



— ADIA Submission Consumer Law Enforcement & Administration

The Productivity Commission has asked for guidance as to whether regulators have achieved proportionate, risk-based enforcement in practice.

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Section 1 – Executive Summary

The Productivity Commission’s review into consumer law enforcement and administration is timely in the view of ADIA. It provides the forum to review the extent to which the Australian Competition and Consumer Commission (ACCC) works with specialist safety regimes.

In this submission ADIA has cited the ACCC’s attempts to regulate the supply of dental products in a manner that is inconsistent with prevailing state / territory government legislation. The intent here is not to debate the merits of the underpinning regulatory standards, but to highlight the challenges associated by the ACCC issuing statements of “position” that have become de facto regulatory standards that have not been subject to the normal scrutiny against which new legislation is typically assessed.

With respect to consumer law enforcement and administration, ADIA is of the view that:

- The dental industry is fully supportive of the benefits associated with the ‘single law – multiple regulator’ model for general consumer protection;
- That the role of specialist regulators such as the Therapeutic Goods Administration (TGA) and state / territory government agencies responsible for chemical regulation should be understood and respected by the ACCC; and
- The ACCC cease publishing statements of its “position” that have, in practice, become de facto regulatory standards.

The Commission has asked for guidance as to whether regulators have achieved proportionate, risk-based enforcement in practice. With respect to the ACCC’s attempts to control the supply of teeth whitening products, there is a demonstrable failure to achieve this outcome.

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12 September 2016

Section 2 – Commentary On The Existing Framework

From the outset, it must be stated that the dental industry is fully supportive of the benefits associated with the ‘single law – multiple regulator’ model for general consumer protection in Australia. In providing a degree of nation-wide consistency, this approach has helped industry both understand and meet its compliance obligations.

The challenges associated with the revised framework arise from the application of the Australian Consumer Law (ACL) and regulatory over-reach by the ACCC. Insofar as its intrusion into dental product regulation is concerned, the ACCC has failed to provide coordination, a consistent approach and collaboration with other regulation. The result is marketplace confusion, higher compliance costs and job losses directly attributed to ACCC action.

ADIA believes that the operation of the ACL and the outcomes for both consumers and business could be enhanced by the ACCC understanding and respecting the roles of specialist safety regulators such as the TGA and state / territory governments that have responsibility for discrete product sectors, such as chemical regulation. In this context, it is appropriate for the ACCC to both respect and preserve current arrangements that provide state / territory government supremacy in such matters.

In this submission ADIA cites the regulation of teeth whitening products to illustrate the challenges that arise when a wayward regulator, in this case the ACCC, sets aside the effectiveness of existing regulatory regimes in order to pursue its own policy objectives. The references to the regulatory arrangements associated with teeth whitening products are tendered not to foster debate on the regulations or the effectiveness of specialist safety regimes, but simply to demonstrate that the latter are effective and that the ACCC needs to respect the same.

As with any aspect of dental product regulation, ADIA is a strong proponent of a regulatory framework that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. With respect to the regulation of dental products, ADIA believes that this outcome can be achieved when the TGA and state / territory governments with responsibility in this area can perform their functions without the intervention of the ACCC.

Section 3 – An Inconsistent & Uncoordinated Approach

There are two possible options for the regulation of teeth whitening products, these being via a Mandatory Standard or the prevailing state / territory regulatory framework supported by the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). There is broad consensus amongst government, business, healthcare professionals and consumers that the latter is working well.

The challenge for industry is that the ACCC has identified a third way unsupported by legislation. It has done this by publishing a “position” statement that has been developed in a manner that is inconsistent with existing regulatory controls.

Mandatory Standards —

Under the *Competition and Consumer Act (Cth) 2010* a Mandatory Standard can be issued that specifies minimum requirements that products must meet before they are supplied. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person. The purpose of a mandatory standard is to make particular safety or information features on products compulsory for legal supply of the product into the Australian market. It is an offence to supply goods that do not comply with mandatory standards.

