supply of consumer goods are truthful. It is an offence to engage in misleading and deceptive conduct.

Cosmetics, including teeth-whitening kits, are also subject to the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*, which requires that ingredients used in cosmetics are declared on the label. This mandatory information standard is intended to enable consumers to identify the presence of ingredients to which they may be allergic or sensitive, or otherwise concerned about, and to allow comparison of different products.

Suppliers of consumer goods are also required to report any serious injury, illness or death associated with consumer goods that they have supplied in Australia within two days of becoming aware of a reportable incident. A supplier who fails to fulfil this mandatory requirement may be found guilty of an offence and be liable for a penalty of up to \$16,500 for a body corporate or \$3,300 for a person other than a body corporate *for each offence*. Further information explaining your Mandatory Reporting obligations, including the online reporting form is available on the Product Safety Australia website at: <http://www.productsafety.gov.au/mandatoryreporting>.

Cosmetic ingredients must be legally permitted for use in Australia and meet requirements under the *Industrial Chemicals Notification and Assessment Act 1989* and comply with the *Cosmetics Standards 2007*. There are also legal requirements and restrictions for certain substances, such as hydrogen peroxide and carbamide peroxide, by virtue of the *Poisons Standard 2011*.

Information explaining your consumer product safety recall obligations, including the online recall notification form, can be found on the Recalls Australia website at <http://www.recalls.gov.au/content/index.phtml/itemId/1000103>.