AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AusBiotech Ltd

Submission to the Therapeutic Goods Administration (TGA), on the

Reforms in the Medical Devices Regulatory Framework Discussion Paper

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Introduction

This paper presents the AusBiotech submission to the Therapeutic Goods Administration (TGA), on the Reforms in the Medical Devices Regulatory Framework proposed in the discussion paper from October 25 2010.

AusBiotech is pleased to take this opportunity to present its views to the TGA to improve approaches to regulation that will enhance the competitiveness of Australian medical device industry, while at the same time ensuring the primary aim of safeguarding Australian public health through appropriate controls of quality, safety and efficacy.

AusBiotech is Australia's Biotechnology Industry Organisation, which represents almost 3000 members, covering the human health, medical devices, agricultural, bioinformatics, environmental and industrial sectors in biotechnology. AusMedtech, part of AusBiotech, is the national industry group that represents the Medical Devices and Diagnostics industry sector. AusMedtech is dedicated to the development, growth and prosperity of the Australian medical technology industry, by providing initiatives to facilitate success in product development and manufacturing with a focus on commercialisation and export success. Supporting future sustainability by encouraging links between industry clusters, research bodies and government, AusMedtech is a leading advocate for industry issues for members nationally and around the world. Our membership includes medtech companies ranging from start-ups to mature multinationals, specialist service professionals, research institutes and universities.

Australia accounts for 1.5-2% of the global medical devices market with over $6.5 billion in revenues and $1.7 billion[12] in exports and has been involved for many years with the Global Harmonisation Task Force (GHTF). With the major countries manufacturing medical devices increasingly aligning their legislation to the GHTF model it is important that the proposed reforms to the Australian regulatory system encourages Australian manufacturers, who invested an estimated $388 million in R&D in 2008/9[3], to improve their international competitiveness and success.

As a key industry stakeholder, AusBiotech is keen to support opportunities for regulatory reform, especially in the areas of improving process efficiency and reducing regulatory burdens that can act as impediments to Australian medical innovation. This should be achievable without compromising timely and affordable patient access to medical devices that are demonstrated to deliver improved outcomes as well as being safe, effective and value for money.

AusBiotech is concerned that with the release of the reform proposals on November 2 there was insufficient notice of the public consultations starting November 13 and furthermore that the Sydney and Melbourne consultations occurred during a time when a number of Australian manufacturers and sponsors were attending or exhibiting at Medica, the largest medical tradeshow in the world. For those who were able to attend the consultations, having only three to four weeks to respond may not have been adequate to prepare a more thorough analysis of cost impacts of the proposed reforms. It has also been noted that the public consultations lacked sufficient detail to enable manufacturers and sponsors to fully understand the implications of the proposals.

History

In October 2002 the TGA implemented a new regulatory system for medical devices based on and consistent with principles of GHTF. Under the ANZTPA (Australia New Zealand Therapeutic Products Authority) proposal New Zealand agreed to adopt Australia's regulatory system for medical devices and in May 2006 ANZTPA Medical Devices Rule was released for stakeholder comment but was subsequently not implemented.

In recent years there have been a number of independent reviews calling for further reforms for the TGA to minimise differences in regulatory requirements between Australia and international regulatory agencies and to make more use of international regulatory assessments. The Productivity Commission's report *Rethinking Regulation,* (January 2006, the "Banks Review") recommended that *"The Australian Government should consider allowing Australian manufacturers to choose a certification body (acceptable to the Therapeutic Goods Administration), based in Australia or overseas, to verify and certify their conformity assessment procedures"*[4] whilst the *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades* (August 2008) suggested that *"The Therapeutic Goods Administration (TGA) should examine the scope to make greater use of acceptable prior overseas assessments. This should include identifying competent inspection bodies overseas. In general, where a device has been approved by such bodies there should be no requirement for a further assessment by the TGA"*[5].

Subsequent consultation and discussion papers provided further input including the *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia (*December 2008) and *Re-classification of Joint Replacement Implants* (October 2009) with the Commonwealth responding in the Review of Health Technology Assessment in Australia (HTA Review), February 2010.[6][7][8]

AusBiotech submission to the HTA review

The Review of Health Technology Assessment in Australia (HTA Review) was released in February 2010 and set new directions for HTA in Australia to support better health care and reduce unnecessary regulatory burdens. Recommendation 8 of the HTA review focused on the role of the TGA in ensuring medical devices supplied to the Australian market are manufactured under appropriate quality controls, safe to use and efficacious in their application. Specifically, that the TGA, in the context of international harmonisation

a) Continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on to the ARTG and marketing in Australia;
b) Respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;

c) Increase the rigour of assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes, and;
d) Develop protocols for information sharing with other HTA agencies through the Single Entry Point on the outcomes of its safety assessments (subject to commercial-in-confidence constraints).

