Australian Dental Industry Association

Ref: 4.8.5 — 16 December 2010

Ms Shelley Tang
A/g Branch Head
Office of Device Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Tang

RE: TGA Proposal – Reforms In The Medical Devices Regulatory Framework

The Australian Dental Industry Association (ADIA) is pleased to provide this response to the proposals from the Therapeutic Goods Administration (TGA) to reform the medical devices regulatory framework.

The attached response has been prepared following consultation with the ADIA membership that supplies approximately ninety-five percent of the dental product available in Australia. It is important to note that the TGA's suite of proposed reforms:

- Substantially alters the existing regulatory arrangements for business;
- Result in very large initial one-off cost to business and significant ongoing costs to business; and
- Introduce a number of regulatory requirements peculiar to Australia which will constitute a technical barrier to trade.

There is a need for the TGA to provide further evidence in support of its proposed reforms. In the documentation provided as part of this suite of proposals the TGA has not defined a market failure, regulatory failure, unacceptable hazard or risk or that suggests the latest proposals are in the public interest.

ADIA looks forward to working with the TGA in the development of a regulatory framework 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.

Yours faithfully

Troy R Williams AFAIM MAICD
Executive Officer

Encl.

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Australian Dental Industry Association Incorporated – ABN 32 003 314 396

Australian Dental Industry Association

Position Paper
Australian Dental Industry Association

TGA's Proposed Reforms In The Medical Devices Regulatory Framework

"We are aware that there are significant costs involved with these changes"

— Comment made at the TGA's Melbourne consultative forum on 23 November 2010 by Shelly Tang, A/g Branch Head, TGA Office of Devices Authorisation

Representing Dental Industry Excellence

Table of Contents

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Executive Summary

The Australian Dental Industry Association (ADIA) is the representative association for the manufacturers, importers and distributers for dental equipment and consumables (hereafter referred to as dental product) supplied in Australia. By the nature of products used in contemporary dental practice the majority of the dental product is classified as a "medical device" for the purposes of the *Therapeutic Goods Act (Cth) 1989* and ADIA members supply more than ninety-five percent of the dental product available in Australia.

It should be recognised that Australia has a system for the regulation of medical devices that is recognised internationally as first-rate. It escalates the regulatory barriers for supplying medical devices in a manner that is commensurate with the risk. Importantly, consistent with the framework established by the Global Harmonisation Task Force (GHTF), the regulatory system seeks to encourage convergence of regulatory practices amongst nations which is important given that Australia constitutes around two percent of the global market for medical devices and, with respect to dental product, more than ninety-nine percent is imported from overseas.

The attractive feature of the current regulatory regime is that it currently maintains a balance between regulatory requirements and risk, and the commitment to a globally harmonised regulatory framework. These features are placed at risk in the proposals outlined in the discussion paper. ADIA recommends a number of alternative solutions which allow the TGA to achieve the desired outcomes and maintains the attractive feature of the current regulatory regime.

ADIA has reviewed the proposals outlined *Reforms In The Medical Devices Regulatory Framework Discussion Paper* and consulted with its membership on the same. It is therefore able to tender the following advice:

General Comment – Regulatory compliance costs
The TGA's proposals substantially alters the existing regulatory arrangements for business and will result in a very large initial one-off cost to business and significant ongoing costs, particularly in the case of Proposal 3(i) and 3(ii).

General Comment – Demonstrated need for change
The TGA has not clearly identified problems that warrant the proposed changes or demonstrated that the proposed regulations are necessary and beneficial, therefore it is clear that the proposed regulations could be better designed.

General Comment – Implementation strategy
It is recommended that the TGA work with the peak representative bodies to develop an implementation strategy prior to the implementation dates. The desired outcome is to promote an awareness of, and compliance with, the changes in their final form.

With respect to the specific proposals, ADIA has reviewed the changes and made specific comments on those that will have a direct impact on the Australian dental industry.

Proposal 1 – Reclassification of joint implants
The proposed changes have no impact on the Australian dental industry thus the Association is not in a position to make comment.

Proposal 2 – Third party assessment bodies
The proposed change will have minimal impact on the Australian dental industry, however the change is supported.

Proposal 2B(i) – TGA Conformity assessment certificates
The proposed change will have minimal impact on the Australian dental industry, however the change is supported.

Proposal 2B(ii) – Premarket scrutiny for implantable medical devices
This proposal is not supported in its current form and ADIA has recommended an alternative solution that addresses the TGA's concerns.

Proposal 2C(i) – EU Notified bodies confidence building
This proposal is supported although it is not possible to determine at this stage the impact it will have on the Australian dental industry.

Proposal 2C(ii) – Australian thirty-party assessment body recognition
This proposal is supported as it will increase competition amongst assessment bodies that support the Australian dental industry.

Proposal 3(i) – ARTG Device inclusion methods
This proposal is not supported in its current form as it will add significantly to regulatory compliance costs and as a result resulted in higher patient charges for dental services. ADIA has recommended an alternative solution that addresses the TGA's concerns.

