Australian Dental Industry Association

Submission to
The Australian Government
Regulation Taskforce

Reducing the Regulatory Burden on Business

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Introduction

Who is the Australian Dental Industry Association (ADIA)?

The Australian Dental Industry Association is a long established association representing 140 number of companies who are primarily involved with the supply of products and services used by the dental profession Our purpose is to advance and represent the interests of the member companies , for the, the community and the oral health care of all Australians.

Why we are interested in making a submission

The ADIA believes it is timely to make this submission in the lead-up to the implementation of the Trans Tasman Regulatory System for Medical Devices. Prior to the establishment of this new body it is important to review the revisions to the Therapeutic Goods Act 1989 enacted in 2002, which will constitute the regulations in the new Trans Tasman Regulatory System.

Section 1: Comments on the Regulatory Compliance Burden for Medical Device Companies in Australia

1.1 Background to the regulation of Medical Devices in Australia by the Therapeutic Goods Administration

In Australia, Medical Devices are regulated under the Therapeutic Goods Act (1989) which is administered by the Therapeutic Goods Administration (TGA).

In 1992 the Commonwealth Government, on advice from the TGA, approved revisions to the *Therapeutic Goods Act 1989*, and regulations, where they applied to the supply and export of Medical Devices in Australia. The revised legislation introduced a regulatory model similar to (but not identical with) the system developed by the European Union.

One of the main objectives of the new system was to incorporate principles of risk management in that:

1. Medical Devices were classified according to the risk posed by their use.

2. The assessment procedures manufacturers' used to confirm their devices were safe and effective and were commensurate with the risk classification of the device.

3. Independent and certificated verification of the manufacturer's assessment procedures for higher risk Medical Devices was required. Manufacturers of the lowest class of Medical Devices were not required to have an independent verification audit.

4. The revised system was predicated on striking a balance between pre-market approval and post-market surveillance activities.

The revised legislation was also introduced to demonstrate the Australian Government's commitment to the work done by the Global Harmonization Task Force (GHTF). The goal of GHTF is to provide a collaborative forum for representatives of member nations' regulatory authorities and industry representatives from the European Union, the United States of America, Japan, Canada and Australia, to promote international convergence in regulatory requirements and practices, in particular to:

- Promote the safety, effectiveness/performance and quality of Medical Devices

- Encourage technological innovation

- Foster international trade

- Serve as an information exchange forum through which countries with Medical Device regulatory systems under development can benefit from the experience of those with established systems and/or pattern their practices upon those of GHTF documents

The GHTF accepts that participating regulatory authorities have the right to regulate domestically according to their sovereign regulations.

1.2 ADIA view on the regulation of Medical Devices by the TGA

ADIA supported the 2002 revision of the *Therapeutic Goods Act (1989)* and regulations to provide a harmonized regulatory model for Medical Devices.

Industry support was based on three important factors:

- The incorporation of a risk based approach to regulation.

- Harmonisation with the regulatory systems of Australia's manufacturing suppliers, both in terms of the actual content of the legislation and the TGA's interpretation and administration of the regulation.

- Cost effectiveness

It was industry's expectation that the harmonized system would reduce regulatory duplication and shorten the approval time to allow Medical Devices onto the Australian market. Three years into the new system for Medical Devices, ADIA now believes this expectation has not been fulfilled. Australian manufacturers and importers face considerable difficulty and costs in moving to the new model. Transition of products has proved to be slow and there is a real risk of products (manufactured locally or imported) not being available to consumers in Australia.

ADIA believes that the majority of current problems for industry result from the regulations' deviation from the European framework with which they were originally intended to be harmonized. The resulting extra work for many Australian Sponsors and their suppliers, on top of regulatory work performed and approved elsewhere in the world, means the Australian system is currently duplicative, difficult and expensive. Even though the new regulatory system is in its early days, ADIA believes that the signs are already becoming obvious that it will negatively impact the growth of the Australian industry and ultimately affect consumer access to state-of-the-art technology.

There is an urgent need to review the Australian regulatory system for Medical Devices. This is particularly relevant due to the rapidly approaching

end of the transition period for all devices to be transferred to the new harmonized system by October 2007. A review is also timely considering the current development of several new legislative instruments, including the Trans Tasman legislation and the IVD regulatory framework due to be implemented in mid 2006.

