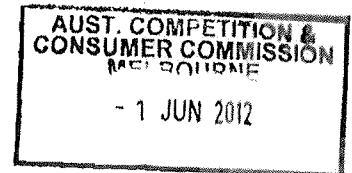


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Australian Dental  
Industry Association

**ADIA**

Ref: 4.8.5M — 29 May 2012



Mr Steve Hutchinson  
Deputy General Manager  
Product Safety Branch  
Australian Competition & Consumer Commission  
Level 34 / 360 Elizabeth Street  
MELBOURNE VIC 3000

Dear Mr Hutchinson

**RE: Regulation of teeth whitening products**

Further to recent discussions between the Australian Dental Industry Association (ADIA) and the Australian Competition and Consumer Commission (ACCC) on the regulation of teeth whitening products, we are pleased to provide an update concerning recent developments and proposals to better regulate this product group.

As you may be aware, the Australian Dental Association (ADA) has requested an amendment to the SUSMP to schedule all teeth whitening products containing hydrogen peroxide and carbamide peroxide to Schedule 4 of the SUSMP. This request is now being considered by a combined committee of the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling (ACMS). ADIA does not support this proposal.

It is important to note that the safety profile of both hydrogen peroxide and carbamide peroxide have been subject to extensive review over many years, and the appropriateness of the current regulatory controls have been affirmed. In its deliberations to set the current scheduling cut-offs for hydrogen peroxide, and subsequently for carbamide peroxide, the National Drugs and Poisons Schedule Committee (NDPSC) established and subsequently confirmed the current Scheduling classifications for hydrogen peroxide and carbamide peroxide and as part of this process the NDPSC comprehensively reviewed the toxicology and safety of hydrogen peroxide. Further, in 2011 the (Environmental Risk Management Authority) ERMA in New Zealand conducted a review of the controls on dental products containing or releasing hydrogen peroxide, as part of its amendment of The Dental Products Group Standard. ERMA's decision, which included a review of the regulatory controls of these products in international jurisdictions, supported cutoffs for tooth whitening product classifications that are consistent with the current SUSMP arrangements. It is noted that the ADA submission to amend the SUSMP did not cite any research, clinical studies or scientific data that warrants a review of the current thresholds.

The ADA proposal does appear to be ill-considered given the ramifications of it for the dental profession. In Victoria, Queensland and the Northern Territory, Schedule 4 products can only be supplied for therapeutic use (not for cosmetic use such as teeth whitening) and in Western Australia they can't be supplied by a dentist. Further, Australian manufacturers and suppliers have tendered advice to ADIA that the proposal, in its current form, unnecessarily raises the regulatory compliance burden and will result in significant additional cost for business. Given the

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relatively small market for teeth whitening products, ADIA has been advised that the likely outcome is that current suppliers of teeth whitening products will withdraw from the Australian market. This would, in all likelihood, shut down the teeth whitening industry in Australia as administered by dentists which may, in turn, lead to an increase in unsafe consumer practices, as well as the importation of unregulated, high concentration hydrogen peroxide or carbamide peroxide whitening products, for example via the Internet.

ADIA is mindful of the recent activity by the Australian Competition and Consumer Commission (ACCC) concerning high concentration hydrogen peroxide and carbamide peroxide tooth whitening kits, particularly do-it-yourself products. The products concerned contain levels of hydrogen peroxide or carbamide peroxide that fall within Schedule 6 of the SUSMP, and have been sold online or through non dental distribution channels. ADIA supports the position that products containing concentrations of peroxide that necessitate Schedule 6 classification, are likely to achieve better efficacy and reduced risks if used under the supervision, in the first instance, of a registered dental practitioner.

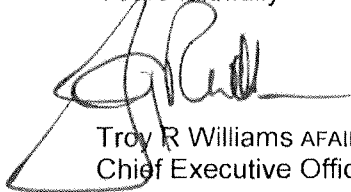
In its response to the ACCS / ACMS request for public comment on the proposal to scheduling all teeth whitening products containing hydrogen peroxide and carbamide peroxide to Schedule 4 of the SUSMP, after consultation with various stakeholders ADIA has proposed an alternative pathway. In its submission, ADIA has recommended that to limit the availability of hydrogen peroxide and carbamide peroxide teeth whitening preparations in Schedule 6 of the SUSMP, they only be made available to dental professionals registered by the Dental Board of Australia (DBA) who would, in the first instance, administer treatment to the patient and then comfortable that there were no adverse reaction, supply the patient with take-home kits. This restriction of access to consumers could be achieved by the addition of new Appendix C entries for hydrogen peroxide and carbamide peroxide. The net result of these proposed new Appendix C entries would be to effectively prohibit use of Schedule 6 teeth whitening preparations other than when supplied to a registered dental practitioner. The existing wording for the Schedule 5 and Schedule 6 entries would remain unchanged. It is noted that this proposed amendment would be consistent with the DBA interim policy on tooth whitening / bleaching published in 2010.