Proposal 3(ii) – Enhancing the identification of medical devices
This proposal is not supported in its current form as it will add significantly to regulatory compliance costs and as a result resulted in higher patient charges for dental services. ADIA further notes that the TGA's proposal is not clear thus needs to be drafted and subject to a further round of consultation.

Proposal 4 – Publishing medical device information on the website
This proposal is not supported in its current form as it will add significantly to regulatory compliance costs and as a result resulted in higher patient charges for dental services. Further, the TGA has not demonstrated that it is in the public interest to publish the range of information it has intimated.

Given that Proposals 1, 2, 2B(i) are supported, ADIA has not made further comment on them in this submission. Detailed comments are made with respect to the remaining proposals.

With respect to those proposals that are designed to increase transparency and the information available to the public and healthcare professionals, ADIA supports the underpinning principles. However, the proposals put forward by the TGA to achieve this policy objective are not supported as they substantially alter the existing regulatory arrangements for business and will result in a very large initial one-off cost to business and significant ongoing costs. We note that there has been little demonstrated demand for many of the changes from either the public or healthcare professionals.

ADIA looks forward to working with the TGA to further refine its proposals.

Troy Williams
Executive Officer
Australian Dental Industry Association

Sydney — 16 December 2010

Opening Comment — Adherence To Best Practice Regulation Principles

The proposals put forward by the Therapeutic Goods Administration (TGA), if implemented in their current form, will have the direct impact of significantly increasing the regulatory burden for sponsors of medical devices, and also delay the introduction of these devices to the Australian market. This is inconsistent with TGA's own view of its role, which is articulated as:

> *The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.*
>
> *The regulatory framework 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.*[1]

The proposals introduce a considerable regulatory burden that results in a very large initial one-off cost to business and significant ongoing costs to business which have not been properly identified by the TGA. The Australian Government's Office of Best Practice Regulation supports a rigorous system for assessing the impact of regulatory changes and promotes well-designed regulation by:

> *Requiring a case to be established for acting in response to a perceived policy problem, including whether regulatory action is required and whether the proposed regulation achieves the policy objective in a manner that minimises the costs for business and the community.* [2]

By any objective assessment the proposals, in their current form, do not meet this test as the arguments in support of the regulation are not strong or entirely absent with respect to some proposals.

The proposals also seek to introduce a number of reforms specific to the Australian market, thus establishing a technical barrier to trade. Australia is a participant in the The Global Harmonisation Taskforce (GHTF) and it is noted that the objectives of this organisation are:

> *to encourage the development of a harmonized regulatory environment, allowing for better protection of public health, and thereby facilitating the availability of medical technologies consistent with the state of the art and current knowledge.* [3]

Given that the proposed changes require changes to manufacturing process for medical devices manufactured overseas and supplied to the Australian market, the proposed changes are inconsistent with the goals that the GHTF is working towards. The result of these proposals is a greater divergence between the Australian framework for the regulation of medical devices and its overseas counterparts, both in GHTF participating nations and others.

Proposal 2B(ii) — Premarket Scrutiny for Implantable Medical Devices

Proposal:

Applications to be selected for auditing Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable medical devices to also be selected for an application audit prior to inclusion in the ARTG.

Background:

- The TGA proposes that Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations (Clth) 2002* be amended to require applications for all Class IIb implantable medical devices to be selected for an application audit prior to inclusion in the ARTG. Medical devices covered by classification rule 3.4 would be subject to this proposal and include maxillofacial implants in addition to bone screws, plates, pins and wires amongst other items.
- No transition period is proposed by the TGA for this part of the proposal. Any application received for these kinds of medical devices after the regulations come into effect will be selected for an application audit. An assessment fee will apply to these application audits and this will be explored in the cost recovery impact statement yet to be developed.

Nature of Change:

- The proposed change substantially alters the existing regulatory arrangements for business, thus it could not be considered a minor change in the context of best practice regulation making.

ADIA Position:

- The proposed changes are not supported in their current form.

The following is offered to allow the TGA to further refine its proposals so that they are consistent with the stated outcomes of the regulatory framework, this being “a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden”.

Problem Assessment:

- It is understood that the origins rest in a demonstrated regulatory failure, identified in the Health Technology Assessment in Australia review, in order to address perceived shortcomings of the TGA evaluation process.
- The TGA has yet to establish a case for proposing its reforms arising from concerns relevant to dental product. Thus the proposed imposition of an additional regulatory burden is inconsistent with an approach in which the level of regulation is commensurate with the risk.

ADIA Comment:

- In preparing a proposal that so as to ensure that TGA assessments support the work of related HTA agencies, the TGA has not identified the adverse implications for the dental industry and its work supplying dental product.