AusBiotech in their submission to the Review of Health Technology Assessment in Australia (HTA Review) in May 2009[9] has sought reform to the issue of Third Party Conformity Assessment for many years and welcomes the proposal that Australian manufacturers should be subject to the same requirements as overseas manufacturers in that they may opt to use CE or other Notified Body to support their ARTG entry. AusBiotech also included recommendations that parallel processes should exist between the TGA and the Department's HTA processes so that the current time delay between regulatory approval and HTA submission and approval is removed and that this would result in significant productivity improvements as well as reducing duplication of processes and associated costs to government and industry. Industry is well aware of the TGA's requirement for full cost recovery however the TGA also needs to recognise that improvements in its own internal processes and productivity are encompassed in these reform proposals in the overall aim of reducing the burden on industry.

Devices Regulatory Reform Proposal Summary

Proposal 1	**1 Reclassification of joint replacement implants** A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.
Proposal 2	**2A Use of third party assessment bodies for Australian manufacturers** That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.
	2B Increasing pre-market scrutiny for implantable medical devices **(i) Devices requiring a TGA Conformity Assessment Certificate to be issued** Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices. **(ii) Applications to be selected for auditing** Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.
	2C Recognition of third party assessment bodies **(i) Confidence building for EU Notified Bodies designated under the MRA** That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers. **(ii) Recognising Australian third party assessment bodies** That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.
Proposal 3	**3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices** **(i) amend the way in which a kind of device is included on the ARTG**; and **(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.**
Proposal 4	**4 Publication of device product information on the TGA Website**

AusBiotech Responses to Regulatory Reform Proposals

Proposal 1. Reclassification of joint replacement implants

- A new classification rule is added to Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.

Proposed wording

- *An implantable load bearing component of a hip, knee or shoulder joint replacement, which functions in a similar way to the natural joint, is classified as Class III.*
- *This clause does not apply to ancillary components or accessories of joint replacements, such as screws, wedges, plates or surgical instruments.*

Proposed implementation as early as possible in 2011, with transition period of 2 years

- For products supplied before implementation, application required before end of transition period
- No effective application at end of transition period, supply must cease
- New products require approved application for Class III device prior to supply

AusBiotech Response Proposal 1

AusBiotech supports proposals that align the Australian regulatory framework with the European Union to minimise the impact of differences in classification rules and to aid international harmonisation. This in line with the recent European reclassification of hip, knee and shoulder implants and AusBiotech believes this should be limited to total joint replacements only.

For partial joint replacements, up-classification from Class IIb to III is inconsistent with international practice as the extent and implementation of such reclassification in the EU is arguable. During the 2010 public consultation in Melbourne the TGA advised they had recently spoken to the EU Commission who confirmed the Medical Devices Directive does capture partial implants however there is insufficient data to show if this has yet been implemented extensively in the EU. AusBiotech would recommend proceeding with caution until additional evidence and data can confirm that such reclassification will indeed improve patient outcomes.

While the data from the National Joint Registry suggests that rate of revision for partial replacements is higher than for total joints, this may be due to design and performance differences in that partial joints are typically used for the more elderly patients who have higher rates of mortality and less stringent requirements. Further, according to the National Joint Replacement Registry supplementary report (Lay Summary, October 2010, pp3-4,)[10] primary partial hip replacements are almost always done for a fractured neck of femur (broken hip) in elderly patients whereas primary total hip replacements are most often done due to severe arthritis. We would suggest that the data be further analysed to allow for age and other factors that may influence

relative risk before implementing changes to reclassify partial joints. The proposed transition timeframe of two years is likely to be insufficient due to the increased regulatory burden of reclassification and we would suggest implementation over four years.

