Australian Dental Industry Association | ADIA

ADIA Submission
EU Regulatory Alignment – Patient Implant Cards

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products. It addresses the proposed requirement for the provision of patient implant cards.

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Content —

This submission reviews the 'alignment with European medical device regulatory framework' consultation paper issued by the Therapeutic Goods Administration. 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) acknowledges and supports the Australian Government's commitment to harmonise Australia's medical device regulatory scheme with that of the European Union (EU); however, ADIA believes that this is best achieved in a manner that is consistent with both the Government's broader regulatory agenda and the Therapeutic Goods Administration's (TGA) own risk-based approach to regulation.

The Australian Government's regulatory principles require its agencies to consider regulation only when it offers the greatest net benefit. The TGA's attention is drawn to the considerable regulatory compliance costs that would be incurred by the dental industry, and ultimately born by patients through increased treatment costs, resulting from the proposed policy requiring the provision of patient implant cards.

ADIA acknowledges that the provision of patient implant cards could yield benefits for patients receiving active implants that are susceptible to failure (mechanical or otherwise), exogenous or environmental interference, or pose a high risk to the safety of patients should failure occur. In this context, the risk of dental implant failure is demonstrably low. Likewise, the nature of dental implants is such that information provided by patient implant cards would be of limited value to patients receiving dental implants. It is noted that healthcare professionals already have the information in accordance with the labelling requirements within the *Therapeutic Goods (Medical Devices) Regulations (Cth) 2002* and that this information could readily be furnished to a patient.

Following consultation with dental implant manufactures and other stakeholders in the dental industry, the adoption of the EU's requirements for patient implant cards is not warranted with regards to dental implants. The proposed reform is not supported by ADIA.

Given the costs of the regulatory compliance burden that the TGA's proposed reforms would place on dental industry suppliers and the absence of any evidence suggesting the safety of patients receiving dental implants would be improved, the proposed policy, insofar as it relates to the dental industry, fails to adhere to the Government's regulatory principles and the TGA's own risk-based approach to regulation.

ADIA does not have a position on the up-classification of surgical meshes and defers to the advice of the Medical Technology Association of Australia (MTAA) in this matter. The points of consideration laid out in this paper are made with respect to the provision of patient implant cards and their impact on the dental industry.

Recommendations —

1. The proposed exemption of dental fillings from the requirement of the provision of patient plant cards should be extended to include dental implants.

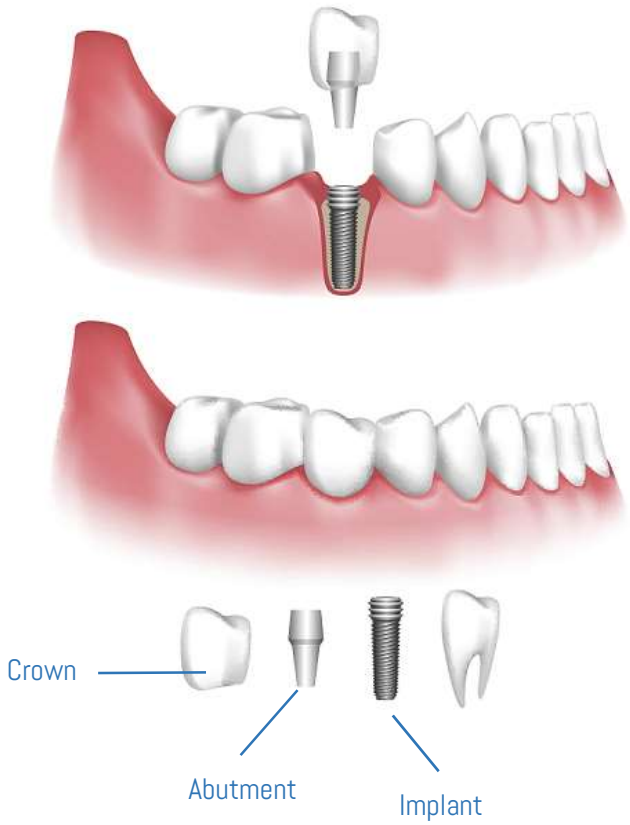
Section 1 –
Patient implant cards in the dental context

Dental implants have been iterated and developed over recent decades resulting in their modern state-of-the-art form being safe, durable, and stable.