- The current framework that supports mutual recognition with major overseas markets is considered to serve the Australian dental industry well. It facilitates the introduction into the Australian market of dental product parallel to, or shortly after product has been released in the European Union, the United States or Canada.
- It is noted that under the system administered by the European Union, an application audit prior top placing a new medical device on the market is only required for higher-risk medical devices (Class III).
- With respect to Class IIb medical devices, the current requirements for a level two application audit are such that compliance with Essential Principles Schedule 1 – Risk Management), and Essential Principles 14, Schedule 1 (Part 8) – Clinical Evaluation is required by Sponsors of Class IIb medical devices. ADIA therefore notes that this constitutes the documentation required for application audit and, it having been tendered to the TGA in the initial submission.
- This proposal significantly increases the regulatory burden and costs of introducing new implantable medical devices to the Australian market and this is likely to have a negative impact on the access of dental product.

Cost Implications:

- In preparing the discussion paper the TGA omitted to include reference to the significant ongoing costs associated with this proposal.

Ongoing compliance costs

- This proposal alters existing regulatory arrangements for business and will result in significant ongoing costs.
- It is noted that the TGA has not identified the ongoing compliance costs that will be incurred by business associated with the proposal. This is a serious oversight.
- The proposal increases to more than $4,000 the fees payable by the Sponsor of a product to the TGA for each medical device. This is a significant increase on the $810 that is currently payable.
- It is estimated that additional regulatory compliance costs to suppliers of dental product are estimated at $50,000 to $100,000 for a Level 2 application audit with significant ongoing costs.

Improved Solution:

Minimum improvements

- That a risk management approach be taken where an application audit is required for types of medical device where safety or performance issues arise.
- That the TGA engage in further discussions to define what safety or performance issues may require an application audit.

Best practice regulatory approach

- That the TGA withdraw this proposal.
- Withdrawing the proposal naturally will not increase the cost of dental products.

Proposal 3(i) — ARTG Device Inclusion Methods

Proposal: Amend the way in which a kind of device is included on the ARTG.

Background:

- The TGA is proposing to require sponsors to itemise the devices and / or various models that are supplied under the same ARTG entry. Sponsors will be required to identify the different models in the application form, to be assessed by the TGA prior to making a decision to include the medical devices on the ARTG. If approved, this list of medical devices identified by model number or trade name will appear as a list of medical devices under the ARTG entry.
- It is proposed that this list of medical devices will be accessible to healthcare providers and consumers in the public view of the ARTG. As new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of medical device. This new model would undergo assessment if the kind of medical device is Class IIb or above, and if it meets the requirements for supply, will be added to the ARTG.
- The TGA believes that this amendment will lead to more detail about what medical devices are being supplied in Australia and: will enhance the regulator's ability to monitor the safety and performance of all devices of that kind supplied in Australia; will ensure that the device being supplied under a particular inclusion is the same kind of device; and enable healthcare providers and consumers to search the ARTG to find the device model.
- The TGA has stated that the assessment of the subsequent variations of devices will result in increased regulatory costs for pre-market assessment but will not impact on the annual charges paid by sponsors. It is proposed to have a transition period with no fees however a fee to vary the inclusion will be charged after this transition period.
- Sponsors will be required to provide this information for all models at the time of entering a new inclusion. Entries currently included at the time of legislative change will have to be updated within a time frame of one year from the legislative changes.

Nature of Change:

- The proposed change substantially alters the existing regulatory arrangements for business, thus it could not be considered a minor change in the context of best practice regulation making.

ADIA Position:

- ADIA accepts there is a need to improve the data on an ARTG entry to allow TGA staff, consumers and healthcare professionals to link a particular medical device with an ARTG entry, however the proposal in its current form is a highly undesirable way to achieve this.

- This proposal is not supported in its current form as it will add significantly to regulatory compliance costs and as a result resulted in higher patient charges for dental services.
- The proposal in its current form puts in place increased regulatory compliance obligations that are excessive to the task of securing the desired outcome.
- ADIA has proposed an alternative solution that assists the TGA achieve its outcomes in a manner that has a significantly reduced regulatory compliance burden compared to the TGA's initial proposal.

The following is offered to allow the TGA to further refine its proposals so that they are consistent with the stated outcomes of the regulatory framework, this being "a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden.

Ambiguity:

- The discussion paper states that "The TGA is proposing to review sponsors to itemize the devices and / or various models that are supplied under the same ARTG entry" and later states "If approved, this list of devices identified by model number or trade name will appear as a list of devices under the ARTG entry".
- In developing the proposal the TGA has failed to recognise that "devices", "model", "model number" and "trade name" are not the same thing from a sponsor's perspective. The TGA needs to clearly define what data it specifically wants on the ARTG entry cognisant of the fact that the selection will have a direct impact on compliance costs.
- It is also difficult to accurately identify what the TGA is seeking as the use of "and / or" and "or" is the discussion paper appears to suggest that a sponsor could itemise "devices", "model", "model number" and "trade name" interchangeably even though they are not the same thing.

Problem Assessment:

- Based upon the TGA's statements in the discussion paper it is assumed that the TGA believes that a regulatory failure has occurred. Given that the proposed change requires a changes to the *Therapeutic Goods Act (Cth) 1989* is it incumbent on the TGA to confirm this assessment or identify another reason as to why changes that incur a large one-off cost to business and significant ongoing costs are warranted.
- The TGA has yet to establish a case for proposing its reforms arising from concerns relevant to dental product. Thus the proposed imposition of an additional regulatory burden is inconsistent with an approach in which the level of regulation is commensurate with the risk.

