Australian Dental Industry Association | ADIA

— Submission
Red Tape in Health Services Senate Inquiry

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products.

It addresses red tape in health services relating to the regulation of therapeutic goods, chemicals and poisons regulation, and diagnostic imaging equipment licencing.

Association of International Dental Manufacturers MEMBER

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Content

This submission is a response to the Senate Select Committee on Red Tape inquiry into Health Services. It has been prepared following extensive engagement with the membership of the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of more than 95% of products used in Australian dentistry.

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Executive Summary

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Senate Select Committee on Red Tape's inquiry into health services.

ADIA is a strong supporter for regulatory framework for dental products, and medical devices more broadly, 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. Red tape invariably leads to increases in treatment costs, limitations on the variety of treatment options, and the restriction of the growth, sustainability, international competitiveness, and job creation capacity of industry.

It is in this context that ADIA takes this opportunity to bring to the Committee's attention issues relating to the regulation of medical devices, Australia's annexation of overseas regulations, chemicals and poisons regulation, and licensing regimes for diagnostic imaging equipment. Based on feedback from businesses in the dental industry, ADIA tenders the following recommendations:

Recommendations —

1. The *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth)* should be passed by the Parliament without amendment.
2. The TGA should use the additional powers granted to it by the above bills to consistently and effectively halt and deter the illegal supply of therapeutic goods in the Australian market.
3. The Australian Government must ensure that regulatory harmonisation with the European Union (EU) is subjected to Australian Government policymaking standards and processes, including the requirement for a Regulation Impact Statement (RIS) to be undertaken.
4. The Australian Competition and Consumer Commission (ACCC) should amend its position and guidance with respect to teeth whitening products, deferring to the current state / territory regulations.
5. The Australian Government should consolidate the regulatory obligations of businesses with respect to the ownership and use of diagnostic imaging equipment via the introduction of national laws to replace the patchwork of disparate regulations and licensing arrangements across states and territories.

ADIA is confident that the recommendations above are practical solutions which would, if implemented, serve to improve the efficacy of regulation and cut unnecessary red tape that imposes cost on business. Further, ADIA publishes the *Australian Dental Industry Red Tape Index* which measures business sentiment regarding red tape that dental industry suppliers face, the latest edition of which is attached (Appendix A). ADIA looks forward to further engagement with the Committee concerning red tape in the health sector.

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Section 1 –

TGA Medicines & Medical Device Regulation

Issue Summary —

It could be reasonably argued five years ago that the regulation of medical devices by the Therapeutic Goods Administration (TGA) placed an unnecessary regulatory burden on industry; however, a current series of reforms is addressing concerns in this area. The reform program stems from the *Expert Panel Review of Medicines and Medical Device Regulation* (MMDR) that produced recommendations which have been accepted by the Australian Government.

The 2016 amendments to the *Therapeutic Goods Act 1989 (Cth)*, augmented by further reforms currently before the parliament, collectively reduce the red-tape faced by not only the dental industry, but the medical devices sector more broadly.

Keys Issues For Consideration —

The MMDR review, conducted over 2014 and 2015, was a comprehensive review of Australia's framework for the regulation of therapeutic goods. The (then) Minister for Health indicated that the Review was a key step in the efforts to remove ineffective regulation and encourage greater competition and innovation in the medicines and medical devices sectors and would complement the Australian Government's 'Innovation and Competitiveness Agenda'.

The objective of the MMDR was to remove or streamline areas of unnecessary, duplicative or ineffective regulation without undermining the safety or quality of therapeutic goods available in Australia. To this end it contained the following in its terms of reference:

> *A safe and effective regulatory framework for medicines and medical devices should balance safety and market access priorities to the benefit of patients and industry and align with the government's commitment to increase productivity and competitiveness.*
>
> Recommendation Twenty
> Review of Medicines and Medical Devices Regulation (2015

In order to achieve this, the scope of the review was to ensure that there is an appropriate balance between risk and benefit in the regulation of therapeutic goods. Further, the panel identified opportunities for reducing red tape burden in the short and long term.