Consistent with this approach, ADIA believes that the Scheduling of hydrogen peroxide and carbamide peroxide in Schedule 5 and Schedule 6 of the SUSMP remains appropriate, and the proposed addition of the Appendix C entries to confine the use of high concentration preparations to under the supervision of a registered dental practitioner, provides additional controls to address the potential risks of inappropriate consumer self selection that resulted in the episodes of misadventure, that instigated the recent ACCC investigation.

ADIA considers that the alternative course proposed by ADIA is consistent with the public safety concerns raised by the ADA, but provides a solution that retains teeth whitening products within a cosmetics regulatory framework. For your information, please find enclosed a copy of ADIA's submission to the Scheduling Secretariat.

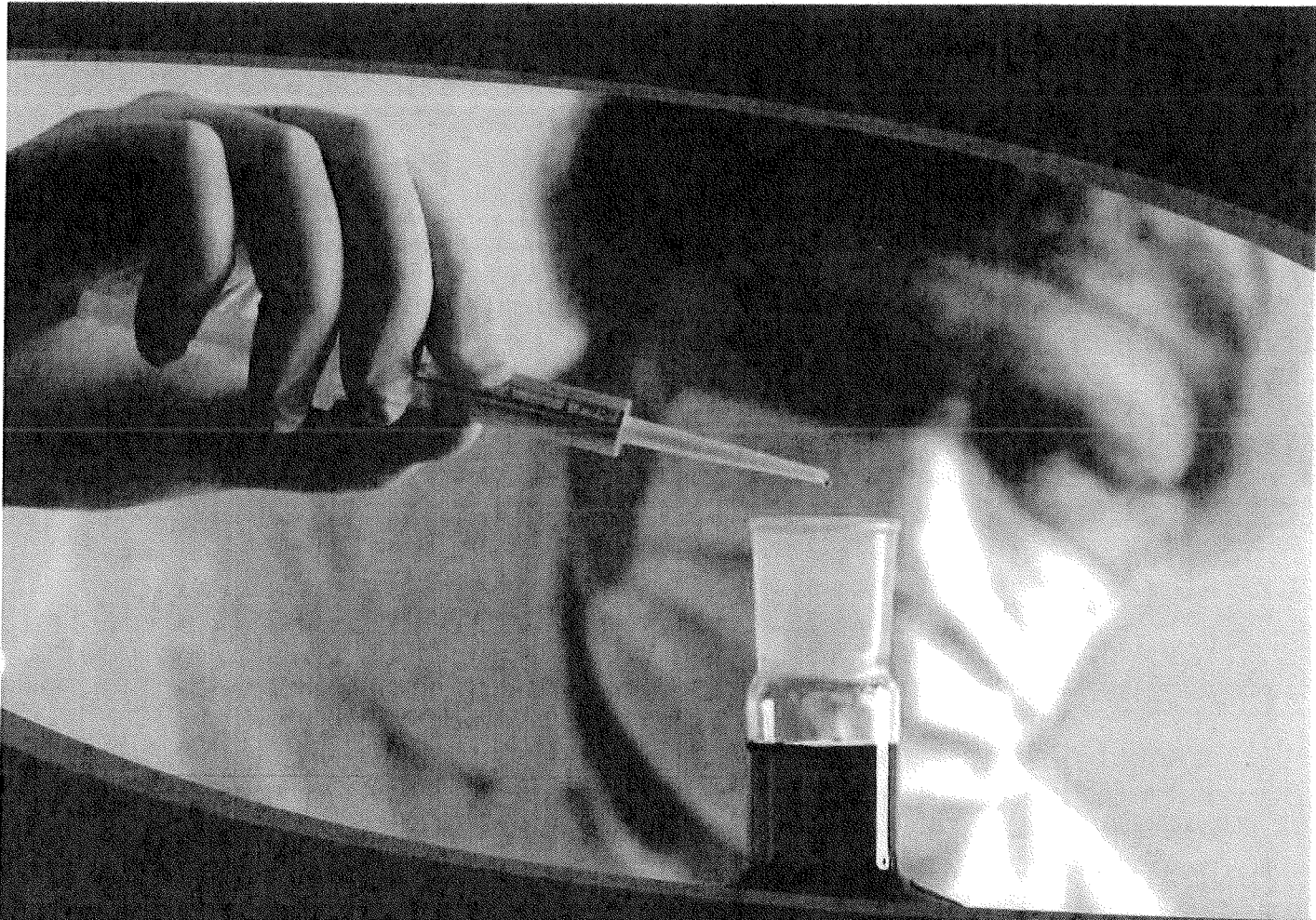
If the TGA has any questions on this matter please contact me at your convenience.