They consist of three main parts; the implant screw itself, an abutment, and the crown (see figure below). The procedure for their placement takes careful planning on the part of a dental surgeon; however, it is relatively risk-free. A hole is drilled in the mandible into which the implant is inserted. An abutment is attached to the implant upon which the crown is installed. The screw is typically made of a material such as titanium that binds with the mandible through a process known as osseointegration.

Dental implants are relatively simple devices compared to other types of implants covered by the TGA's proposed regulatory reforms such as pacemakers or replacement joints. Dental implants contain no moving, electrical or mechanical components, and are constructed from stable materials due to decades of iteration resulting in a low risk of device failure.

The proposal by the TGA to require patient implant cards to be issued along with all implantable medical devices, in the form that has been proposed, would capture dental implants despite the exception of dental crowns (which have also been exempted in the EU legislation).



Section 2 –
Impact on industry and patients

The requirement for suppliers to ensure that implant cards are provided to patients is fraught with complexity for the industry and, as a natural consequence, will increase regulatory compliance costs. In many cases, dental implants pass through multiple parties including manufacturers, importers, wholesalers, suppliers, and finally healthcare professionals before they reach the patient. Each party will need to implement compliance measures for the scheme to effectively operate; adding administrative costs at every level. The resulting significant compliance costs for the dental industry will need to be fully studied. Increased compliance costs may ultimately be shifted on to the patient in the form of higher treatment costs.

In considering whether to adopt the EU's patient implant card proposals, ADIA recommends that this be approached in the context of the *Australian Government Guide to Regulation* that includes the following requirement on the TGA:

> *Remember that imposing disclosure obligations on a large number of businesses or community organisations can impose significant red tape burdens – make sure the problem you are trying to fix is large enough to justify the cost of compliance.* [1]

Advice to ADIA from the dental industry provides strong indications that if the TGA includes dental implants in new patient implant card proposals, the additional compliance costs will result in some products being withdrawn from the Australian market and increase the cost and complexity of the introduction of new dental implants.

For all the financial costs and negative externalities that this policy would impose on both the dental supply industry and patients alike, the benefits afforded to dental implant patients as a result are limited, not have they been identified by the TGA.

The value offered to patients by patient implant cards bearing the information required under the new EU regulations varies with respect to the type of implant being used. For example, warnings regarding the precautions one must take when fitted with a pacemaker are of significant relevance and value to a patient. The same degree of value however simply does not exist for patients receiving dental implants which require few precautions to be taken. The TGA's position that 'it would be inefficient to regulate a tongue depressor with the same rigour as a pacemaker' therefore also applies in this case. [2]

The provision of information to patients that is not actionable or consequential to their needs is of limited value to then. The TGA should therefore consider the value of the information provided to patients instead of pursuing disclosure for the sake of disclosure, particularly when regulations aimed at achieving this are burdensome to suppliers and patients alike.

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[1] Australian Government Guide to Regulation (2014). p. 23
[2] TGA Website: Article – The Regulation of Medical Devices (11 November 2011) – Accessed 25 August 2017

The use of dental implants to treat patients is currently done so as part of a broader treatment plan in which information relevant to the patient's individual needs is already disclosed by the healthcare professional. The current scheme is effective insofar as the healthcare professional, unlike the manufacturer or supplies, has both direct contact with the patient and an intimate understanding of their individual treatment. The TGA has not demonstrated that a systemic deficiency exists in the information provided to patients regarding their dental implants under the current scheme. Regulation in the absence of a clearly defined problem is incongruous the *Australian Government Guide to Regulation* which states that a regulator must;

- *Clearly identify and define the problem [they] are trying to solve.*
- *Demonstrate why it is a problem: are there risks or other dangers to be mitigated?*
- *Offer evidence about the magnitude of the problem and the costs of not doing anything.*
- *Explain which, if any, current government measures have sought to address this problem.*
- *Establish why those measures are not working.* [3]

Moreover, the proposed method of disclosure through the provision of physical cards is inconsistent with Australia's National Digital Health Strategy which aims at moving towards the digitisation the health service ecosystem to reduce administrative burden and improve service delivery. The TGA's proposal is incongruent with a critical success factor identified in the strategy requiring;

> *...commitment, cooperation and collaboration across all governments. Given the significant investment in digital health being made across health services and governments, a national approach must acknowledge, complement and build on these developments.* [4]

The TGA proposal that it is 'anticipated that information on implantable medical devices would increasingly be entered into a patient's MyHealth record in coming years' [5] insufficiently mitigates this problem as it stands to create onerous and costly duplication arrangements for both industry and government.