Based on this, the review identified that greater flexibility in approval pathways for medical devices would improve the efficiency of market approval in Australia without compromising on the safety, quality, efficacy or performance of medical devices. An expanded range of approval pathways, particularly with respect to the recognition of assessment reports made in comparable regulatory jurisdictions to that of Australia, would, if implemented, significantly cut unnecessary red-tape, reduce compliance costs, and improve market access to quality and safe therapeutic goods.

The Australian Government in 2016 accepted a number of the key recommendations made by the review panel and has undergone a process of implementing the legislative changes necessary to implement these recommendations. Two Bills currently before Parliament deal specifically with the implementation of these recommendations. These are the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* and *Therapeutic Goods (Charges) Amendment Bill 2017*. The dental industry strongly supports the measures contained in these Bills which will cut red-tape and modernise Australia's regulatory framework governing the supply of therapeutic goods. In this context, the following issues should be considered by the Committee:

Third Party Conformity Assessment —

Under the current arrangements in the *Therapeutic Goods Act 1989 (Cth)*, conformity assessments can only be conducted by the TGA. The Bills amend the Act to provide the TGA with the power to designate a body or bodies located in Australia to undertake conformity assessments of medical devices for the Australian market. Such bodies would need to meet specific criteria established by the TGA following consultation with patient groups and industry as well as undergo ongoing compliance monitoring. The TGA would also retain the ability and capacity to undertake its own assessments.

There are multiple benefits associated with this amendment for patients, healthcare professionals, and industry. The presence of multiple third-party conformity assessment bodies would create competition in the delivery of prompt and high-quality product assessments in Australia and reduce the cost of assessment. These reduced compliance costs will reduce cost inputs in the supply of medical devices by the dental industry and as a result, patients will have access to more affordable oral healthcare. Likewise, patients, dental healthcare professionals, and industry alike will benefit from a more efficient product approval framework for medical devices that will broaden the range of medical devices, and therefore clinical options, that are available in Australia.

ADIA is of the opinion that, over time, this reform will provide a pathway for the dental industry and medical devices sector more broadly, to introduce new and innovative patient diagnostic and patient treatment options more quickly and cheaply than would otherwise be the case.

As the Australian Government does not provide significant funding to oral healthcare, compared to that which it provides to other healthcare sectors, the ability to rationalise and reduce the costs of product assessment and certification is an important mechanism with which it can improve oral healthcare affordability for Australians.

Improved recognition of comparable overseas regulators —

The MMDR review addresses the important question with respect to what exactly regulatory rules and procedures are trying to solve, and how effectively and efficiently they are doing this. To address this, the MMDR sought to determine in which ways the Australian regulator duplicates the efforts of other Australian and/or overseas organisations and, if so, whether this duplication resulted in enhanced protections for the Australian community or if it just slowed access by Australian consumers to innovative technologies. To this end, Bills

currently before parliament will amend the *Therapeutic Goods Act 1989 (Cth)* to improve Australian recognition of the work of overseas regulators.

The *Therapeutic Goods Act 1989 (Cth)* in its current form already allows for the use of work of comparable overseas regulators in evaluating the safety and efficacy of medicines. Likewise, the Act in its current form also allows for the TGA to utilise the work of comparable overseas regulators in evaluating medical devices, however to a limited extent compared to that of medicines.

The Bills will allow for the TGA to identify appropriate designating authorities responsible in jurisdictions (primarily in the European Union (EU)) that are comparable to its own standards that are applied to the conduct of conformity assessments and have effective systems and process in place to ensure that these standards are upheld by 'notified' bodies that undertake assessments. Conformity assessments produced by these designated authorities that have met appropriate criteria (such as technical competence, quality management systems, track record, and transparency) could then be accepted by the TGA.

