22nd November 2005

Ms. Vickii Wales
Regulation Taskforce
PO Box 282
BELCONNEN ACT 2616

Dear Ms. Wales,

Thank you for the opportunity to provide a submission to the Regulation Taskforce. The Medical Industry Association of Australia Inc submission is enclosed.

The Medical Industry Association of Australia Inc represents more than 150 manufacturers, importers and distributors of medical devices and diagnostic reagents in Australia.

The Association's membership plays a vital role in the Australian health care system by supplying non-pharmaceutical medical devices and *in-vitro* diagnostics to hospitals, medical professionals and patients.

We welcome the Taskforce's inquiry as it provides the opportunity to examine and recommend reform to aspects of the health care system.

We would welcome the opportunity to expand on our submission through any planned hearing process.

Yours sincerely

Brian Vale
Chief Executive Officer

Enclosure: MIAA Submission

Medical Industry Association of Australia

Submission to
the Australian Government
Regulation Taskforce

Reducing the Regulatory Burden on Business

November 2005

Contents

Introduction

Who is the Medical Industry Association of Australia (MIAA)?

MIAA is the peak industry body representing the $3 billion medical device and *in vitro* diagnostics industry, inclusive of manufacturers, importers and distributors of medical devices and diagnostic reagents. Our members account for over 85% of the non-pharmaceutical products used in the diagnosis or treatment of disease.

The 150 or so member companies of MIAA play a vital role in the healthcare system by supplying non-pharmaceutical medical products to hospitals, medical professionals, insurers and patients. Products range from familiar items such as syringes and wound dressings through to high-technology implanted devices, hospital capital equipment, sophisticated diagnostic products, self-care items and laboratory consumables.

MIAA is affiliated with like industry bodies in the USA, Japan, Europe, New Zealand and Canada and participates extensively in the Global Harmonisation process for medical devices, ensuring a move towards converged or harmonised manufacturing and regulatory standards. This supports public safety and assists with containing healthcare costs.

Why we are interested in making a submission

MIAA believes it is timely to make this submission in the lead-up to the implementation of the Trans Tasman Regulatory System for medical devices and diagnostics. 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.

This Regulation Task Force also occurs as Australia approaches the introduction of a new regulatory framework for all *in vitro* diagnostic (IVD) products supplied in Australia.

The MIAA also works with Government departments on Commercial and Taxation issues to improve the efficiency of transactions involving their jurisdictions. This submission provides an opportunity to review issues where a more efficient procedure would benefit both parties.

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

1.1 Background to the regulation of medical devices and *In Vitro* Diagnostics (IVDs) in Australia by the Therapeutic Goods Administration

In Australia, medical devices and *in vitro* diagnostic (IVD) products 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 of the Global Harmonization Task Force (GHTF). The goal of GHTF is to provide a collaborative forum for representatives of member nation's 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.

Under the auspices of the National Coordinating Committee on Therapeutic Goods (NCCTG), the TGA is currently developing a regulatory framework for all IVD products supplied in Australia. As for the medical devices framework, the upcoming IVD system appears to be based on the European system with the inclusion of certain GHTF recommendations.

1.2 MIAA view on the regulation of medical devices and *in vitro* diagnostics by the TGA

MIAA supported the 2002 revision of the *Therapeutic Goods Act (1989)* and regulations to provide a harmonized regulatory model for medical devices and *in vitro* diagnostics.

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, MIAA 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.

MIAA 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, MIAA 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, MIAA 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 and performance for patients and users of medical devices, but the costs of the domestic inspections, 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 $6000 for regular surveillance audits every 12 to 20 months.

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

The Cochlear Nucleus Freedom System 4 serves as a good example to demonstrate these issues. This device manufactured in Australia, consists of an implantable component plus a speech processor which can be worn either behind the ear or as a body pack.

The following table compares international regulatory approval times for the various parts of the device. It clearly shows that compared to other regulators, approval through the TGA is slow.