[3] Australian Government Guide to Regulation (2014), p. 17
[4] National Digital Health Strategy (2017), p. 52
[5] TGA, 'Alignment with European medical device regulatory framework' (2017) p.9

Section 3 –
Government's regulatory commitments and principles

The TGA is proposing that patient implant cards be provided for 'all implantable medical devices' except certain articles including 'dental fillings' to achieve alignment with the EU Medical Device Regulation that came into force in May 2017. Insofar as this is understood to mean that patient implant cards would be required to be issued with dental implants, ADIA believes that this approach is inconsistent with a number Australian regulatory guidelines and principles detailed below.

While intra-jurisdictional regulatory harmonisation can in some circumstances be beneficial it must not be allowed to evolve into the wholesale outsourcing of regulation policy development; particularly when doing so would result in the imposition of foreign regulations that do not satisfy the Australian Government's own regulatory principles and guidelines. This appears to be the case in this policy proposal.

The 'one size fits all' approach of the proposed change is inconsistent with the *Regulatory Performance Framework* that requires that;

> *Actions undertaken by regulators are proportionate to the regulatory risk being managed.* [6]

ADIA acknowledges the merit of the provision of patient implant cards for medical devices where the risk is high given the increased risk of failure associated with their complex construction and operation, their susceptibility to environmental or other exogenous factors, as well as the potentially severe consequences of their failure. Dental implants on the other hand pose by comparison inherently low risk both in terms of the likelihood of failure as well as the consequence of failure; both of which require consideration as per the *Australian Government Guide to Regulation*. [7]

With respect to dental implants, the design characteristics is that they feature no moving parts or joints, electrical or mechanical components, or fluids. Nor do they pose a significant risk to the well-being of the patient in the extremely rare instance of their failure resulting from their isolation from vital organs and ease of identification and correction. The evidence of these considerations is borne out in the TGA's own Database of Adverse Event Notifications where from July 2012 to May 2017 only a single instance of dental implant device failure was reported. [8]

There is no evidence to suggest that a patient implant card bearing the information prescribed in the proposed regulatory changes would have mitigated the failure of the implant or otherwise improve the patient's recovery. Consistent with the *Australian Government Guide to Regulation* it is incumbent on the TGA to provide this information when imposing new regulatory compliance burden on business:

> *The public [doesn't] just need to know what you've decided; they want to know why and on what information and arguments your decision was based'*. [9]

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6 Regulator Performance Framework (2014), p. 4
7 Australian Government Guide to Regulation (2014), p. 19
8 TGA Website - Database of Adverse Event Notifications (n.d.) accessed 1/09/2017
9 Australian Government Guide to Regulation (2014), p. 7

Subjecting low-risk dental implants to the same patient disclosure regime as active high-risk implants such as pacemakers, gynaecological meshes, breast implants, and hip implants is disproportionate with respect to the risk being managed. The proposed change is therefore not only inconsistent with the Regulatory Performance Framework but also the TGA's own risk-based policy;

> *Our 'risk-based' approach to regulating therapeutic goods is designed to ensure that regulation is only used where absolutely needed and, then, only to the extent needed to protect and advance public health. In practice, this means the level of regulation—and our regulation and compliance efforts—is commensurate with the risks posed by particular therapeutic goods.* [10]

Recommendation twenty of the *Expert Panel Review of Medicines and Medical Devices Regulation* which serves as the impetus for the proposed change itself not only specifies the 'adoption of a risk-based approach to variations to medical devices' but also recommends that 'should the (TGA) seek to apply specific requirements, there must be a rational to do so'. The TGA has failed to establish a rationale or case for reform with respect to dental implants outside the context of alignment with the EU.