ADIA Comments:

- As a matter of principle ADIA supports transparency in the decision making process and the provision of information to the public and healthcare professionals to assist them in making informed decisions.
- If the proposal is to be taken at face value, it would not be possible to supply the medical device until the application for a "new model" is processed. This being so, medical devices

may be unnecessarily withheld from the market place due to a modification that has no impact upon the operation, efficacy, safety or patient outcomes. This will result in necessary delays in introducing the latest product to the Australian marketplace.

- Advice to ADIA is that from the dental industry alone, the number of changes to ARTG entries arising from the need to comply with the proposal in its current form is likely to be in the range of fifty each week. When coupled with the total number out of the entire medical devices sector, it is likely that the TGA will need to process between five hundred and one thousand changes each week. This is likely to have a direct and adverse impact on processing times for other applications.

ARTG Entry information

- The TGA needs to more accurately identify what information it is seeking to be included on the ARTG as "devices", "model", "model number" and "trade name" are not the same thing.
- If the intent is simply to allow the TGA, Sponsor, consumer or healthcare professional to look at a medical device and verify that it is on the ARGT, the "trade name" should suffice assuming the IT infrastructure that supports the ARTG is modified to accommodate this as a search query, although the TGA has not stated that this will occur.
- If the TGA elects to use the "model", "model number" the workload associated with regulatory compliance significantly increases. ADIA has been advised by a Sponsor of an autoclave that there are four model numbers for a device that is identical in all respects except for that the casing is available in four different colours (white, off-white, grey and light brown). Similarly, a Sponsor of dental tools has indicated that many tools which are identical in all respects have two model numbers simply because there are left and right-handed versions of the same (the only difference being a bend in the metal shaft), this a minor change that no impact on the use, operation of efficacy of this medical device would require two changes to the ARTG entries. These are not isolated examples as the dental industry has advised that as many as five thousand "model numbers" apply to less that two hundred devices which are the same in all respects except for a few minor details. This situation is clearly absurd.

Defining A New Model

- The discussion paper indicates that "As new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device".
- There is a need for clearly define what constitutes a new "model", that is to specify at what point in time the ARTG entry needs to take place. With respect to equipment, a change to the colour of control panel fascia may constitute a new model thus trigger the need to update the ARTG entry,

changes are benign and do not affect device's use, operation, efficacy or in any way affect patient health outcomes.

IT Requirements

- In its discussion paper the TGA has correctly identified that "Changes to the IT system will need to occur so that sponsors can enter/change/add to the list of products under each entry".
- The TGA has not indicated that it will update the public ARTG website interface that would facilitate a search by "devices", "model", "model number" and / or "trade name". Without this change the benefits of the proposal are negated as it will not be possible to achieve none of the stated outcomes of the proposal, that being to "enable healthcare providers and consumers to search the ARTG to find the device model".
- The TGA could revise its eBusiness portal to allow Sponsors to update an ARTG entry on a fee-free basis.

Implementation timeframe

- The discussion paper indicates that sponsors will be required to provide the additional information at the time of entering a new inclusion and this is supported.
- With respect to ARTG included at the time of the legislative change the discussion paper indicates a one year time frame to update entries. If the proposal is adopted in its present form Sponsors of dental product will be required to include nearly thirty thousand new data items in the various ARTG entries, indeed one Sponsor will need to include an additional eight thousand data items. Fast-tracking amendments to ARTG entries to meet the twelve month compliance window will result in a very large initial one-off cost to business.
- In order to reduce the regulatory compliance costs associated with the proposal ADIA recommends a three-year implementation timeframe.
- In its current form the proposal is inconsistent with the *OECD Guiding Principles for Regulatory Quality and Performance* as the proposals, in introducing requirements specific only to the Australian market, introduce unnecessary barriers to trade and investment. The proposal, contrary to the OECD guidelines, further limit market openness in the regulatory process and also serve to weaken economic efficiency and competitiveness.

Cost Implications:

- In preparing the discussion paper the TGA omitted to include reference to the fact that there is a very large initial one-off cost to business and significant ongoing costs.
- During a public consultation forum held on 23 November 2010 in Melbourne the Acting Branch Head, TGA Office of Devices Authorisation did state "*We are aware that there are significant costs involved with these changes*".

Initial one-off costs

- This proposal alters existing regulatory arrangements for business and will result in a very large initial one-off cost to business.

- It is noted that the TGA has not identified the initial one-off costs that will be incurred by business associated with the proposal, this is a serious oversight.
- The proposal in its current form will require Sponsors of product to update current ARTG entries with the model number of each type of therapeutic device. It is important to note that the dental industry will be required to provide nearly thirty thousand new data items in the various ARTG entries over a twelve month period.
- Given the need to fast-track compliance, it is estimated that this will increase regulatory compliance costs to industry by 1.0% to 1.5% in the initial twelve months.
- There are a range of additional costs associated with this proposal such as the need to provide advice and guidance to staff within a business about the changes and additional regulatory compliance obligations associated with updating an ARTG entry each time a model number changes.