Proposal 2. Third party conformity assessment bodies and supporting reforms

- Aimed at creating "level playing field", whilst addressing concerns over regulation of higher risk devices
- Package of reforms to be considered together, not as independent proposals
- Use of third party assessment bodies for Australian manufacturers (**proposal 2A**)
- Increased pre-market scrutiny for implantable medical devices (**proposal 2B**)
- Recognition of third party assessment bodies (**proposal 2C**)

Proposal 2A. Use of third party assessment bodies for Australian manufacturers

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

- Removes requirement for Australian manufacturers to have certification issued by TGA
- Subject to proposals 2b and 2c, with no transition required

AusBiotech Response Proposal 2A

AusBiotech in their submission to the HTA review has been seeking this reform for many years to remove an unfair restriction on Australian manufacturers and welcomes the proposal that Australian manufacturers should be subject to the same requirements as overseas manufacturers in that they may opt to use CE or other Notified Body to support their ARTG entry. This follows on from our response in March 2009[11] to the discussion paper *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia* in December 2008 (AusBiotech Submission 3rd Party CA March 2009)

There is some concern that concessions granted in 2a may be nullified in 2b for some products, for example, Dynek's Class IIb and Class III products.

AusBiotech is concerned that linking proposal 2a to proposals 2b and 2c would result in additional delays to reforms and increase the regulatory burden on manufacturers of higher risk medical devices.

Proposal 2B. Increasing pre-market scrutiny for implantable medical devices

- TGA certification required for all **implantable** Class III and AIMD devices; and
- Mandatory application audit to be required for all Class IIb **implantable** devices.

Proposal 2B (i). Devices requiring a TGA Conformity Assessment Certificate to be issued

Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD **implantable** medical devices.

- remove the reference to medical devices manufactured outside Australia, to capture Australian made devices of these types.
  - **Examples:** Implantable pacemakers and defibrillators, Ventricular assist devices, Prosthetic heart valves, Breast implants
- Implications for devices currently included on the basis of EC certification
- Proposed transition time of 4 years
- Joint replacement devices reclassified as Class III still subject to two year transition

Proposal 2B (ii). Applications to be selected for auditing

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

- No transition required – will apply to new applications only

AusBiotech Response Proposal 2B

The proposal to increase pre-market scrutiny is based on the HTA review recommendation 8c to "increase the rigour of regulatory assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes". The HTA Review concluded that the TGA should re-assess its current requirements for pre-market assessment of higher-risk devices for entry in to the market, with a view to addressing perceived shortcomings.

The discussion paper and the HTA Review do not provide evidence of regulatory failure in higher risk devices apart from anecdotally and AusBiotech is concerned that this proposal will likely lead to substantial increases in resources required and costs thus increasing the regulatory burden for manufacturers of higher risk devices without necessarily resulting in improved safety outcomes.

There is also likely to be a substantial increase in the range of devices requiring conformity assessment by the TGA and some doubt that the TGA may not have sufficient resources to issue CA certificates in as reasonable a timeframe as pre-existing Notified Bodies , resulting in potentially lengthy and costly delays in obtaining market approval.

The proposed changes would mean that the TGA would require a direct Conformity Assessment rather than the current Level 2 Application Audit for this class of devices. The potential burden of increased fees per device is estimated to be 8-fold for Class III and AIMD implants. AusBiotech does not support this proposal due to the potentially enormous increase in regulatory burden and associated costs.

It is also unclear whether some products already approved for market might now be covered by 2b or whether they can be accepted using CE Mark certification as in 2A and which mechanisms will need to be implemented to avoid a second round of change for joint implants. The proposed requirement for all Class IIb implantable devices to be selected for an application audit should also include provisions for mandatory timeframes to enable companies to plan product introductions more effectively.

Proposal 2C. Recognition of third party assessment bodies

- 3rd Party consultation generally agreed that TGA should oversight assessment bodies
- Proposal 2C (i) involves undertaking confidence building of CABs designated under the MRA
- 2C(ii) relates to the recognition process for Australian 3rd party assessment bodies

Proposal 2C (i). Confidence building for EU Notified Bodies designated under the MRA

That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

- EC-Australia MRA in revision – expected to come into force early in 2011
- Allows for 2 year confidence building period and designation of CABs
- TGA proposes to give greater weight to acceptance of MRA certificates, to encourage use of the MRA

Options may include

- Only accepting EC certificates from MRA designated Notified Bodies; and
- Requiring mandatory application audit for applications supported by certification from non-MRA designated NBs
- May require review of concept of TGA Conformity Assessment Certificate
- Support during 3rd party consultation process for TGA's role in designating CABs
- Also agreement that TGA should have responsibility for final decision on supply

AusBiotech Response Proposal 2C (i).