Yours faithfully



Troy R Williams AFAM MAICD  
Chief Executive Officer

Encl.



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## Submission — Australian Dental Industry Association

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Proposed amendments referred by the delegate for scheduling advice for consideration by a joint meeting of the ACCS and ACMS - Hydrogen peroxide and Carbamide peroxide

**ADIA**

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The Australian Dental Industry Association (ADIA) tenders this submission to the Department of Health and Ageing pursuant to Regulation 42ZCZK of the *Therapeutic Goods Regulations (Cth) 1990*, with regard to the proposed amendment to the scheduling of hydrogen peroxide and carbamide peroxide when used in teeth whitening preparations, to be included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

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ADIA Reference: 4.8.5M

# ADIA

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## Introduction

The Australian Dental Industry Association (ADIA) tenders this submission to the Department of Health and Ageing pursuant to Regulation 42ZCZK of the *Therapeutic Goods Regulations (Cth) 1990*, with regard to the proposed amendment to the scheduling of hydrogen peroxide and carbamide peroxide when used in teeth whitening preparations, to be included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

**With respect to the proposal to amend the scheduling of hydrogen peroxide and carbamide peroxide when used in teeth whitening preparations, it is noted that the original proponent, the Australian Dental Association (ADA), no longer supports its proposal. In this extraordinary environment, it is recommended that the proposal simply be rejected.**

ADIA recognises that there may be a risk to public health associated with over-strength teeth whitening products, and presents a considered alternative solution for consideration. It is believed that the current scheduling of hydrogen peroxide and carbamide peroxide in Schedule 5 and Schedule 6 remains appropriate. To address the potential risks of inappropriate consumer self selection of teeth whitening products containing hydrogen peroxide and / or carbamide peroxide, it is proposed to include new Appendix C entries for hydrogen peroxide and carbamide peroxide to confine the use of high concentration teeth whitening preparations to under the supervision of a professional registered by the Dental Board of Australia (DBA). Consistent with this approach, ADIA considers that the current Schedule 5 entry and the exemption from scheduling for low concentrations of hydrogen peroxide and carbamide peroxide (3% hydrogen peroxide or 9% carbamide peroxide, or less) are appropriate, as there is no indication of regulatory failure or public safety concern at these levels.

ADIA appreciates the dilemma faced by the ACCS and the ACMS in inviting public comment on a proposed amendment that no longer enjoys the support of its proponent, however it is hoped that the alternative approach detailed in Chapter 3 provides a robust, evidence-based solution.

Troy R Williams AFAM MAICD  
Chief Executive Officer  
Australian Dental Industry Association

24 May 2012

## Chapter 1: Current arrangements

The current Scheduling approach for teeth whitening products containing hydrogen peroxide and carbamide peroxide in the SUSMP can be summarised as follows:

- a. Preparations containing 3% hydrogen peroxide or 9% carbamide peroxide, or less, are unscheduled;
- b. Preparations containing from more than 3% hydrogen peroxide up to and including to 6% hydrogen peroxide or from more than 9% carbamide peroxide up to and including 18% carbamide peroxide, are included in Schedule 5; and
- c. Preparations containing above 6% hydrogen peroxide or above 18% carbamide peroxide are included in Schedule 6.

In its previous deliberations to set appropriate scheduling cut-offs for hydrogen peroxide, and subsequently for carbamide peroxide, the National Drugs and Poisons Schedule Committee (NDPSC) established and subsequently confirmed the above Scheduling classifications. As part of these reviews, the NDPSC comprehensively reviewed the toxicology and safety of hydrogen peroxide.

ADIA supports the current percent cutoffs confirmed by the NDPSC following its previous review of these substances for the unscheduled, Schedule 5 and Schedule 6 entries for hydrogen peroxide and carbamide peroxide, as providing appropriate levels of control for the safe use of preparations containing these substances.