ADIA supports the use of mandatory standards in circumstances where there is no alternative mechanism to provide for effective consumer protection such as with toys and certain safety products. Conversely, ADIA does not support the introduction of a Mandatory Standard where there are existing mechanisms to provide for consumer protection, such as for the control of therapeutic products and chemicals.

An important feature of a Mandatory Standard is that when considering whether such an instrument is necessary, the Australian Government conducts research and consults with industry and consumer representatives to develop a regulation impact statement (RIS). The RIS weighs up evidence of:

- Current market forces influencing the product and market;
- Causes of potential dangers;
- Options for reducing the risk for consumers; and
- Potential economic and social impact of regulatory and non-regulatory measures.

ADIA's support for Mandatory Standards, mirrored by stakeholders across both business and consumer groups is that the RIS process identifies risks, identifies other possible approaches and only then sees the introduction of new statutory controls once the full impact of their introduction have been assessed.

With respect to teeth whitening products, ADIA is not an advocate for this approach to be used to regulate the supply of teeth whitening products. It has only referenced this policy option to identify the possible regulatory options – and this option has been disregarded – for the ACCC to introduce product regulatory standards. ADIA is of the view that the existing state / territory government regulatory controls of the supply of teeth whitening products is adequate and should be accepted by the ACCC.

Regulatory Framework For Teeth Whitening Product Regulation —

The regulatory standards for teeth whitening products are set out in the SUSMP (also commonly referred to as the Poisons Standard) that are given effect by different, but broadly consistent, state / territory government legislation.

The SUSMP is a Legislative Instrument for the purposes of the *Legislative Instruments Act (Cth) 2003*. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons.

Scheduling is a national classification system that controls how medicines and poisons, in this case teeth whitening products, are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety.

As with Mandatory Standards issued pursuant to the *Competition and Consumer Act (Cth) 2010*, the controls associated with supply of medicines and poisons are made as a result of a transparent process that takes account of the input of all stakeholders which is considered by a statutory expert panel.

As stated earlier, this reference to the arrangements associated with teeth whitening products are tendered not to foster debate on the regulations or the effectiveness of specialist safety regimes, but simply to demonstrate that the latter are effective and that the ACCC needs to respect the same.

The framework for the supply of teeth whitening products, controlled as it is via the SUSMP referenced in state / territory government legislation, enjoys considerable support amongst industry, healthcare professional and consumer groups.

Teeth Whitening Product Regulatory Standards In Brief —

New regulatory standards for teeth whitening products that came into force on 1 May 2013, by way of an amendment to the SUSMP, clarified the continuation of general sales status (*i.e.* over-the-counter) for teeth whitening products containing 6% or less hydrogen peroxide and / or 18% or less carbamide peroxide, as long as they meet the requirements set out in the SUSMP.

Teeth whitening products containing concentrations of hydrogen peroxide and / or carbamide peroxide greater than this are permitted to be supplied by registered dental professionals as take-home kits to patients as part of their dental practice. The take home kits are an integral part of the professional teeth whitening procedure, which is initiated by the dental professional. Supply of these higher concentration products would only occur after an initial consultation in which the registered dental professional was satisfied that the patient was a suitable candidate for this treatment option. This is consistent with the Dental Board of Australia's Scope of Practice Registration Standards (June 2014).

In August 2014 the ACCC released a *Product Safety Bulletin* concerning teeth whitening products for at-home use that references teeth whitening products containing hydrogen peroxide and carbamide peroxide. Of concern is that it directly contradicts the SUSMP as referenced in state / territory government legislation.

ACCC Develops Its Own View On Teeth Whitening Products —

The ACCC has stated that that do-it-yourself teeth whitening products supplied for home use are consumer goods and cosmetics, notwithstanding the fact that they are also a chemical where arrangements for the lawful supply is set out in the SUSMP referenced in state / territory government legislation. In the aforementioned *Product Safety Bulletin* the ACCC has stated that:

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

The ACCC has stated that the basis for its intervention was media reports citing injuries associated with do-it-yourself teeth whitening products. Furthermore the ACCC has cited data from Australian Poisons Information Centres containing alleged reports of teeth whitening products causing injury; however, a review of these reports that were obtained by ADIA as a result of request made under the *Freedom of Information Act (Cth) 1982* established that these reports were non-specific and would, in the normal course of events, not be relied upon by government as a cause for regulatory reform.