	Australia	EU	FDA	Canada
Implant component	12 months	4 months	8 months	6 months
Speech processor (A) (ear pack)	6 months	4 months	Included in system submission (see above)	6 months
Speech processor (B) (body pack)	Continuing after 3 months	2 months	<1 month	Continuing after 1 month

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.

Ultimately it is 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?

If the medical device is approved for reimbursement, the costs may be ultimately borne by the taxpayer. If not, it is the direct Australian consumer who bears the additional costs. 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 certification body, either based in Australia or overseas, to verify and certify their conformity assessment procedures (so long as the certification body was acceptable to the TGA) 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.

b) The Australian definition of the Central Circulatory System

The Australian regulatory system classifies any medical device that comes into contact with the Central Circulatory System (CCS) as Class III. This is a high risk classification which requires the submission of a Design Dossier review.

In the Australian legislation, the definition is more extensive than the definition under the European framework, covering additional parts of the CCS. This means that the devices covered by the extra part of the Australian definition are Class III in Australia and Class IIb (a lower risk category that doesn't require Design Dossier review) under the EU Medical Devices Directive.

What is the regulation?

Regulation 1.3 of the Therapeutic Goods (Medical Devices) Regulations 2002.

What is the underlying objective of the regulation?

The underlying objective of the regulation is to place all medical devices used in the TGA's definition of CCS under Class III, with associated Design Dossier reviews.

Does it achieve its objective?

The regulation does appear to achieve its objective in terms of safety and performance for patients and users of medical devices used in the CCS. However, the costs involved in generating Design Dossier Reviews which are not required elsewhere in the world means that many of these products approved and used safely in the US and the EU, are being taken off the Australian market. MIAA can provide examples on request.

The unique Australian definition of the CCS is also inconsistent with the objective to harmonise our system with the frameworks of our major manufacturing partners and thus to facilitate trade.

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

The unique Australian definition of the CCS means that the TGA requires technical information for some cardiovascular devices which is not required for regulatory approval elsewhere in the world. The additional requirements have not been shown to confer additional benefits to patients. The costs in generating Design Dossier reviews specifically for the Australian market (less than 2% of the world market) are significant.

What is the opportunity cost?

Australian distributors of state-of-the-art cardiac equipment are not encouraged to supply their full range of products.

Who pays the costs?

The medical device industry loses marketing opportunities and Australian healthcare consumers have access to a narrower range of certain cardiac devices than their European and Northern American counterparts.

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?

MIAA believes the definition of the CCS under Regulation 1.3 adds unnecessary complexity to submissions for some cardiovascular devices, with no demonstrated concomitant regulatory or safety benefits.

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?

MIAA believes that the regulation should be changed to include the same definition as in the EU Medical Devices Directive. This would mean that the level of technical information supplied by CE marked manufacturers would be sufficient to satisfy the Australian requirements.

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. MIAA 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. MIAA 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?

MIAA 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.

Section 2: Reducing Regulatory Burden on the Reimbursement of Medical Devices

2.1 Background

The Department of Health & Ageing (DoHA), Prostheses Secretariat, regulates the process by which private health insurance funds must reimburse the cost of surgically implanted prostheses to their members. Sponsors (manufacturers and suppliers) of devices must provide comprehensive clinical data to enable assessment of effectiveness and comparative effectiveness before reimbursement amounts are centrally negotiated. Prostheses and the amounts to be reimbursed are shown in the "Prostheses List". Although it is a prerequisite that devices must be first approved by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG), sponsors of devices may launch concurrent applications with the TGA and the Prostheses Secretariat, although processing in the latter office is limited until ARTG listing is achieved. TGA applications may be lodged electronically while 12 hard copy Prostheses Applications (with four copies of supporting clinical data) must be lodged with the Prostheses Secretariat.

While there is function specific data required of applications to the TGA and the Prostheses List, there is considerable overlap of clinical data which indicates that a single dual purpose application submitted electronically would provided economies and efficiencies for sponsors of relevant devices.