ADIA supports these amendments which would product assessments conducted by overseas comparable regulators recognised by the TGA.

This would remove the need for onerous and costly duplication of conformity assessments and reduce delays in supplying safe and effective products in the market. Dental patients would therefore benefit from increased access to safe and effective treatment as well as reduced healthcare costs. The TGA's identification of overseas designated authorities based on strict criteria will ensure that that these assessments are conducted to an appropriate standard comparable to that of the TGA's own assessments and thereby maintain public safety.

Sanctions & Penalties —

Existing monitoring and punishment provisions in the *Therapeutic Goods Act 1989 (Cth)* do not allow the TGA to sufficiently address the illegal supply of therapeutic goods and the public is thereby exposed to unacceptable risk.

The Government accepted a recommendation made in the MMDR Review report that in reviewing the legislative framework underpinning the regulation of therapeutic goods, consideration should be given to the broadening of the investigation and enforcement powers available to the TGA, noting that '...broadening enforcement powers will benefit consumers'.

In keeping with this commitment, the *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth)* together will amend existing legislation to strengthen the Therapeutic Goods Administration's (TGA) statutory powers to address the illegal supply of therapeutic goods in Australia. This will be achieved through a significant and necessary expansion of the TGA's enforcement and investigation powers. The result of these amendments is a strengthening of the product safety outcomes that are the policy objective of the regulatory framework for the supply of therapeutic goods in Australia.

Under the Act, infringement notices are restricted to use in relation to alleged breaches where strict liability applies or where the office is associated with a

civil penalty. An infringement notice gives a person, to whom the notice is issued, the option of either paying the penalty set out in the notice to expiate the offence or contravention of a civil penalty provision, or electing to have the matter dealt with by a court.

The Australian Government has previously stated that the current arrangements associated with the issuance of an infringement notice are commensurate with the civil penalty provisions under the Act, the legal test being proof beyond reasonable doubt that the use of the therapeutic goods would be likely to result in harm or injury to a person.

Therefore, in circumstances where illegal supply can be proven but, by the nature of the medical devices supplied, no harm or injury to a person is likely the Act offers no effective deterrent to illegal supply. The TGA has therefore been powerless insofar as low-level infractions of the illegal supply provisions are concerned.

ADIA therefore supports without qualification amendments contained in these Bills which represent a significant improvement over the existing scheme which left many instances of illegal supply unaddressed, ADIA stresses the need for the TGA to act fairly, transparently and consistently. While the Bills will provide the TGA with broader statutory powers to issue infringement notices, the TGA must demonstrate that it is willing to use these powers to penalise illegal supply and should not exercise discretion in such instances. Requiring parties that have contravened the Act to undergo additional compliance training should therefore only be considered as an additional requirement in addition to a penalty rather than an alternative.

ADIA views the legislation before Parliament is a meaningful and practical demonstration of the Australian Government's commitment to reducing red tape for industry. These reforms contained in the Bills are long overdue and will ensure that the framework for dental products 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.

Recommendation/s —

1. The *Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 (Cth)* and *Therapeutic Goods (Charges) Amendment Bill 2017 (Cth)* should be passed by the Parliament without amendment.
2. The TGA should use the additional powers granted to it by the above bills to consistently and effectively halt and deter the illegal supply of therapeutic goods in the Australian market.

Section 2 –
Annexation of Overseas Regulations

Issue Summary —

The Therapeutic Goods Administration's (TGA) inappropriately literal of Recommendation Twenty of the review of medicines and medical devices regulations (MMDR) and its failure to adhere to Australian Government regulatory principles and procedures has resulted in the abrogation of the Australian Government's policymaking apparatus and its subordination to that of the European Union (EU).