1.3 Regulations

In the following section of this submission, ADIA would like to comment on several problem areas for industry arising from the current Medical Device regulatory system.

a) TGA monopoly on conformity assessment for Australian manufacturers

The revisions to the *Therapeutic Goods Act 1989*, enacted in October 2002, mandated inspections by the TGA of Australian Medical Device manufacturers who wished to supply their products in Australia. The same Act permits the TGA to accept CE certification for Medical Devices manufactured overseas, even if those products are the same as those manufactured in Australia. Australian manufacturers are therefore put at a distinct disadvantage in terms of direct costs and opportunity costs when compared with their overseas competitors.

What is the regulation?

Regulation 4.1(1) of the Therapeutic Goods (Medical Devices) Regulations 2002.

What is the underlying objective of the regulation?

The objective is to verify, through an independently certified and on-going auditing program, that a manufacturer of a Medical Device has developed and implemented appropriate conformity assessment procedures for their products.

Does it achieve its objective?

The regulation does appear to achieve its objective in terms of safety, performance for patients and users of Medical Devices but the costs of the domestic inspections together with the limited auditing resources in the TGA and the agency's time delays, are putting Australian manufacturers at a significant trade disadvantage without a concomitant regulatory benefit.

In what way does the regulation impose a burden on business?

Australian manufacturers of Medical Devices now have to bear a higher

regulatory cost than their direct competitors from overseas. Some Australian manufacturers are moving their operations off-shore with the consequential loss of jobs and skills.

Although it is difficult to determine actual costs, the following table illustrates the point. This comparative data on regulatory cost and approval time ratios has been compiled by an Australian Medical Device manufacturer supplying in both Australia and Europe. While it is a single example of a current device it does serve to make some comparisons with the European system.

	Europe	Australia
Market size	10	1
Regulatory cost ratio	1	3.6
Market cost recovery ratio	1	36

This table shows it is 36 times more difficult for this company to recover regulatory costs from sales in Australia than in Europe. This situation is created by compulsory TGA inspections, the associated fees and the small size of the market.

Initial costs for these inspections typically range from approximately $20,000 to $200,000 (if the device contains an unapproved medicinal component) with costs of $6,000 for regular surveillance audits every 12 to 20 months.

Significant delays in the inspection program have also created distinct marketing delays for Australian manufacturers. TGA who have a monopoly as the only regulatory approval body, across all risk classes, is proving to be slow compared to other regulatory agencies.

What is the opportunity cost?

Short approval times are very important for the Medical Device industry as the industry is characterised by rapid technological development and relatively short windows for returns on investments. Australian manufacturers are at a distinct marketing disadvantage when compared with their overseas competitors. This is because the current regulatory requirements do not allow them to choose an acceptable accreditation body apart from the TGA to enable them to get their product to market quickly. In many cases the companies have a working relationship with certifying bodies through their QA certification and have been granted a CE mark. This certification is recognised in Europe but is not recognised in Australia.

For many examples, it is ultimately Australian patients and users of Medical Devices who lose the opportunity to quickly benefit from using high quality Australian-made devices.

Who pays the costs?

The cost of regulation of dental products is reflected in the cost of products and this is ultimately born by the consumer. Indirect costs for the Australian

economy also accrue when Australian companies are compelled to move their operations off-shore to supply back into Australia.

In what way is the burden imposed by the regulation unnecessary, or in what way is the regulation unnecessarily complex, taking into account the objectives of the regulation?

The TGA accepts certification from overseas Notified Bodies for products which present the same risk as those manufactured in Australia. The revised legislation has been in effect for three years and the TGA has not demonstrated that their mandated certification program of Australian manufactured devices has resulted in better benefits for Australian patients than those provided by imported and approved products.

The TGA may argue that the revised legislated requirement for conformity assessment procedures by manufacturers, combined with independent verification auditing programs, has produced an effective regulatory system, at least in a pre-market sense. However, the costs that the Australian industry has had to bear have been totally disproportionate.

Could the regulation and / or its administration be reformed or simplified to reduce the compliance burden on business, while still allowing the underlying policy objective to be achieved? If so, how?