Ongoing compliance costs

- This proposal alters existing regulatory arrangements for business and will result in significant ongoing costs.
- It is noted that the TGA has not identified the ongoing compliance costs that will be incurred by business associated with the proposal other than the need to pay the required fee to vary an ARTG entry, this is a serious oversight.
- As noted the proposal is expected to require the dental industry to enter and maintain nearly thirty thousand new data items in the various ARTG entries. To ensure that the data is properly maintained businesses, both large and small, will need to amend their regulatory compliance frameworks. Advice available to ADIA is that, as a minimum, some four thousand ARTG entries will need to be amended on an annual basis and it is estimated that this will increase regulatory compliance costs to business by 0.75% on an ongoing basis.

Improved Solution:

- The TGA has yet to establish a case for proposing its reforms and it needs to address whether regulatory action is genuinely required and that the proposed changes achieves the policy objectives in a manner that minimises the costs for business and the community.
- Before proceeding with the proposed changes further, ADIA recommends that consistent with the framework established by the Australian Government's Office of Best Practice Regulation, the TGA should review the range of alternative options to provide an adequate analysis of the costs and benefits of the feasible option.
- Notwithstanding the need for the TGA to address the aforementioned issue, specific to the current proposal ADIA proposed both minimum improvements and a second set that s consist with a best practice regulatory approach and these are listed below.

…/cont.

Minimum improvements

- That the proposal be amended to remove the ambiguity thus specify whether it is the "model", "model number" or "trade name" that is to appear in an ARTG entry and prior to selecting an option, the TGA properly identifies the ongoing costs associated with each option (they are not the same).
- That the TGA engages with the *TGA Regulatory & Technical Forum for the Devices Sector* to define what constitutes new model which would trigger an update to the ARTG.
- That the TGA upgrade the public ARTG website interface that would facilitate a search by the relevant data string (the TGA's selection of "model", "model number" or "trade name").
- That the TGA reconfigure its eBusiness portal to allow a Sponsor to include the new information on a fee-free basis.
- That the proposal be implemented 24 months from the amendment of the *Therapeutic Goods Act (Cth) 1989.*

Best practice regulatory approach

- That the proposal be amended to require only a "trade name" that is to appear in an ARTG entry.
- That the TGA engages with the *TGA Regulatory & Technical Forum for the Devices Sector* to define what constitutes new model which would trigger an update to the ARTG.
- The TGA could revise its eBusiness portal to allow Sponsors to update an ARTG entry on a fee-free basis.
- That the TGA upgrade the public ARTG website interface that would facilitate a search by the relevant data string (the TGA's selection of "model", "model number" or "trade name").
- That the proposal be implemented 24 months from the amendment of the *Therapeutic Goods Act (Cth) 1989.*

Proposal 3(ii) — Enhancing The Identification of Devices

Proposal: Enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

Background:

- The TGA is also proposing to amend the legislation to require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device (e.g. the product labels, instructions for use or packaging of the device).
- This is expected to increase visibility of the ARTG number for medical devices to enable healthcare providers and consumers to easily identify medical devices approved for supply, and assist in cross referencing the device with the ARTG record. This change will also greatly enhance the TGA's ability to identify, and better manage those medical devices that have been supplied to the Australian market without first gaining approval by the TGA.
- This amendment is in line with medicines regulations which require the AUSTR or AUSTL number on the label.
- The TGA has stated that this change should not adversely impact on regulatory costs as sponsors are already required to publish their contact details on the information that accompanies a medical device. This amendment would only require sponsors to add the ARTG number to their contact details.
- The TGA proposes to implement this proposal 12 months following the amendment of the regulations.
- Sponsors will be required to label all devices with the ARTG number in accordance with Regulation 10.2 (amended) and essential principle 13.2 *Information to be provided with medical devices – location.*

Nature of Change:

- The proposed change substantially alters the existing regulatory arrangements for business, thus it could not be considered a minor change in the context of best practice regulation making.

ADIA Position:

- The proposed change is not supported.
- The TGA has already proposed arrangements that allow the public and healthcare practitioners to clearly identify whether a medical device appears on the ARTG, thus this proposal change is unnecessary.
- The proposal carries a very large initial one-off cost to business and significant ongoing costs.

The following is offered to allow the TGA to further refine its proposals so that they are consistent with the stated outcomes of the regulatory framework, this being "a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden."