In 2011 the (Environmental Risk Management Authority) ERMA in New Zealand conducted a review of the controls on dental products containing or releasing hydrogen peroxide, as part of its amendment of The Dental Products Group Standard. ERMA's decision, which included a review of the regulatory controls of these products in international jurisdictions, supported cutoffs for tooth whitening product classifications that are consistent with the current SUSMP arrangements. The ERMA included in its consideration the regulatory importance of Trans Tasman harmonization, and the relevance of the minimisation of trade barriers for Australian exporters when there is no risk to public health.

## Chapter 2: ADA Proposal

It is noted that the proposal put forward for comment has been tendered by the Australian Dental Association (ADA) and did not make use of the recommended form. Further, in failing to address key criteria, the ADA has demonstrated it is not familiar itself with the requirements set out in the Scheduling Policy Framework. Further, the ADA proposal is ill formed and without merit insofar as the ADA has not tendered for consideration any new scientific evidence or raised issues of fact that warrant a review of current arrangements.

The safety profile of both hydrogen peroxide and carbamide peroxide have been subject to extensive review over many years, and the appropriateness of the current regulatory controls have been affirmed. Again, it is noted that the ADA has not tendered any research, clinical studies or scientific data that warrants a review of the current thresholds.

The rationale for the ADA submission to the Scheduling Committee's is assumed to be solely in response to the ADA's stated interest in public safety, although it is noted that it is trade restrictive in nature insofar as it suggests that only dentists should have responsibility for the sale to the public of teeth whitening products containing any concentration of hydrogen peroxide and / or carbamide peroxide. ADIA does not believe that the ADA has fully understood the implications of their proposal on the availability of tooth whitening products.

### Commercial impacts

As the peak representative body for suppliers of quality dental product, ADIA has undertaken considerable consultation with its members on the proposal. Businesses that supply dental product are of the one view, this being the proposal currently before the ACCS and ACMS is unnecessary, given the absence of robust scientific evidence (including clinical trials) to support the change.

Australian manufacturers and suppliers have tendered advice to ADIA that the proposal, in its current form, unnecessarily raises the regulatory compliance burden and will result in significant additional cost for business. Given the relatively small market for teeth whitening products, ADIA has been advised that the likely outcome is that current suppliers of teeth whitening products will withdraw from the Australian market.

Significantly, one of the suppliers who has signaled an intent to withdraw from the Australian market is a domestic manufacturer, thus if the proposal is accepted a directed consequence will be job losses.

In the proposal, the ADA refers to cases of injury, and cites one case where a Schedule 6 product was used by a non-dental professional. ADA also selectively cites a single study from the body of evidence that supports safe and effective use of hydrogen peroxide in teeth whitening. The study referred to in the ADA submission discusses potential adverse events which may occur when non dental professionals provide high concentration peroxide tooth whitening. The study concludes that the involvement of dental professional is required to

minimise risks for high concentration peroxide containing tooth whitening products. It could be argued that the selective citation of this study is self serving for the ADA's interests in the commercial supply of teeth whitening services (*i.e.* using the SUSMP to restrict provision of teeth whitening services by registered dentists), however it is ADIA's perspective that the scheduling control framework is not to be used to achieve commercial objectives.

ADIA does support the view that tooth whitening preparations containing high concentrations of hydrogen peroxide or carbamide peroxide (*i.e.* in those preparations included in Schedule 6) should be used under the supervision of a registered dental practitioner in the first instance, available for supply to patients upon recommendation of professional registered by the DBA. However, ADIA considers that the ADA's proposal is not an appropriate regulatory solution for products that are cosmetics.

Teeth whitening products are regulated as cosmetics under the *Industrial Chemicals (Notification and Assessment) Act (Cth) 1989*, and when teeth whitening products contain concentrations of hydrogen peroxide or carbamide peroxide at levels subject to the SUSMP, the additional labeling and packaging controls of Schedule 5 and Schedule 6 of the SUSMP apply.

Conversely, Schedule 4 is for medicines, and is the domain of prescription medicines for humans and animals. The definition of "medicines" in the *Therapeutic Goods Act (1989) 1989* requires that they are therapeutic goods. In the Record of Reasons of the NDPSC February 2005 meeting (item 9.1, p56), the committee confirmed:

*The TGA currently does not register tooth whitening products because they are considered to be cosmetic and not therapeutic goods*

This is confirmed in the *Therapeutic Goods (Excluded Goods) Order No. 1 2011*, which specifies that dental whitening and bleaching products are "declared not to be therapeutic goods". Since dental whitening and bleaching products are excluded goods, and therefore not medicines, ADIA views a proposal to consider their inclusion in Schedule 4 inappropriate.