By permitting Australian manufacturers to choose a TGA acceptable certification body, either based in Australia or overseas, to verify and certify their conformity assessment procedures would be a simple and extremely effective reform to reduce the current compliance burden. This would then approximate practices which have been adopted by all other major health regulators, including the US FDA.

Could any alternatives achieve the underlying policy objective while imposing less of a burden on business? If so, how?

The concept of manufacturers undertaking conformity assessment procedures and having those procedures verified through independent auditing programs has been the result of many years of negotiations, often at the international level. Proposing an alternative to that concept would not be conducive to further the cause of fostering international trade and converging regulatory requirements. The main issue of contention is how it has been interpreted domestically and imposed on the Australian industry. The answer lies as for the previous section, namely, permitting choice of acceptable certification bodies for Australian manufacturers of Medical Devices.

The Australian Government has committed to the work of the Global Harmonization Task Force (GHTF) and yet is not implementing systems that reflect international practice.

b) GMDN coding system adopted by the TGA

While the industry recognises that the regulator needs a uniform system for the identification of devices, the selection of the GMDN has complicated the regulatory burden for our industry.

What is the regulation?

Regulation 1.7 of the Therapeutic Goods (Medical Devices) Regulations 2002.

What is the underlying objective of the regulation?

The objective is to identify devices being registered on the ARTG.

Does it achieve its objective?

The objective is achieved to the extent that the system identifies devices with a code, but the shortcomings of the system lead to a burden on Australian sponsoring companies.

What are the shortcomings of the GMDN coding system?

The GMDN coding system has a number of major shortcomings

1. Manufacturers in many parts of the world are not familiar with the GMDN coding system. While European manufacturers are aware of the system they are not required to use it in a regulatory environment. In the USA, the country producing the largest amount of dental products, the GMDN system is not used and is virtually unknown.
2. The range of GMDN codes is incomplete and the device descriptions often misleading. The GMDN is deficient in having no suitable codes in other areas.
3. The TGA's on-line registration system DEAL does not facilitate the easy identification and use of the GMDN coding system.
4. Australia is the first country to use the GMDN in a regulatory environment.

In what way do these shortcomings impose a burden on business?

1. As the GMDN code system is not familiar to many manufacturers they have not coded products to this system. This then becomes a burden for the Australia company sponsoring the device as they have to identify and apply a code.
   Even when a manufacturer can supply a code, the code cannot be keyed directly into the application as the layout of the TGA website does not permit this.
2. The use of the GMDN code system has created many difficulties for business. Not all the products used in Australia have a GMDN code however companies do not know this when initiating an application whether or not the code they seek is in the system. Consequently much time can be wasted searching for non-existent codes. If a code

is not on the list, an application can be made to GMDN through TGA for a new number. This is a very time consuming matter and because the issuing of new codes by GMDN can take many weeks, listings of new products on to the register are delayed. Alternatively, a direct application for a new code costing E700 can be made to GMDN.

Even if a device is on the list and because descriptions can be misleading, much time can be wasted finding the correct device. The TGA website does not permit searches by GMDN code.

While the device list is limited, the balance to this is the products that could be grouped, such as dental instruments, are instead listed individually adding considerably to the cost of industry's TGA administration. As part of TGA's brief is to provide cost effective health care to the community, this is not achieved when the burden of additional listing costs is placed before industry.

3. The TGA's on-line registrations system, DEAL, does not specifically ask for the GMDN Codes, only the description that goes with the code. Even the slightest variation in the description can lead to a misclassification and/or rejection of the application. This can be an expensive mistake for industry. There is no link between the GMDN code for a product and the Risk Classification. This has lead to the same product being classified and coded differently for different Sponsors. The lack of consistency identifying the correct GMDN code and the correct Risk Classifications of a product is costing the industry time and money.
4. The inability of the DEAL system to identify any basic mistakes in the Classification and Coding of products leads to increased numbers of applications being rejected.
5. As Australian is the first country to use the GMDN in a regulatory framework, shortcomings of the system become problematic and burdensome on Australian sponsoring companies. The Licensing arrangements the TGA currently has with GMDN are restrictive in the way the GMDN can be view and used by Australian companies. The arrangements are not flexible enough to allow Australian industry easy access and searching of the GMDN system

Who pays the costs?