Ambiguity:

- There is a lack of consistency in the discussion paper which makes it difficult to fully understand what the TGA is seeking to achieve – does it want the ARTG number on the "device", "product labels", "instructions for use", or "packaging" of the device.
- The discussion paper states that "The TGA is also proposing to amend the legislation to require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device (e.g. the product labels, instructions for use, or packaging of the device)". This is inconsistent with another section of the discussion paper that states "Sponsors will be required to label all devices with the ARTG number in accordance with Regulation 10.2 (amended) and essential principle 13.2 – Information to be provided with medical devices, location)".
- The contradiction can be found in the fact that Essential Principle 13.2 states that it must appear on the device "unless it impracticable" and only then can it appear on the packaging, leaflet, in printed documents or other appropriate media.
- The TGA has added further confusion as in assessing cost implications the TGA has stated that "This change should not adversely impact on regulatory costs as Sponsors are already required to publish their contact details on the information that accompanies a medical device" which is inconsistent with Essential Principle 13.2 which permits this option only "unless it impracticable" to include the information on the device.

Problem Assessment:

- Given that the proposed changes to the Regulatory amendment, it is required that the TGA to demonstrate that the TGA clearly define a market failure, regulatory failure or unacceptable hazard or risk. None of these have been identified in the position paper prepared by the TGA.
- Before pursuing any change in this area, the TGA needs to further review the matter and clearly identify the problem or issues that give rise for the need for action.

Proposal Comments:

- As a matter of principle ADIA supports transparency in the decision making process and the provision of information to the public and healthcare professionals to assist them in making informed decisions.
- The proposal in its current form does not make it clear whether the ARTG number is to appear on the "device", "product labels", "instructions for use", or "packaging" of the device. Each option has a differing regulatory compliance option and therefore cost.
- Of the dental product in Australia is it estimated that some 99.8% by item quantity (around 98% by value) are manufactured overseas, thus the proposals that will require Australian only production runs for dental product. The consequence of this is that it will [a] increase costs of dental product in Australia and [b] lead to Sponsors withdrawing product from Australia as it is no longer commercially viable to supply it locally.
- The proposed twelve months timeframe will introduce an

excessive regulatory compliance obligation on business given the reliance of Sponsors on dental product and packaging produced overseas which will need to be designed in meet requirements specific only to Australia.

- In its current form the proposal is inconsistent with the *OECD Guiding Principles for Regulatory Quality and Performance* as the proposals, in introducing requirements specific only to the Australian market, introduce unnecessary barriers to trade and investment. The proposal, contrary to the OECD guidelines, further limit market openness in the regulatory process and also serve to weaken economic efficiency and competitiveness.

Cost Implications:

- The TGA has incorrectly assumed that "This change should not adversely impact on regulatory costs", a statement that has no basis in fact and the proposal should not be allowed to progress on this basis.
- In preparing the discussion paper the TGA omitted to include reference to the fact that there is a very large initial one-off cost to business and significant ongoing costs.

Initial one-off costs

- This proposal alters existing regulatory arrangements for business and will result in a very large initial one-off cost to business.
- The proposal states that "the TGA proposes to implement this proposal 12 months from the amendment of the regulations". This is an impossibly tight timeframe that will lead to dental product that is currently in the marketplace being subject to a recall. Further, the recalled dental product and dental product that is currently in production or in a Sponsor's storage facility will need to be destroyed and replaced with new product. It is estimated that this will increase regulatory compliance costs by 2.0% to 3.5% in the initial twelve months.

Ongoing compliance costs

- This proposal alters existing regulatory arrangements for business and will result in significant ongoing costs.
- The proposal states that "Sponsors will be required to label all devices with the ARTG number …" and the major cost of this is the need for Australian-only production runs for the 99.8% of dental product (by quantity) that is supplied in Australia. The alternative is to have equipment labeled in Australia.

Improved Solutions:

- The TGA has yet to establish a case for proposing its reforms and it needs to address whether regulatory action is genuinely required and that the proposed changes achieves the policy objectives in a manner that minimises the costs for business and the community.
- Before proceeding with the proposed changes further, ADIA recommends that consistent with the framework established by the Australian Government's Office of Best Practice Regulation, the TGA should review the range of alternative options to provide an adequate analysis of the costs and

benefits of the feasible option.

- Notwithstanding the need for the TGA to address the aforementioned issue, specific to the current proposal ADIA proposed both minimum improvements and a second set that s consist with a best practice regulatory approach and these are listed below.

Minimum improvements

- That the TGA remove the ambiguity in its proposal to require that the ARTG number on the information that accompanies the medical device (as opposed to the medical device itself or packaging).
- That the proposal be implemented 24 months from the amendment of the regulations.
- This is the lowest-cost option although still inconsistent with the stated outcomes of the regulatory framework, this being “a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden.”

Best practice regulatory approach

- That the TGA withdraw this proposal. The outcome is largely achieved by proposal 3(i) that will allow the TGA, the public or healthcare professionals to identify whether a device appears on the ARTG.
- Withdrawing the proposal naturally will not increase the cost of dental products.

Proposal 4 — Publication of device product information

Proposal: Publication of device product information on the TGA website.

Nature of Change:

- The proposed change substantially alters the existing regulatory arrangements for business, thus it could not be considered a minor change in the context of best practice regulation making.