Keys Issues For Consideration —

The Australian Government accepted Recommendation Twenty of the MMDR Review in which the Panel recommended that the regulation of medical devices in Australia should be aligned with that of the EU in order to improve harmonisation of regulation:

> *Recommendation Twenty*
>
> *The Panel recommends that:*
>
> 1. *The regulation of medical devices by the Australian NRA is, wherever possible, aligned with the European Union framework including in respect of the:*
>   a. *Classification of medical devices;*
>   b. *Essential Principles/Requirements.*
>   c. *Adoption of a risk-based approach to variations to medical devices.*
> 2. *Should the Australian NRA seek to apply specific requirements, there must be a clear rationale to do so.*
>
> Review of Medicines and Medical Devices Regulation
> Department of Health (2015)

Here the intention of the panel is clear; that Australia should align its medical device framework with that of the EU though only when there is a reason to do so. While ADIA is supportive of this in-principle, this is conditional on such reform aligning with an Australian Government approach to regulation making that requires government intervention is necessary – that is a demonstrated market failure exists (e.g. a risk to patient safety can be proven). It is not acceptable that Australia simply adopt EU Medical Device Directives without first assessing their relevance to Australia. Importantly, although this approach will create differences in Australian and EU regulatory standards for medical devices, it does not increase the regulatory burden on Australian business nor impede access to new and pioneering medical technology from overseas.

An excellent example of the TGA adopting EU regulations without identifying the need for government intervention in the Australian marketplace can be found with a proposal for manufacturers of implantable medical devices to provide a patient information 'card'.

In July 2017, the TGA proposed a regulatory change to require implant manufacturers to produce and provide a physical 'card' to patients. This change was proposed in order to align Australia's medical device regulations with those of the EU. set out in EU Directive 2017/745 and adopted in April 2017, requiring the provision of physical 'cards' for implants. The EU policy formulation requires that dental implants be subject to this requirement.

Australia's dental industry has raised a number of concerns with respect to this proposal – one that creates additional red tape – that subjects relatively low-risk medical devices such as dental implants to the same requirements as high-risk medical devices such as heart pacemakers. Here it can be readily argued the TGA has stepped award from its risk-based approach to regulation, something it argues underpins the entire medicines and medical device regulatory framework.

Over past decades successive Australian Governments have sought to ensure that that if regulation is used, the economic, social and environmental benefits must justify the costs, and that the distributional effects are considered and the net benefits are maximised. The *Australian Government Guide to Regulation* (2014) published by the Department of Prime Minister and Cabinet sets out the framework within which Australian Government departments must consider and develop regulation.

The only justification provided by the TGA in its consultation paper for the introduction of this regulation is regulatory harmonisation with the EU and a vague intent to 'improve information flow to patients and doctors'. No specific problems associated with existing information 'flow' were identified, nor were alternatives to regulation considered. This does not meet the Australian Government's policymaking standards which requires policymakers to;

> *Clearly identify where there is a legitimate reason for government to intervene... [and] identify alternatives to government action.*
>
> The Australian Government Guide to Regulation
> Department of Prime Minister and Cabinet (2014)

Further, the Department of Health has stated that TGA, acting on the advice of the Office of Best Practice Regulation (OBPR), is not required to create a 'new' regulatory impact statement on the basis that the adoption of the European Union's patient implant card requirement implements Recommendation Twenty of the MMDR.

ADIA has determined through a Freedom of Information request (FOI) tendered to the Department of Health that the regulatory burden costings associated with the Government's response to the MMDR was completed on 21 January 2016.

This means that the Department is relying regulatory burden costings from 21 January 2016 to justify its adoption of a EU regulation that was implemented on 5 April 2017 – over fourteen months later. It follows that the Department could not measure the regulatory burden of a proposal before it was even conceived.

In citing the costings associated with the Government's acceptance of the MMDR recommendation as commensurate to having measured the cost of all future proposals to harmonise with EU regulations, even those that do not yet exist, the Department is acting as if it possess a *cart blanche* to adopt any EU regulation without subjecting it to a regulatory impact statement or indeed, other Australian regulatory standards.