As advised, if the Scheduling Committee were to determine to include these substances in Schedule 4, ADIA member Companies have indicated that the regulatory compliance costs associated with this would result in the decision by most, if not all, of the suppliers of tooth whitening products to withdraw their products from the Australian marketplace. In this environment and given the high level of consumer interest in teeth whitening, the consequence of this action may result in dental practitioners and consumers sourcing products through alternate channels of distribution, such as the internet. Such products would be non compliant with the local regulatory requirements, and consequently would be unlikely to provide appropriate instructions to ensure safe use for teeth whitening. The inadvertent outcome of this proposal would be the denial of access for dentists and patients to compliant products, and the likely increase of significant consumer risk, due to the use of non compliant products.



## Chapter 3: ADA Revised Position

On 11 May 2012 the ADA wrote the Department of Health and Ageing in terms which effectively withdrew its initial proposal and outlined an alternative regulatory solution. ADIA fully appreciates the difficulties this places ACCS, ACMS and Secretariat in, given that the process of seeking public comment on one proposal had commenced, only to have that organisation walk away from its initial position and then provide an alternative proposal. That said, ADIA takes this opportunity to provide preliminary comments on the ADA's revised position.

The most recent ADA correspondence (referenced above) is not fully formed and suggests considerable confusion.

The ADA has continued to suggest that the matter be considered by the ACCS and ACMS, however the ADA's revised proposal acknowledges the lack of necessity to regulate peroxide teeth whitening products in the therapeutic schedules, principally Schedule 4. ADIA, in light of this change, questions the need for this matter to be considered by the ACMS.

In this subsequent communication with the Scheduling Secretariat, the ADA now suggests that any teeth whitening products containing concentrations of greater than 6% hydrogen peroxide or greater than 18% carbamide peroxide (Schedule 6 preparations) should be restricted to registered health practitioners use, and the "use" of such product be confined to "in surgery". The ADA has suggested that this position has been formed by its "professional experts" however no advice as to how such thresholds were arrived at has been provided, no scientific data cited nor clinical trial referenced. This is not a solid basis upon which to restrict patient access to certain teeth whitening products.

The revised ADA position is contradicted by that organisation's own advice to the ACCC in April 2012 which stated:

*Whether or not teeth whiteners (of any concentration) are administered under the dentists direct supervision within a practice, or whether such courses of treatment are subsequently prescribed to that patient for their self administered use in the home by their dentist – the ADA's view is that the dental profession has the appropriate qualifications and expertise to not only apply such substances in surgery, but to also give directions to patients on their own (self) use outside of the dental practice.... To restrict this practice would be akin to preventing medical practitioners from prescribing drugs for home consumption on the basis that the patient may overdose and thus consumption of the prescribed drug must be in the medical surgery. This practice of home consumption of the drug is permitted as authorities recognise that accompanying the prescription of the drug was the provision of advice from the medical practitioner/pharmacist as to how to administer the drug. This same situation applies to the provision of teeth whitening substances to patients. Dentists will have provided instructions and advice to the patient- just as was the case for the drug prescription provided by the medical practitioner.*

Furthermore the ADA wrote to the Dental Board of Australia (DBA) on 24 April 2012 seeking clarification of the DBA teeth whitening policy. The ADA advised in this correspondence that the ACCC interpretation of "used" as it appears in the DBA policy to be:

*...excessively and unnecessarily restricting dental practitioners practice to only being able to perform teeth whitening treatments and procedures in the surgery. ... Provision of advice from dentists following clinical consultations on the use of teeth whitening kits can adequately address any safety concerns. Requiring patients to return to dental surgeries for repeated applications of teeth whitening products would be akin to medical practitioners being required to have patients return to the medical practice surgery each time a prescription drug was taken by a patient.*

The ADA further stated that:

*The ADA is greatly concerned about the Commissions view on the applicability of the CCA to restrict dentists' ability to practice and issue teeth whitening products for home use as part of their patients course of treatment. Patients that self-administer teeth whiteners issued by dentists do so following instructions given during clinical consultation. This allows patients to use these products safely.*

The ADA's position to the ACCS/ACMS that Schedule 6 products must be used "in surgery" is inconsistent with its own stated position as articulated to these key stakeholders above. ADIA does not support the ADA view as proposed to the ACCS/ACMS.