Background:

- Currently the TGA publishes limited information about medical devices included on the ARTG. The information can be viewed through the publicly accessible version of the ARTG, published on the E-business TGA website.
- Currently, available information is limited to: Label name of the inclusion; identity and address of the sponsor; identity and address of the manufacturer; conditions applied to the entry; the product identified by GMDN code; effective date of the inclusion; intended purpose of the device; and unique device identifier (for Class III and AIMD's only).
- By comparison, the FDA publishes far more comprehensive information about a range of approved devices. This information can be, but is not limited to: General announcement of a device approval; copy of the approval letter; summary of safety and effectiveness data; instructions for use; patient instructions; and web links to general resource information – NIH information, clinical papers, etcetera.
- Product Information (PI) is data that provides health professionals with a summary of the essential scientific information to allow the safe and effective use of a medicine under nearly all circumstances. As a condition of registration certain medicines, mainly those prescribed by a doctor, are required to have a PI document which provides information relating to the safe and effective use of the medicine, including information regarding the medicine's usefulness and limitations. PI documents are agreed with the Therapeutic Goods Administration (TGA) as part of the medicine's approval process before it can be made available in Australia. The information in these documents assists doctors, pharmacists and other health professionals in prescribing and dispensing medicines and also in their consultations with patients, such as to better educate a patient on the medicine they are being given. PI should contain the following information: Name of the medicine; description; pharmacology; clinical trials; indications; contraindications; precautions; adverse effects; dosage and administration; overdosage; presentation and storage conditions; name and address of the sponsor; poison schedule of the medicine; and date of approval.
- In the interests of improving the transparency and accountability in our decision making processes, the TGA is proposing to develop a similar program for medical devices. The TGA is seeking advice in relation to the publication of such information about medical device assessments. Specific

issues which need to be addressed include the types or classes of devices which should be included in such a scheme such:

a. Only higher risk classification devices such as Class III and AIMD;
b. All medical devices including lower risk classification devices;
c. All higher risk medical devices, and 'more interesting' lower risk devices where the technology is new or innovative for example.

- The TGA has sought comment on the information which should be included when published, including the depth of that information and responsibility for authorship of the information (i.e. the manufacturer or the TGA).
- The TGA is also seeking advice whether to publish, or not, information relating to rejected applications and should all rejections be published, including lower risk classifications such as Class I and II? The TGA is also considering the information which should be released if the application is rejected and the reasons for rejection.

ADIA Position:

- The proposed change is not supported in its current form. Although as a matter of principle ADIA supports transparency in the decision making process, the proposal goes beyond what is necessary to achieve this.
- ADIA supports the publication of information about medical device assessments only for higher risk medical devices including Class III and AIMD.
- The proposal to publish information on rejected applications is not supported in any form.
- The proposal carries a very large initial one-off cost to business and significant ongoing costs.

The following is offered to allow the TGA to further refine its proposals so that they are consistent with the stated outcomes of the regulatory framework, this being "a risk management approach designed to ensure public health and safety while at the same time freeing industry from any unnecessary regulatory burden."

Ambiguity:

- It is acknowledge that the discussion paper states that the TGA is canvassing a range of options including whether: Only higher risk classification devices such as Class III and AIMD; all medical devices including lower risk medical devices; all higher-risk medical devices and 'more interesting' lower risk devices where the technology is new or innovative for example.
- Before proceeding further the TGA needs to clearly articulate what its preferred option is as the impact on business is varies considerably with each option.

…/cont.

Problem Assessment:

- The discussion paper has not established a market failure, a regulatory failure that an unacceptable risk or hazard exists to warrant the proposed change.
- It is acknowledged that there may be grounds on social goals / equity issues (such as individuals or groups being unable to access available market information) for the proposed change, however the discussion paper has not articulated a demand from Government, business, the public or healthcare professionals for the proposed change.

Proposal Comments:

- As a matter of principle ADIA supports transparency in the decision making process and the provision of information to the public and healthcare professionals to assist them in making informed decisions.
- ADIA supports the publication of information about medical device assessments only for higher risk medical devices including Class III and AIMD.
- If the proposed framework was applied to all classes of devices, the becomes a considerable disconnect between the regulatory burden and compliance costs to the product and the risk associated with it, particularly for Class I and Class IIa devices.
- It is acknowledged that information tendered to the TGA to support its decision making process may be made available to a third-party (*i.e.* other than the TGA and the applicant) as a result of a Freedom of Information (FoI) request. This is acceptable as such information is provided in the context of the application and other documents to support the application, and it is reasonable to assume that a third-party seeking this through the FoI process will understand the context. However for the TGA to publish the information on its website the very real prospect of it being taken out of context occurs as documents may readily be accessed out of context and / or on an individual basis as a result of an internet search engine search (*e.g.* Google or Yahoo).
- The possibility that the TGA will publish information which may be taken out of context will require sponsors to carefully review what information is supplied to the TGA, subjecting it to review, editing and legal check, thus increasing the regulatory compliance costs to business.
- With respect to the publication of information concerning rejected applications, this is inconsistent with making information available concerning medical devices that are available (as opposed to not available) to the market.