The TGA's failure to measure the cost of the regulatory burden of the implant card requirement constitutes a violation of the fourth principle of the Australian Government's policymaking framework:

> *Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.*

The Australian Government Guide to Regulation
Department of Prime Minister and Cabinet (2014)

If the Department continues to use Recommendation Twenty of the MMDR as justification to annex any and all European regulations without subjecting them to Australian Government policymaking standards and processes, it stands to reason that the Department has subjugated its policymaking powers to the EU. This is cause for grave concern among industry and has broad reaching implications.

The approach of the TGA could be reasonable seen as rendering Australia as little more than a legislative client of the EU; adopting without appropriate levels of scrutiny regulations that by their very nature of the decision-making process are products of compromise in order to reconcile the competing interest of different EU member states. In essence, Australia is simply adopting EU requirements without amendment; a notion that recent developments in EU membership have demonstrated is contentious even among European member states themselves.

Further, the TGA's unjustifiably literal interpretation of Recommendation Twenty insofar as it is used to justify the wholesale adoption of EU regulations without subjecting them to appropriate scrutiny undermines the Government's response to Recommendation Two and therefore represents an erosion of Australian sovereignty:

> ***Recommendation Two – Government Response***
>
> *The Commonwealth accepts Recommendations One and Two and recognises that maintenance of Australia's capacity to undertake assessments of therapeutic goods and of sovereignty of decision-making is an important assurance to consumers, and underlines Australia's strong reputation as a regulator of therapeutic goods.*

Recommendation Two
Government's Response to the Review of Medicines and Medical Devices Regulation (2016)

ADIA therefore objects in the strongest possible terms the *de facto* outsourcing of Australia's policymaking function to the European Union or other foreign jurisdictions based on an unjustifiably narrow interpretation of Recommendation Twenty of the MMDR Review.

Recommendation/s —

3. The Australian Government must ensure that regulatory harmonisation with the European Union is subjected to Australian Government policymaking standards and processes, including the requirement for a Regulation Impact Statement (RIS) to be undertaken.

Section 3 –
Chemicals & Poisons Regulation

Issue Summary —

Businesses in the healthcare sector face challenges in meeting their compliance obligations with respect to chemicals and poisons regulation as a result of the Australian Competition and Consumer Commission (ACCC) approaching product supply issues in a manner that is different from the prevailing and accepted state / territory government regulatory framework.

There are opportunities to reduce red-tape associated with chemicals and poisons regulation as a result of the ACCC withdrawing from this regulatory area and allowing the prevailing state / territory regulations to prevail.

Keys Issues For Consideration —

The ACCC has published product safety guidance that is inconsistent with prevailing state and territory legislation. In placing requirements on the supply of teeth whitening products in excess of those made under state and territory legislation, the ACCC is acting beyond of the remit afforded to it by the *Competition and Consumer Act 2010* (Cth).

The lack of clarity and certainty that has arisen from this unjustified regulatory duplication subjects industry to the costs of additional regulatory burden, limits treatment options available to healthcare professionals, and undermines the Australian Government's efforts to support the Council of Australian Government's (COAG) development of nationally consistent standards.

The ACCC in August 2014 published a 'Product Safety Bulletin' entitled '*What you need to know about: Safety of do-it-yourself (DIY) teeth whitening products for at home use*.' This bulletin is merely guidance that has no force in law. The bulletin advises that while the guidance contained therein 'does not apply to teeth whitening services provided by appropriately registered practitioners using chemicals and equipment on patients or clients in a surgery or commercial premises' it does apply to 'those service providers that also supply DIY teeth whiteners to their clients or patients for home-use'. Having established this, the bulletin advises that dental practitioners must 'not supply DIY teeth whitening products for home use that contain more than 6 per cent hydrogen peroxide or 18 per cent carbamide peroxide.'