2.2 Regulations

What are the regulations?

a) Submission of ARTG Applications

Inclusion of devices on the ARTG is regulated by guidance through Device Electronic Application Lodgement (DEAL).

b) Prostheses List Applications

Application forms for the Prostheses List are distributed via DoHA's website: http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-privatehealth-providers-circulars.htm . Circular PHI 44/05 of 29 August 2005 provided application forms for the February 2006 Prostheses List which were required to be submitted by 7 October 2005. Sponsors were allowed until 18 November 2005 for ARTG inclusion, otherwise prostheses applications were

unable to be processed further. 12 copies of applications with four copies of clinical data are required. Sponsors are responsible for notifying DoHA of ARTG listing approval i.e. neither the TGA nor DoHA accept responsibility for communication of listing approval between them.

What is the purpose of the regulations?

The purpose of the current regulations is to direct the manner and content for submission of ARTG and Prostheses List applications.

Do the Regulations Achieve their Objectives?

MIAA accepts that the regulations achieve their objectives but maintains that there is scope for significant improvement. This fact was acknowledged when DoHA established the Prostheses e-Commerce System User Group with industry to "provide advice on electronic lodgement of applications for the Prostheses Schedule, including investigating the possibility of integrated lodgement of applications for TGA approval…"

In what ways do the regulations impose a burden on business?

The regulations require two applications for two approvals when one application should be able to achieve the same objective. This would reduce sponsor staff time in preparing applications and with electronic lodgement of prostheses applications, would obviate the need to provide numerous paper copies with commensurate savings in postal costs.

What is the annual cost to business created by the regulation?

All medical devices for supply within Australia must be included on the ARTG, whilst approximately 9,000 items on the Prostheses list have been processed through the Prostheses Secretariat at some time. DoHA receives upwards of 300 applications per six month period. Although an industry consultant has estimated that the average cost of preparation of a Prostheses List application is $2,000 (either as a consultant's fee or the value of staff time), it is not likely that this entire amount would be saved by a dual purpose application form. However the overlap in preparation of the two applications does offer some savings as does the replacement of manual submissions by electronic. There is considerable cost to business with respect to lost sales if the ARTG listing is not conveyed to the DoHA Secretariat before the cut-off date.

Who pays the costs?

Device sponsors not only meet their own costs but from FY 2006/07 their participation costs will be based on full cost recovery. This will mean that sponsors will pay for system inefficiencies.

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 objectives of the regulation can be achieved without compromise through a single application process. Both TGA and DoHA can work together on common requirements and maintain task specific requirements discretely within the application.

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?

As above, this reform does not jeopardize application of policy.

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

This is a simple and straight forward reform with a single solution, with no alternative if efficiency of effort is to be achieved.

Section 3: Reducing Regulatory Burden on Commercial Arrangements for the Medical Devices Industry

3.1 GST on Medical Devices

What are the regulations?

A New Tax System (Goods and Services Tax) Act 1999 (GST Act) and especially Schedule 3 of the Act and its Regulations and the Supply of Prostheses under Hospital Treatment.

What is the underlying objective of the regulations?

While initially all goods were intended to have GST applied, it was later determined certain basic goods and services would be exempt, including medical care to the consumer. Certain Medical Aids and Appliances (MAA) are GST-free if they are:

(a) covered by Schedule 3 of the *A New Tax System (Goods and Services Tax) Act 1999* (GST Act) or subsequent regulations, and

(b) specifically designed for people with an illness or disability, and

(c) not widely used by people without an illness or disability.

All three elements must be satisfied for the medical aid or appliance to be GST-free.