ADIA supports the position that Schedule 6 teeth whitening products can be supplied by a dentist, after a clinical consultation, and the teeth whitening regimen can include at home elements when supported by appropriate patient instructions for safe use.

## Chapter 3: Alternative proposal

ADIA is mindful of the recent activity by the ACCC concerning high concentration hydrogen peroxide and carbamide peroxide tooth whitening kits, particularly do-it-yourself products. The products concerned contain levels of hydrogen peroxide or carbamide peroxide that fall within Schedule 6, and have been sold online or through non dental distribution channels. ADIA supports the position that products containing concentrations of peroxide that necessitate Schedule 6 classification, are likely to achieve better efficacy and reduced risks if used under the supervision, in the first instance, of a registered dental practitioner.

Consequently, ADIA proposes an amendment to the availability of hydrogen peroxide and carbamide peroxide teeth whitening preparations in Schedule 6, to limit their access to DBA registered professionals who would, in the first instance, administer treatment to the patient and then comfortable that there were no adverse reaction, supply the patient with take-home kits. This restriction of access to consumers could be achieved by the addition of new Appendix C entries for hydrogen peroxide and carbamide peroxide. The net result of these proposed new Appendix C entries would be to effectively prohibit use of Schedule 6 teeth whitening preparations other than when supplied to a registered dental practitioner. The existing wording for the Schedule 5 and Schedule 6 entries would remain unchanged.

It is noted that this proposed amendment would be consistent with the DBA Interim Policy on Tooth whitening / bleaching published in 2010.

Suggested drafting for the new Appendix C entries is as follows:

*Appendix C entry (new):*

**HYDROGEN PEROXIDE** (excluding its salts and derivatives) in teeth whitening preparations containing more than 6 per cent (20 volume) of hydrogen peroxide **except** in preparations supplied through a registered dental practitioner.

**CARBAMIDE PEROXIDE** (excluding its salts and derivatives) in teeth whitening preparations containing more than 18 per cent of carbamide peroxide **except** in preparations supplied through a registered dental practitioner.

ADIA considers that this amendment is consistent with the public safety concerns raised by the ADA, but provides a solution that retains teeth whitening products within a cosmetics regulatory framework.

As advised, ADIA believes that the Scheduling of hydrogen peroxide and carbamide peroxide in Schedule 5 and Schedule 6 remains appropriate, and the proposed addition of the Appendix C entries to confine the use of high concentration preparations to under the supervision of a registered dental practitioner, provides additional controls to address the potential risks of inappropriate consumer self selection that resulted in the episodes of misadventure, that instigated the recent ACCC investigation.

ADIA considers that the current Schedule 5 entry and the exemption from scheduling for low concentrations of hydrogen peroxide and carbamide peroxide (3% hydrogen peroxide or 9% carbamide peroxide, or less) are appropriate, as there is no indication of regulatory failure or public safety concern at these levels.

## Introduction – Australian Dental Industry Association

Formed in 1925, ADIA is the peak national association representing the suppliers of quality dental product and services to dentists and allied oral healthcare professionals. The ADIA membership represents businesses that supply around more than ninety-five percent of the nation's purchases of dental product and consumables which are valued at an estimated \$860 million per annum.

ADIA members have the opportunity to contribute to the development of not only the Association, but also the broader dental industry, through a number of national committees that address regulatory, technical, skills and industry promotional issues. A national board of seven leading professionals attends to governance matters and sets the strategic direction of the Association.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. The Association provides advice to agencies including the TGA and the National eHealth Transition Authority (NeHTA), often nominating industry representatives to government committees and working groups. The Association also supports its members in the development of technical standards for dental products and consumables, nominating industry representatives to committees of both Standards Australia and the International Standards Organisation (ISO).

ADIA builds partnerships between dentists and the suppliers of dental products and services. The Association is the organiser of the nation's premier dental trade show, the highly acclaimed *ADX Dental Exhibition*, which attracts more than four thousand dentists and allied oral healthcare professionals every year.

At an international level, ADIA is a founding member of the International Dental Manufacturers (IDM), the Geneva-based global confederation of national dental trade associations. ADIA is also a supporting member of the World Dental Federation (*Fr. Federation Dentaire Internationale – FDI*).

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports the development of both TAFE and university courses relevant to the dental industry and the Association delivers the widely acclaimed *ADIA Introduction To Dentistry Course*.

The ADIA national office is based in Sydney and the Association is active in all mainland states.

More information can be found online at [www.adia.org.au](http://www.adia.org.au)

**ADIA**

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