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1 July 2013



Australian Dental Association Incorporated  
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Dear 

**RE: Dental practitioners supply of teeth whitening products for patients' self-use at home**

Thank you for your letters of 11 March 2013 and 4 April 2013 regarding the recent Poisons scheduling decision on hydrogen peroxide and carbamide peroxide in do-it-yourself (DIY) teeth whitening products. In your letters, you have sought clarification on whether the Australian Competition and Consumer Commission's (ACCC) current position on this issue would alter as a result of revisions made to the *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). The recent Scheduling decision does not alter the ACCC's position as stated in our letter of 13 July 2012, as the available injury data and expert scientific opinion appears not to have changed since the initial recall actions of 2011-12 were taken.

The recent revisions that took effect on 1 May 2013 created a new entry in Appendix C which prohibits the manufacture, supply, and use of teeth whitening preparations containing more than 18% carbamide peroxide and 6% hydrogen peroxide. I understand that in order to provide access to higher strength preparations for dentists, it was necessary that the prohibition created by the new Appendix C exempt teeth whitening preparations manufactured for and supplied solely by registered dental practitioners as part of their dental practice. However, I understand that the new prohibition entry and the accompanying confirmation that the current Scheduling of teeth whitening preparations in Schedules 5 and 6 of the Poisons Standard remained appropriate reflects a heightened concern in relation to teeth whiteners.

The position that the ACCC has in relation to DIY teeth whitening products containing concentrations of more than 6 per cent hydrogen peroxide or more than 18

per cent carbamide peroxide is that these products are inherently unsafe for self-administered home use. As noted above, and explained in earlier correspondence this view is based on scientific assessments and injury data and is internationally consistent.

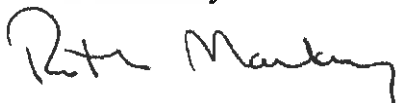
Following the recent decision to amend the Poisons Standard the ACCC has met with officials from the Australian Health Practitioner Regulation Agency (AHPRA), the Dental Board of Australia (DBA) and the Office of Chemical Safety (OCS) which provides the Secretariat for Scheduling. It is our understanding that the final form of words used in the Appendix C entry was not based on an assessment of the safety of DIY teeth whiteners but rather, that the Delegate did not regard the Poisons Standard as the appropriate vehicle for regulating the practice of dentistry.

The regulation of dentistry and the registration of dentists is the responsibility of AHPRA and the DBA. Our recent meeting with officials from these agencies has confirmed that the current policy only permits registered dental practitioners with education, training and competence in teeth whitening/bleaching to use tooth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent. The ACCC understands that the word "use" in the policy is deliberate and should not be regarded as allowing the 'supply' of over-strength products by dentists for self-administered home use. We understand the DBA is reviewing its interim policy on teeth whitening with a view to making it a permanent policy. AHPRA further confirmed that its regulatory controls do not extend to protecting consumers who access DIY teeth whitening products for self-administered home use from any source.

In your correspondence you suggested that the prescription of medicines by registered medical practitioners is analogous to dentists or pharmacists supplying teeth whiteners for DIY home use. I do not understand this to be the case. Prescription medicines are therapeutic goods which are subject to regulatory controls administered by the Therapeutic Goods Administration (TGA). Teeth whiteners are specifically excluded from being therapeutic goods and are therefore not subject to the provisions of the Therapeutic Goods Act or oversight by the TGA. It is therefore appropriate that the ACCC ensure that consumers are protected from potentially hazardous consumer goods as intended by the Australian Consumer Law, which is administered by the ACCC.

I trust that this letter clarifies the ACCCs perspective on the safety of DIY teeth whiteners. I would like to emphasise 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