The advice above is inconsistent with state and territory legislation governing the supply of scheduled substances. The *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*. It classifies poisons into schedules for inclusion in relevant legislation of state and territory legislations. It does not have any force outside of, or independent from, the effect it is given in state and territory legislation. The relevant state and territory legislation giving effect to the SUSMP are;

- *Poisons and Therapeutic Goods Act 1966 No 31 (NSW)*
- *Drugs, Poisons and Controlled Substances Act 1981 (VIC)*
- *Health Act 1937 (QLD)*
- *Controlled Substances Act 1984 (SA)*

- *Medicines and Poisons Act 2014 (WA)*
- *Poisons Act 1971 (TAS)*
- *Medicines, Poisons and Therapeutic Goods Act 2008 (ACT)*
- *Medicines, Poisons and Therapeutic Goods Act 2012 (NT)*

The legislation above giving effect to the SUSMP restricts the supply of teeth whitening products containing greater than 6% hydrogen peroxide and 18% carbamide peroxide to 'preparations manufactured for, and supplied solely by, registered dental practitioners as part of their dental practice'.

It should be noted that the SUSMP specifically uses the term 'supplied' rather than 'used'. The definition of 'supply', or activity of supply as otherwise understood, in all of the state and territory legislation above allows for the provision of teeth whitening products containing restricted concentrations of carbamide peroxide and hydrogen peroxide by dental practitioners to their patents. Therefore, advice provided by the ACCC that dental practitioners must 'not supply DIY teeth whitening products for home use that contain more than 6 per cent hydrogen peroxide or 18 per cent carbamide peroxide' is inconsistent with every state and territory's statutory implementation of the SUSMP.

Further, the ACCC's position is inconsistent with the expert clinical advice that informed the SUSMP. As the SUSMP was developed, the Department of Health & Ageing considered the option of restricting the supply of high-strength teeth whitening to use by dentists "for direct in-clinic use". However, the Department's final decision was remove the restriction 'for direct in-clinic use', thereby enabling dentists to supply products to patients for in-home use. The following rationale informed the decision;

> *The delegates have decided that the wording of the interim decision to list the highest strength teeth whitening preparations in Appendix C is to be amended to remove the restriction "for direct in-clinic use". The delegates considered this to be too restrictive to dental practitioners in the exercise of their professional practice and it did not accurately reflect the advice of the expert advisory committees.*
>
> Scheduling delegate's final decisions: Advisory Committee on Chemicals Scheduling
> Department of Health & Ageing (2013)

It is therefore clear that the ACCC's product safety guidance is inconsistent with both the legislative requirements of states and territories and the clinical expert rationale that informed their requirements. Further, the ACCC in placing requirements in excess of those made under state and territory legislation, is engaging in regulatory overreach beyond the remit afforded to it by the *Competition and Consumer Act 2010 (Cth)*. The result of this unjustified regulatory duplication is the imposition of costly regulatory and compliance burden on industry and the restriction of treatment options available to healthcare professionals' contrary to clinical expert advice.

If it is the intention of the ACCC to further restrict the supply of teeth whitening products beyond what is currently permitted in state and territory legislation it must apply for an amendment to the SUSMP through the *Scheduling Policy Framework for Medicine and Chemicals*. However, it should be noted that in the restriction for the sole supply of these products 'for direct in-clinic use' was considered by the scheduling delegates and ultimately removed as it was decided that the limitation was 'too restrictive to dental practitioners in the exercise of their professional practice and did not accurately reflect the advice of the expert advisory committees.'

Alternatively, the ACCC may issue a mandatory product safety standard through the *Competition and Consumer Act 2010 (Cth)* to further restrict the supply of teeth whitening products. However, it should be cognisant of both the aforementioned explicit rationale that informed the language of the SUSMP schedule entry as well as the resulting regulatory duplication that would both subject business to the costs of additional regulatory burden and undermine the Government's efforts to support COAG in the development of nationally consistent standards.