The challenge is that the “position” as determined by the ACCC directly contradicts the framework for the supply of teeth whitening products set out in the SUSMP as referenced in state / territory government legislation, something confirmed by several jurisdictions in writing to ADIA.

As a result of the ACCC’s publication of a “position” on arrangements for the supply of a product for which there already exists effective regulation, there is considerable marketplace confusion.

ACCC Position Not Subject To Scrutiny —

The “position” taken by the ACCC has become a de facto regulatory standard, one that businesses observe. The outcome is that a new control exists on the supply of products that has not been subject to the scrutiny that typically exists when such instruments are introduced.

In the normal course of events, it could be reasonably expected that if the ACCC wanted to give practical effect to its “position” it would pursue this via one of two courses, these being:

1. An amendment to the SUSMP; or
2. The introduction of a Mandatory Standard.

Either of these options would require the ACCC to clearly articulate the need for reform, present the underpinning evidence for independent expert scrutiny and allow for all stakeholders to comment on the proposed changes. Furthermore, if the ACCC was to undertake the second course of action, this being the introduction of a Mandatory Standard, the potential economic and social impact of regulatory and non-regulatory measures would be assessed.

In establishing a “position” that has become a de facto regulatory standard, the ACCC has established market controls on the regulation of products that have not been subject to the normal processes of regulation making.

As stated earlier, this example associated with the supply of teeth whitening products is offered in order to demonstrate that insofar as the ACCC is concerned, it has failed to coordinate its activities with existing regulators and has acted in a manner that produces an inconsistent approach to regulation and has been taken independently of other regulators.

Section 4 – ADIA's Recommendations To The Commission

In undertaking this study of the ACL regulatory regime the Commission has stated that it will assess the issues through the broad prism of consumer welfare and regulatory efficiency. The information tendered by ADIA is designed to support the Commission's work in this regard.

To assist the Commission complete its study, ADIA respectfully suggests that the following be considered:

- The practical effect on businesses and consumers of the ACCC publishing a statement of “position” that becomes de facto product standards; and
- The appropriateness of the ACCC publishing a statement of “position” as opposed to seeking to achieve the same outcomes via conventional means (e.g. publication of a Mandatory Standard).

There is no doubt that in issuing a statement of “position” the ACCC has stated a position that is inconsistent with that of other specialist regulators – which is regrettable. In this context, ADIA respectfully suggests that:

- The Commission recommends that the role of specialist regulators such as the TGA and state / territory government agencies responsible for chemical regulation should be understood and respected by the ACCC; and
- The Commission recommends that the ACCC cease publishing statements of “position” that, in practice, become de facto regulatory standards.

The Commission has asked for guidance as to whether regulators have achieved proportionate, risk-based enforcement in practice. With respect to the ACCC's attempts to control the supply of teeth whitening products, there is a demonstrable failure to achieve this outcome.

Appendix A – Teeth Whitening Product Regulatory Standards

The regulatory standards for teeth whitening products that came into force on 1 May 2013 clarified the continuation of general sales status for teeth whitening products containing 6% or less hydrogen peroxide and / or 18% or less carbamide peroxide, as long as they meet the requirements set out in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Teeth whitening products containing concentrations of hydrogen peroxide and / or carbamide peroxide greater than this are permitted to be dispensed by registered dental professionals to patients as part of their dental practice.