Ref: http://www.ato.gov.au/businesses/content.asp?doc=/content/14229.htm

These criteria were intended to provide the MAA GST free to consumers who would not usually have been able to claim back the GST. Other MAA, which are referred to as devices by the TGA, usually have GST added by the Supplier when provided to the purchaser, which is typically a hospital or laboratory; the purchaser then claims back the GST. There are however certain exceptions to this general rule, e.g. where a patient is supplied a prosthesis as part of hospital treatment.

Do the Regulations achieve this objective?

The current regulations do largely achieve their objective of providing the medical products GST free to the consumer, albeit through a fairly complex set of regulations and processes.

Is the set of Regulations unnecessarily complex?

We believe the current set of regulations and processes is unnecessarily complex. The objective has to be achieved through a correct understanding and application of:

1. Items on Schedule 3 which are GST free. There is recognition by the ATO that the items on this list do not represent all medical aids and appliances that are used by people in the community. While it is theoretically possible to have items added to the list, in practice this has proved extremely difficult.

2. Items Not on Schedule 3, but which ARE supplied to the consumer as part of hospital treatment, and are therefore GST free. This again requires a thorough understanding by the parties involved of the supply chain path.

3. Items Not on Schedule 3 and which are NOT supplied as part of hospital treatment, and therefore have GST applied. This GST is then claimed back by the purchaser, provided the purchaser is registered for GST.

There is an administrative burden in maintaining the level of expertise through the supply chain to correctly determine which of these three mechanisms to apply, and new staff and new products often lead to a disconnect between the parties which takes further resources to resolve.

Could the Regulations be simplified?

The MIAA proposes that the objective could be achieved more simply by making ALL the medical devices GST free through the supply chain that are effectively GST free to the end consumer. This would reduce the administrative burden with its associated costs. It is our understanding that it would be revenue neutral for the Government as the GST is rebated to the purchaser under the current system.

3.2 State Health Purchasing Contracts

What are the regulations?

Each State Health Purchasing Department maintains its own contract templates which are used for tender and contract conditions. In NSW there are even different templates and conditions used depending on whether the NSW Dept of Health has engaged the NSW Dept of Commerce to issue their tender or whether they issue it themselves at an Area Health Service level.

What is the objective of the regulations?

The objective of providing a template for contract conditions is to reduce the costs to purchasers and suppliers of developing, administering and responding to tenders and contracts.

Is the objective achieved?

At a State level the adoption of a standard format provides a reasonable achievement of the objectives. However, at a national level the benefits are lost when each State has a different format and set of conditions. In this situation suppliers expend a large resource familiarizing themselves with the requirements of each tender/contract and determining the correct response. These costs are ultimately passed on to the purchaser.

Is the set of regulations unnecessarily complex?

National Health Information Management Advisory Council established the National Supply Chain Reform Task Force (NSCRTF) in July 2000 to support joint planning by governments, hospitals, purchasing agencies and product suppliers. The NSCRTF recognized the administrative burden of the current contracting arrangements and established the Standard Contracts Terms and Conditions (SCTAC) Working Group to develop standardized national documents for contracts and tenders.
Ref: http://www.healthsupplychain.gov.au

Could the Regulations be simplified?

Yes, the SCTAC Working Group developed a draft set of documents that have been available since 2003.

What is the problem?

Although the States representatives helped develop the Standard Documents and agree in principle to their adoption, they still have not done so, citing administrative and legal procedures. In addition, tender conditions that are more demanding in one state than in others, eg. level and type of insurance required, incur costs that are particular to that State and can not be amortized across national sales.

What is the Solution?

We suggest that this Task Force consider ways of encouraging use of a standard contract across Federal and State jurisdictions. The only jurisdiction using a form of the documents is Health Purchasing Victoria and they have modified them from the original.

CONCLUSION

The MIAA 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 and diagnostics 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 and ultimately result in reduced choice of products for Australian healthcare workers and their patients.

Finally, this submission has also made observations around Tax laws and the Tendering/Contracting processes adopted by the Federal and State Governments. While conceding that these may be potentially more difficult to address, it is nonetheless important to bring these to the notice of the Taskforce.