



Australian
Competition &
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Dr Troy R Williams
Chief Executive Officer
Australian Dental Industry Association
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Dear Dr Williams

Re: Regulation of teeth whiteners

Thank you for your letter dated 3 April 2012, in response to our letter dated 16 March 2012 explaining the regulatory position for DIY teeth whiteners.

I note that the Australian Dental Industry Association (ADIA) has subsequently met with ACCC officers to clarify the situation. I did want to respond to your letter however and apologise for the delay in doing so.

Mr Hutchison's April letter to you was intended to set out the regulations currently applicable to DIY teeth whiteners. In doing this, the ACCC has not created any new requirements but has sought to outline the requirements which have been in place for some time. We sought your support in making requirements clear.

The ACCC's position is that DIY teeth whitening products containing concentrations of more than 6 % hydrogen peroxide or more than 18 % carbamide peroxide are inherently unsafe for self-administered home use.

Self administering teeth whitening products, whether paint-on or tray-type, entails additional risks to consumers as contact between the bleaching agent and the oral soft tissues is inevitable and significant ingestion of the bleaching substances occurs. Misuse of teeth whiteners is also clearly foreseeable. Over-application of the bleaching gel, excessive frequency and excessive duration of bleaching are known to occur with DIY teeth whitening products. Accidental ingestion of poisons by children is a further concern. In one reported case a toddler died as a result of ingesting a small volume of only a 3% solution of hydrogen peroxide.

Concentrations of hydrogen peroxide above 6% reduce the margin for error and increase the severity of injuries sustained as a result of these foreseeable misuses.

The ACCC has formed this view based on the positions outlined in a range of informed sources.

- European Union Scientific Committee

The expert opinion published by the EU¹ cited studies which estimated that up to 25% of the bleaching gel is ingested. The opinion determined that the Margin of Safety was unacceptably low and concluded that the use of tooth whitening products containing more than 6% hydrogen peroxide is not considered safe for use by consumers. These risks can be avoided in the dental surgery where the use of gingival retractors and dental dams prevents contact with the gums and mouth tissue and eliminates ingestion.

Existing Australian law is consistent with this international expert opinion with the Poisons Standard and Dental Board policy establishing a framework reflecting this.

- Poisons Standard

The Poisons Standard currently classifies preparations (other than hair dyes) containing more than 6% hydrogen peroxide or 18% carbamide peroxide as Schedule 6 'Poisons'.

Schedule 6 Poisons must be labelled as Poisons, with that signal word intending to alert users to their danger. Required Schedule 6 labelling includes advising users not to induce vomiting if swallowed; to flush the skin with running water if contact occurs; and to contact the Poisons Information Centre.

Classification into Schedule 6, invokes the prohibitions set out in paragraph 18, which prohibits the label of a Schedule 6 Poison from including messages, either directly or by implication, that contradict, qualify or modify those required statements.

DIY teeth whiteners necessarily instruct that the poison be taken directly into the mouth and placed in close proximity to the skin/gums. Bearing in mind particularly the finding that up to 25% of a bleaching gel is ingested, it would seem clear that such instructions do contradict the required messages. In addition to these inherent contradictions many products, including those supplied by dentists, have contained statements such as 'won't damage gums or teeth' or highlighting the 'appealing cool minty flavour' (of the poison).

The ACCC's view is that these requirements are not only consistent with international concerns about the level of hydrogen peroxide and carbamide peroxide in teeth whiteners, but appear to prohibit their sale. The ACCC does not, however, enforce the Poisons Standard.

¹ European Union 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

- Dental Board Policy

The ACCC has drawn to your attention the Dental Board of Australia's interim policy, made under section 39 of the *Health Practitioner Regulation National Law* legislative scheme, which 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."

The supply of teeth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent for use by persons other than appropriately trained, registered dental practitioners appears to be inconsistent with the *Health Practitioner Regulation National Law* requirements.

- *Competition and Consumer Act (CCA)* implications

Broadly the CCA sets out that where it is foreseeable that consumer products will or may cause injury the Commonwealth Minister may order a compulsory recall of the goods, ban them or set standards in relation to them.

The ACCC accepts that it is possible to apply concentrations above 6% hydrogen peroxide (or equivalent) professionally, safely. However it does not accept that it is safe for consumers to administer teeth whitening preparations above these limits unsupervised in the home environment.

In fact, in ordering a compulsory recall of DIY teeth whiteners supplied by the Pro Teeth Whitening (Aust) Pty Limited on 6 February 2012, the Minister for Competition Policy and Consumer Affairs determined that it is foreseeable that over-strength DIY teeth whiteners, will, or may, cause injury.

Where teeth whiteners are supplied by dentists for at home use this sale is captured by the *Competition and Consumer Act 2010* (the Act).

The Act defines the act of supply of consumer goods as including sale, exchange, lease, hire or hire-purchase. There is no distinction made between types of suppliers and the Act does not confer on the Minister, or the ACCC, any means to exempt specific groups from being subject to the definition of supply.

The Act defines consumer goods as "goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption". Accordingly, drugs or chemicals administered by medical practitioners or dentists to treat patients in their surgery are not considered to be consumer goods. However teeth whitening products supplied by anyone, including dentists, for personal/home use are considered to be consumer goods.

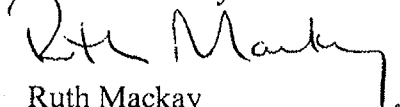
Consequently the ACCC is not able to distinguish between dentists and other providers of DIY teeth whitening kits. However it is not clear that the ACCC should make such a distinction if it were open to it to do so.

The ACCC has a significant amount of injury data related to teeth whiteners. Data provided to the ACCC by Poisons Information Centres indicates a consistent pattern of injuries arising from the use, or foreseeable misuse, of DIY teeth whitening products at home. During the period Jan 2005 - Jan 2012 there were 61 recorded calls involving apparent injuries from teeth whiteners. While the brand and origin of the products are not always recorded, kits or procedures provided by dentists are notably represented. Products supplied by dentists were able to be identified in 14 incidents, which represent 23% of such cases.

These cases illustrate the safety concerns around self administered home use of teeth whiteners despite product instructions being provided. A number of cases involved accidental ingestion of the bleaching gel by young children. The injury cases do not provide any compelling evidence that the DIY teeth whiteners supplied by dentists are less injurious than the products supplied through other channels.

I trust that this letter clarifies the ACCCs perspective on the safety of teeth whiteners. I wish to reiterate that the position outlined above does not preclude DIY teeth whitening products being supplied directly to consumers at concentrations of up to 6% hydrogen peroxide or 18% carbamide peroxide, nor does it restrict the supply of teeth whitening chemicals at any concentration to registered dental practitioners for use on patients in their surgery.

Yours sincerely



Ruth Mackay
General Manager
Product Safety Branch