Current regulatory standards —

The regulatory standards for teeth whitening products are set out in the SUSMP (also commonly referred to as the Poisons Standard) that are given effect by the following state and territory government legislation:

- Medicines, Poisons and Therapeutic Goods Act (ACT) 2012
- Poisons and Therapeutic Goods Act (NSW) 1966
- Medicines, Poisons and Therapeutic Goods Act (NT) 2012
- Health Act (Qld) 1937
- Controlled Substances Act (SA) 1984
- Poisons Act (Tas) 1971
- Drugs, Poisons and Controlled Substances Act (Vic) 1981
- Poisons Act (WA) 1964

It is important to note that these Acts referencing the SUSMP are the only legislation that pertain to the supply of teeth whitening products.

As the SUSMP entries limit dispensing of higher-strength teeth whitening products containing greater than 6% hydrogen peroxide and greater than 18% carbamide peroxide to “registered dental professionals to patients as part of their dental practice”, it is important that professionals dispensing such products be mindful of their obligations under the Health Practitioner Regulation National Law.

What products can be dispensed —

The entries for teeth whitening products containing hydrogen peroxide and carbamide peroxide of 6% or less hydrogen peroxide and 18% or less carbamide peroxide allow general sale (e.g. through supermarkets) of these products. In this respect there is no change to the regulatory controls for

these products from the arrangements that existed prior to the updated regulatory standards coming into effect.

From 1 May 2013, teeth whitening products containing concentrations of greater than 6% hydrogen peroxide and / or greater than 18% carbamide peroxide can only be dispensed by registered dental practitioners as part of their dental practice. It is expected that the practical outcome will be that after a patient consultation, a dentist can use both use higher-strength teeth whitening products within their surgery and also dispense patients with take-home kits. It is important to note that the policy on teeth whitening developed by the Dental Board of Australia (DBA) under Section 39 of the Health Practitioner Regulation National Law Act (National Law), as in force in each state and territory, states that teeth whitening products should only be used by a registered dental practitioner with education, training and competence in teeth whitening.

It is envisaged that the dental industry (*i.e.* product suppliers) is able to sell these products to registered dental practitioners (but not directly to the public) for this purpose.

Who can lawfully supply product —

State and territory government legislation permits the sale of teeth whitening products containing 6% or less hydrogen peroxide and / or less than 18% carbamide peroxide as general sales products, as long as they meet the requirements set out in the SUSMP. These include requirements that teeth whitening products containing between 3 and 6% hydrogen peroxide or between 9 and 18% carbamide peroxide to be clearly labelled as a Schedule 5 product. The SUSMP requires prominent warnings about ingestion and contact with skin, including Poisons Information Centre contact details, and the display of “CAUTION” on the front label.

Similarly, state and territory government legislation adopt the provisions of the SUSMP to permit the dispensing of teeth whitening products containing greater than 6% hydrogen peroxide and / or 18% carbamide peroxide by registered dental professionals to patients as part of their dental practice. These Schedule 6 products are required by the SUSMP to also include prominent warnings about ingestion and contact with skin, including Poisons Information Centre contact details, and the display of “POISON” on the front label. Suppliers of dental products are able to sell these higher-strength teeth whitening products to registered dental professionals only.

Appendix B – The Australian Dental Industry Association

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of dental products.

The ADIA membership ranges in size from the local operations of multi-billion dollar corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

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. To this end, ADIA is a strong advocate for reforms that cut red-tape and allow businesses in the dental industry to grow, create jobs and operate sustainably.

Australia's largest healthcare trade show, *ADX Sydney*, is convened biennially by ADIA and attracts nearly ten thousand stakeholders from across the Asia-Pacific's dental and oral healthcare community. ADIA also convenes regional trade shows in Adelaide, Brisbane, Melbourne and Perth that provide a platform for the growth of member businesses.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports skills development across the dental industry. An pioneering partnership with MEGT sees the group training model used to employ apprentices and trainees across the industry and the *CSU – ADIA Graduate Certificate in Small Business Management* provides support for mid-career professionals.

Consistent with ADIA's role as the peak body for manufacturers and suppliers, ADIA is a member of the Australian Chamber of Commerce & Industry (AusChamber), the nation's foremost grouping of employer organisations. Amongst other affiliations is ADIA's membership of the association of International Dental Manufacturers (IDM), the Swiss-based global body for the dental industry.