The lack of consideration of other potential policy options, including the consequences of no regulatory change, is equally concerning. Despite the warning in the Australian Government Guide to Regulation that 'presenting one *fait accomplis* option is not acceptable', it appears that this is exactly what the TGA has done. Even the questions asked of stakeholders with respect to patient implant cards all presuppose the implementation of this single policy option and primarily focus on the technical details of its enforcement. Given that this policy would constitute more than a simple machinery of Government change, it is difficult to foresee how the TGA could effectively justify its implementation in the required Regulatory Impact Statement (RIS) in the absence of the consideration of alternative policy options. Likewise, no consideration is given to potential regulatory offsets that would be mandated in the RIS.

The TGA does not have the power to enforce the patient implant card policy that is being proposed. While the TGA has the power to regulate the supply of medical devices it concedes that it does not have the power to regulate healthcare professionals themselves.[11] This is key to the effective implementation of the proposed policy as patients do not receive implants and associated information from suppliers directly but rather from their healthcare professional. Therefore, the enforcement of the proposed requirements for the provision of implant cards to patients would instead fall under the auspice of the Australian Health Partitioner Regulation Agency (AHPRA).

Notwithstanding the impracticality of the enforcement of the proposed policy, it fails to adhere to numerous of the Government's own regulatory principles and, if it were to be adopted, would make the TGA's achievement of the Australian Government regulatory performance framework's KPIs problematic to say in the least.

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10 TGA Website: Product regulation according to risk (Undated - Accessed 25 August 2017) www.tga.gov.au/node/4046, accessed 1/09/2017

11 TGA Website: Article – What the TGA doesn't do (2 August 2011 – Accessed 25 August 2017) www.tga.gov.au/node/3830

Appendix –
Response to questions

Do you have any suggestions about effective ways to ensure that the patient ID card reaches the patient?

ADIA submits that as a best-practice approach to regulation requires that dental implants be excluded from the proposed regulatory reforms, thus the question is not relevant.

To 'ensure that the patient ID card reaches the patient' the TGA would be required to regulate not only medical device suppliers but also healthcare professionals themselves which fall outside of the TGA's legislative mandate and arguably the Australian Government's, with practitioner regulation being a matter for state / territory governments under the Australian Constitution.

Do you have any comments or suggestions on alternative or additional strategies to promote the provision of the implant card to the patient?

ADIA submits that as a best-practice approach to regulation requires that dental implants be excluded from the proposed regulatory reforms, thus the question is not relevant.

Mandating the provision of physical cards to patients is inconsistent with Australia's National Digital Health Strategy and the proposal to incrementally add this information to patients' Myhealth record would create onerous and costly duplication arrangements for both industry and government.

Are there any issues of unintended consequences that may arise out of this change?

The change would incur financial costs to Australian dental industry suppliers that may be passed on to patients in the form of higher treatment costs.

Advice to ADIA from the dental industry provides strong indications that if the TGA includes dental implants in new patient implant card proposals, the additional compliance costs will result in some products being withdrawn from the Australian market and increase the cost and complexity of the introduction of new dental implants.

In the context of the cost of a dental implant the compliance costs are high and, if the proposal is to be extended to include dental implants, is something that will need to be determined in the context of a Regulatory Impact Statement (RIS).

If there are issues, provide suggestions for mitigating them?

The proposed exemption of dental fillings from the requirement of the provision of patient plant cards should be extended to include dental implants.

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. A 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 (ACCI), 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.

In 2017 ADIA was named 'association of the year' by Associations Forum, a national body dedicated to supporting not-for-profit organisations on matters of governance, financial sustainability, policy advocacy and member engagement.

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 —

ADIA	Australian Dental Industry Association
AHPRA	Australian Healthcare Practitioner Regulation Agency
EU	European Union
IDM	(Association of) International Dental Manufacturers
KPI	Key Performance Indicator
MTAA	Medical Technology Association of Australia
RIS	Regulatory Impact Statement
TGA	Therapeutic Goods Administration