Cost Implications:

- As the TGA has not identified its preferred option it is not possible to fully assess the costs to business associated with the proposal.
- Any decision to require additional information to be published will result in ongoing compliance costs, with their being an escalation in costs commensurate with the amount of information the TGA requires to be published.

Improved Solution:

- As the TGA has has not established a market failure, a regulatory failure that an unacceptable risk or hazard exists to warrant the proposed change nor demonstrated that there are social goals / equity issues (such as a demand from individuals or groups being unable to access available market information) that require the proposal to be progress, it is recommended that it be withdrawn.

Achieving
Best Practice Regulation

The proposals in their current form include a very large initial one-off cost to business and significant ongoing costs to business which have not been identified by the TGA, or have been seemingly dismissed. In this environment is not advisable for the TGA to proceed with the changes until the costs have been properly quantified.

A Regulatory Impact Statement (RIS) is required as the proposals in their current form will have a significant regulatory impact on business and substantially alter existing arrangements.

Given that the proposals carry a significant costs and are likely to restrict competition, there is a need for the TGA to clearly articulate what the change is necessary. The position paper released by the TGA does not identify a market failure, substantial regulatory failure, unacceptable hazard or risk nor has it demonstrated a demand amongst the public or healthcare professionals that would warrant change based upon social goals / equity issues (such as individuals or groups being unable to access available market information, goods or service).

Closing Comment — Supporting a failing regulatory framework

As a matter of principle the Australian Dental Industry Association (ADIA) supports the work of the Therapeutic Goods Administration (TGA) in reviewing the regulatory framework established by the *Therapeutic Goods Act (Cth) 1989* to ensure that it reflects the needs of contemporary healthcare. For this reason ADIA acknowledges and commends the TGA on putting forward the proposed changes and engaging in a process of industry consultation, a process that has allowed ADIA to recommend changes that minimises the adverse impact that the proposed changes in their unaltered form would have. However, ADIA believes that the TGA has a more urgent policy priority, this being to address the purchase and subsequent supply of medical devices via the internet.

It is acknowledged that the TGA currently has no jurisdiction to address the importation of medical devices via the internet. Thus its first policy priority should be to work with the relevant Australian Government departments agencies to full identify the extent of the problem, verify the risks to consumers and patients and identify possible solutions.

ADIA recommends a whole of government approach to the issue.

In the current environment in which medical devices are imported and distributed into Australia via the internet the framework established by the *Therapeutic Goods Act (Cth) 1989* is increasingly being rendered irrelevant – it is a failing regulatory framework. That the TGA continues to argue that it is an issue for another arm of government is the metaphoric equivalent of the boy plugging a hole in the dyke with his finger whilst the boy entire dyke structure are swamped by a tsunami.

The need for urgent action is best demonstrated by the TGA's proposals which, if adopted in their current form, will result in a very large initial one-off cost to business and significant ongoing costs. These are only costs borne by companies that supply product through legitimate channels. Individuals and companies operating outside legitimate channels and import product via the internet are not burdened by the costs associated with the proposed regulatory changes and therein have a commercial advantage.

Whilst the importation of medical devices via the internet is permitted to go largely unchallenged, any increases in regulatory compliance cost serve only to make more attractive the option of importing medical devices via the internet.

ADIA reaffirms its commitment to work with the TGA to achieve its stated outcome in a manner that does not unnecessarily increase compliance costs, however it is respectfully suggested that the first policy priority should be to address the importation and subsequent supply of medical devices via the internet.

1 *What The TGA Does* (www.tga.gov.au/about/tga.htm) — Therapeutic Goods Administration, Accessed 7 Dec 2010
2 *Best Practice Regulation Handbook* — Department of Finance & Regulation, 2010
3 *GHTF Guiding Principles* — Global Harmonisation Task Force, May 2005

Introduction — Australian Dental Industry Association

The Australian Dental Industry Association (ADIA) is the national organisation representing the interests of companies that supply dental products and services to dentists and allied oral healthcare professionals. It represents approximately two hundred and fifty companies that supply around $800millon of dental product and consumables in Australia.

The Association was formed in 1925 when representatives from the various dental trade houses in Sydney, Melbourne and Adelaide met to safeguard the interests of the nascent dental industry. Harmed by the unethical practices, poor standards and suspect salesmanship of the time, it was agreed that there was a mutual benefit in coming together to regulate and improve business practices – as a result of ADIA's work the actions and reputation and integrity of the dental industry have markedly improved.

Over the years the services provided by ADIA to support the dental industry have evolved and the *2010-15 ADIA Strategic Plan* outlines a range of initiatives to assist the dental industry understand and influence the commercial, technical and regulatory environment in which the dental industry operates.

The Association is the organiser of the nation's premier dental trade show, the highly acclaimed *ADX Dental Exhibition.*

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.

ADIA provides advice to agencies including the Therapeutic Goods Administration (TGA) and the National eHealth Transition Authority (NeHTA), often nominating industry representatives to government committees and working groups.

ADIA 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).

At an international level, ADIA is a members 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*.

More information can be found online at www.adia.org.au

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