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

Appendix B – Abbreviations

ACCC	Australian Competition and Consumer Commission
ACCI	Australian Chamber of Commerce & Industry
ACL	Australian Consumer Law
ADIA	Australian Dental Industry Association
DBA	Dental Board of Australia
IDM	International Dental Manufacturers
RIS	Regulatory Impact Statement
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration

■ ADIA MEMBER BUSINESSES ■

3M Oral Care A.R. Medicom Acteon Australia / New Zealand A-dec Australia ADR Dental AHP Dental & Medical Ainsworth Dental Airport Function Centre AJ Barber Alldent Alphabond Dental Amalgadent Dental Supplies Ampac Dental Anthos in Australia ANZ Health AP Design Ark Health Auspharm Australasian Dental Practice Australasian Dentist Australian College of Dental Education Australian Imaging Australian Medical Suction Systems Babich Maintenance & Steriliser Services Bambach Saddle Seat Biodegree Biodental Technologies BioHorizons Australia Biomedex Biomet 3i Bite Magazine Body Logic Resources BOQ Specialist Borg Dental Bourke Dental Supply Carestream Dental Carl Zeiss Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates CMA EcoCycle Colgate Oral Care Coltene-Whaledent International Commodore Joinery Complete Financial Balance Critical Dental Curaden Swiss Data Vision Australia Dentacast Australia Dental Axxess Dental Business Brokers Dental Concepts Dental Depot (QLD) Dental Fitout Projects Dental Innovations Dental Installations Dentalife Dentaurum Australia Dentavision Dentequip Dentist's Choice Dentplex Dentpro Dentsply (Australia) Designer Surgeries Designs for Vision Digital Dental Discus Dental Australia DPL Australia Dunedin Dental Attachments Durodent Dental Supplies DURR DENTAL AG East Coast Dental Services ECOVIS Clark Jacobs Elite Fitout Solutions Empire Dental Devices Erskine Dental Essology Fairway Dental Finlease (Aust) First Dental GC Australasia Dental Geistlich Pharma Australia Glamsmile GlaxoSmithKline Gritter Dental Gulmohar Dental Gunz Dental Hayes Handpiece Australia Heine Australia Henry Schein Halas Heraeus Kulzer Australia HICAPS Hogies Australia Horseley Dental Supplies Hu-Friedy Mfg Co Inc ID Health Impulsdent Australia Independent Dental Supplies Inline Medical & Dental Innovatio Dental Supplies Ivoclar Vivadent Johnson and Johnson Pacific Kerr Corporation Leading Dental Levitch Design Australia Lorchant Dental Macono Orthodontic Laboratories Marda Investments Med & Dent (WA) Medfin Australia Medi-Dent Medical Dental Solutions NQ Medical Equipment Services Medifit Medigrow Medilend Melbourne Dental Miniflam Australia Minimax Implant (Dentium Australia) Mobile Clinics Australia (Kuipers) Mocom Australia Momentum Management Myofunctional Research Co NAOL Australia National Compliance Australia Neoss Australia Nobel Biocare Nova IT Group NSK Oceania One Dental Optima Healthcare Group Orien Dental Supplies Osseo Dental Osstem Australia Osteon Medical Ozdent Dental Products Australia Pegasus Dental Services Practice Sales Search Praktika Presidential Prime Practice Professional Dentist Supplies Profile Financial Services Purus Health and Medical Technologies RCR International Ridley Dental Supplies Right Time Business RJ Dental Sales & Service Roland DG Australia Rural Health Workforce Australia RutiniDent Dental Supplies SDI Ltd Sieverts Radiation Protection Consultancy Sirona Dental Systems Software of Excellence South Austral Southern Implants Australia Stoneglass Industries Straumann Suntech Dental Equipment Services Supreme Orthodontic Supply (Aust) Surgery Plus Solutions TrollDental Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Veden Australia VOCO Australia W&H Wellsites West Coast Dental Depot Whiteley Corporation William Green Wisbey Dental Xcellent Dental World XYZ Dental



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