Recommendation/s —

4. The Australian Competition and Consumer Commission (ACCC) should amend its position and guidance with respect to teeth whitening products, deferring to the current state / territory regulations.

Section 4 –
Diagnostic Imaging Equipment Licensing

Issue Summary —

The dental industry is a key supplier of digital imaging technology that helps dentists to diagnose, plan and monitor treatments. The regulatory standards associated with the use, ownership and operation of this technology can be found in a diverse set of state / territory legislative standards. This results in additional compliance burden for suppliers in addition to those users operating across multiple state / territory jurisdictions.

The present state-based approach imposes significant red tape on industry and therefore warrants that the Australian Government consolidate the regulatory obligations of suppliers of diagnostic imaging equipment through the introduction of national laws.

Keys Issues For Consideration —

The regulation of the supply and use of diagnostic imaging equipment is currently governed by a combination of differing regulations and licensing regimes in states and territories. As is often the case where states and territories are tasked with administering regulations, there is inconsistency across jurisdictions with respect to the requirements and compliance obligations that the dental industry and oral healthcare professionals must adhere to.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) itself acknowledges that this inconsistency leads to difficulties in compliance for suppliers and healthcare professionals:

> *Differences in radiation legislation and regulatory policy among the nine jurisdictions can sometimes prove problematic for users of radiation sources operating in more than one jurisdiction.*
>
> Webpage: National Uniformity
> Australian Radiation Protection and Nuclear Safety Agency (Accessed 19/02/2018)

These inconsistencies make it difficult for the dental industry to furnish oral healthcare professionals across the country, and the compliance burden associated with it imposes costs on business. These costs are passed on to patients and governments in the form of increased diagnostic imaging costs.

The Australian Government has sought to address part of this issue through the development of the *National Directory for Radiation Protection* (NDRP) in cooperation with states and territories which acts as a uniform national framework for radiation protection in Australia.

While ADIA is supportive of the work of ARPANSA in seeking to improve uniformity of requirements across states and territories, a situation that until recently existed in Western Australia is an instructive example of the red tape that faces the dental industry.

Until November 2017, the Radiological Council of Western Australia (RCWA) required dentists to hold post-graduate degrees in maxillofacial radiology or oral radiology to own and operate cone-beam computed topography (CBCT) imaging equipment. This requirement was inconsistent and substantially onerous in comparison with those in other states and territories and had the practical outcome that virtually no dentist in the state could own or operate CBCT imaging requirement. This severely limited diagnosis options for Western Australian patients and increased the cost of treatment due to the need to refer patients to radiologists.

Following sustained advocacy by ADIA, the Western Australian Government announced in November 2017 that it would reform CBCT listening requirements to reflect a more appropriate framework consistent with other states and territories.

While ADIA is supportive of recent reform undertaken by the Western Australian Government, this episode is instructive of the problems associated with inconsistent requirements across states and territories that persist despite the best efforts of ARPANSA. Ultimately, there is justification for the Australian Government moving to consolidate the regulatory obligations of business via the introduction of national laws.

Recommendation/s —

5. The Australian Government should consolidate the regulatory obligations of businesses with respect to the ownership and use of diagnostic imaging equipment via the introduction of national laws to replace the patchwork of disparate regulations and licensing arrangements across states and territories.

ADIA An Introduction

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of ninety-five percent of the products used in Australian dentistry.

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

Abbreviations

ACCC	Australian Competition and Consumer Commission
ADIA	Australian Dental Industry Association
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
COAG	Council of Australian Governments
CBCT	Cone-beam computed topography
EU	European Union
IDM	(Association of) International Dental Manufacturer
MMDR	Review of Medicines and Medical Devices Regulation
NDRP	National Directory for Radiation Protection
RIS	Regulatory Impact Statement
SUSMP	Standard for Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration

ADIA MEMBER BUSINESSES

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