



Ref: 4.8.5M — 3 April 2012

FILE No:
DOC
MARS/PRISM:

Mr Steve Hutchinson
 A/General Manager – Product Safety Branch
 Australian Competition & Consumer Commission
 GPO Box 3131
 CANBERRA ACT 2602

AUST. COMPETITION &
 CONSUMER COMMISSION
 CANBERRA
 03 APR 2012

Dear Mr Hutchinson

RE: Regulation of teeth whitening product

The Australian Dental Industry Association (ADIA) is the peak representative body for the manufacturers and suppliers of quality dental product and, in this capacity, has an interest in the regulation of teeth whitening products and the related regulatory enforcement action of the Australian Competition and Consumer Commission (ACCC). ADIA welcomes the ACCC's interest in effectively enforcing regulatory standards that pertain to the supply of teeth whitening products and seeks advice from the ACCC on its current enforcement activities.

ADIA has been provided with a copy of the ACCC's correspondence to the Australian Dental Association (ADA) dated 16 March 2012 that outlines the ACCC's current concerns and activities. Of note is the ACCC's comment that:

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.

This view is inconsistent with the dental industry's current understanding and on this basis, in order to ensure that the dental industry meets its statutory obligations with respect to supply of product, it is important that ADIA understand the basis for this interpretation and the obligations of manufacturers and suppliers so that these can be conveyed to industry.

On a related matter, ADIA notes the ACCC's preferred long-term regulatory option for the dental profession and industry to submit a joint application to the Poisons Scheduling Secretariat recommending that high concentration of over the counter teeth whitening products (above 6% hydrogen peroxide and 18% carbamide peroxide) be brought within *Schedule 4: Prescription only medicine/prescription animal remedy* of the Standard for the Uniform Scheduling of Medicines and Poisons. As noted in ADIA's correspondence to the

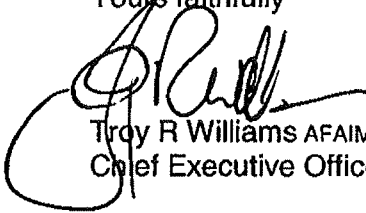
Australian Dental Industry Association Incorporated
 ABN 32 003 314 396
 National Office: GPO Box 960, Sydney, NSW, 2001
 Government Affairs: GPO Box 1, Canberra, ACT, 2601
 e: national.office@adia.org.au www.adia.org.au
 t: 1300 943 094 f: 1300 943 794

Uniform Scheduling of Medicines and Poisons. As noted in ADIA's correspondence to the ACCC dated 10 February 2012, this option is not supported as would introduce a regulatory compliance regime excessive to the identified risk, unnecessarily raising the regulatory compliance threshold to the extent that teeth whitening products will be withdrawn from the Australian marketplace and in so doing jeopardise Australian manufacturing jobs. ADIA also notes that the ACCC's course of action may be anti-competitive in nature, prohibiting the use and / or supply of teeth whitening products by appropriately trained and registered oral healthcare professionals.

ADIA has commenced the process of applying to the Therapeutic Goods Administration (TGA) to have teeth whitening products regulated as an Other Therapeutic Good, a regulatory option for therapeutic goods which are neither medicines nor medical devices.

In order to allow the dental industry to work with the ACCC to progress shared interests, we seek a meeting in order to better understand the ACCC's concerns and outline current regulatory reform activities.

Yours faithfully



Troy R Williams AFAM MAICD
Chief Executive Officer