The cost of Australia's adoption of the GMDN is borne by Australian companies sponsoring product on the ARTG.

How could the regulations be reformed to achieve the objective while not increasing the burden on business.

There needs to be a review of the GMDN as applied in the Australian regulatory framework. The Risk Classification of devices should be taken into account in order to group Devices under a single code. This would achieve the risk objective of the TGA, reduce the number of individual Devices

requiring registration on the ARTG and therefore reduce the regulatory burden on Australian sponsoring companies.

c) Inability to change sponsor without a new application

Under the previous regulatory system for Medical Devices (active prior to 2002 and until Oct 2007 which marks the end of the transition period to the new system) it was possible to change product sponsor automatically, with a simple notification to the TGA. The same applies to the system currently used by the TGA to regulate medicines.

Under the definition of "kind of Medical Device" in the Act, certain variables are listed which, when changed, require a new inclusion on the ARTG and a new application. Probably unintentionally, "Sponsor" is listed as one of these variables.

What is the regulation?

Kind of Medical Device – Section 41BE of the Act.

What is the underlying objective of the regulation?

To ensure that all documentation is supplied to the TGA in its correct current form and linked to the correct sponsor.

Does it achieve its objective?

It does achieve its objective but the requirement is duplicative, expensive and has poorly defined timeframes.

In what way does the regulation impose a burden on business?

Change of sponsor is a frequent occurrence in industry as distribution arrangements constantly change. It can also occur very quickly. The current process, requiring a separate application and approval step, incurs all the fees related to a new application process. Industry finds it difficult to plan for sponsor changes as the approval timeframes are not predictable.

This issue has been brought to the TGA's attention, and they have agreed to treat each sponsor change on a case by case basis. ADIA believes this approach does not fix the underlying problem and lacks transparency. As for other therapeutic goods sectors, sponsor changes for Medical Device Sponsors need to be supported by a short and transparent regulatory process.

What is the opportunity cost?

While Medical Device Sponsors are caught in the window between changing Sponsor and the application approval, they are not permitted to legally supply their products. This presents lost marketing opportunities and threatens consumer access to important therapeutic goods.

Who pays the costs?

Industry pays the cost as marketing opportunities are potentially lost over the window period between change of sponsor and the application approval. Australian healthcare consumers also pay the cost as devices previously approved and available through another commercial source become unavailable until they are re-evaluated and re-approved by the TGA.

In what way is the burden imposed by the regulation unnecessary, or in what way is the regulation unnecessarily complex, taking into account the objectives of the regulation?

If the product being transferred to another sponsor is included in the new harmonized system under a current inclusion, regulatory documentation should be in order. ADIA believes that it should be part of the transfer process for each sponsor to check this and agree on currency.

It should not be necessary for the complete regulatory submission (which may have been recently reviewed and approved) to be re-approved on change of sponsor.

Could the regulation and / or its administration be reformed or simplified to reduce the compliance burden on business, while still allowing the underlying policy objective to be achieved? If so, how?

ADIA believes that sponsor transfer should be automatic, with a simple notification to the TGA, as for the previous Medical Devices system and for other therapeutic goods. The regulation should be revised to provide for a transparent abridged process to allow automatic sponsor transfer for the Medical Devices sector.

CONCLUSION

The ADIA urges the Australian Government Regulation Taskforce to seriously consider the issues of regulatory burden and inequities which exist under the current regulatory system for Medical Devices before they are enshrined in the new legislation for the Trans Tasman Regulatory Agency. The regulatory issues raised in this paper are those that have arisen from new or amended legislation or are the products of Australian Government regulation duplicating international regulation.

These issues put Australian manufacturers at a distinct disadvantage in terms of direct and opportunity costs and negatively impact the growth of the Australian industry.

While Australian Government policy signs up for mutual recognition and global harmonisation, the regulations put in place create unique Australian requirements that are burdensome, inefficient, add cost to the Australian healthcare system, provide no additional benefit to the community and ultimately result in reduced choice of products for Australian healthcare workers and their patients.