AusBiotech supports this proposal and recognises that the competence of Notified Bodies is critical and should be subject to rigorous assessment and supervision. Also noted is that the TGA has already had over seven year's experience with the medical devices regulatory framework, based on the GHTF model and could use this accumulated experience and evidence to shorten the timeframe of confidence building as well as consider extending this proposal to include Notified bodies that the TGA accepts CE certification from as equivalent to TGA Conformity assessment Certification. The TGA could also start with a subset of Notified Bodies already recognised under the MRA and seek further advice from the European Competent Authorities and Industry to identify those most acceptable. The industry expects that the TGA should move

to implement this swiftly otherwise it may be perceived to be unnecessarily delaying the uptake of this important area of reform.

Proposal 2C (ii). Recognising Australian third party assessment bodies

That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

AusBiotech Response Proposal 2C (ii).

AusBiotech supports this proposal for further consultation to discuss options for designation and the extent of acceptance of third party certification and suggests that where an acceptable overseas Competent Authority has designated a Conformity Assessment Body then this should be considered acceptable by the TGA as meeting Australian requirements. The TGA could play a role as an accrediting body whilst also being subject to independent assessment if it intends to continue to act as a Conformity Assessment Body.

Proposal 3. Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

(i) amend the way in which a kind of device is included on the ARTG; and

(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

Rationale

- Enhance TGA's ability to monitor safety and performance
- Ensure that the devices being supplied are the "same kind of device"
- Enable healthcare providers and consumers to identify legally supplied devices

Proposal 3(i). Amend the way in which a kind of device is included on the ARTG;

- Require identification of devices and/or models that are supplied under the same ARTG entry
- Provision for one entry per kind of device would remain, but individual devices supplied under that entry to be listed
- Accessible in the public view of ARTG
- As for "export only" solution
- 12 month transition period for entries existing at time of legislative change
- No fee to add data to existing entries
- Applications for new entries require list of all devices to be supplied under that entry

- Subsequent addition of new devices/models will require application for variation

AusBiotech Response Proposal 3(i)

AusBiotech supports this proposal in principle as it would allow increased visibility but has had feedback noting that Industry requires clarification on requirements, definition of "models" and "individual devices", and is concerned that this could cause huge increases in item listings and resultant increases in administrative burdens and increased regulatory costs. A means to minimise such burdens should be considered and the processes for adding new models should not result in increased delays to market access. The requirement for an application for variation for each subsequent addition on new devices/models could result in extensive lists of products that may make it harder for healthcare professionals and the public to access relevant information.

Proposal 3(ii). Enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

- Amend regulation 10.2 to require ARTG number on the label (placed in accordance with Essential Principle 13.2)
- Proposed 12 month transition period

AusBiotech Response Proposal 3(ii).

AusBiotech understands the need to be able to identify approved devices especially in situations such as recalls but does not support the proposal to add the ARTG number to existing labels or an additional label, or instructions for use or packaging, which could be or e-labelling on CD/DVD. Feedback has shown major concerns about whether there is available space on labels, the additional resources required for the management of existing inventories which may have to be relabelled and timelines for implementation. It is expected to be costly and labour intensive, and if the information is already available under the eBS system then it becomes a duplication of effort. An improved eBS interface and search functionality may be a effective addition, and consideration of alternate technologies that incorporate a Unique Product Identifier such as RFID tags.

Proposal 4. Publication of device product information on the TGA Website

- Commensurate with changes made for medicines in October 2009 – AusPar, CMI, PI
- Also in accordance with move towards greater transparency

Issues for discussion

- Types of devices
- Information to be published, and depth of that information

- Responsibility for authorship and updating
- Publication of rejections

AusBiotech Response Proposal 4

AusBiotech supports the principle to provide greater transparency and improved access to information to health professionals and consumers. This proposal warrants further discussion and consultation and raised several issues:

- Whose resources are committed to maintaining and updating the data?
- Controls over the level of appropriate information consistent with the user profile
- Compliance with advertising standards
- Consideration about whether to publish information on rejected applications and whether this applies to all devices or higher risk devices only
- Disclosure of commercially sensitive information and measures available to protect sensitive information.

AusBiotech additional comments on reforms

"Me-too" technology accessing funding via MBS item numbers, without proof of clinical effectiveness, economic benefit or outcomes relative to the technology assessed by MSAC

When TGA reviews and registers a Class 11A device on the ARTG, TGA do not review the performance of the device, but rather the safety and manufacturing standards. The issue this presents is that there is a massive disconnection of the TGA to the MSAC process, in that the MSAC process refers and relies on the TGA approval and initially believed that the TGA did perform a comparative review of the performance of products from the first to market and subsequent brands.

The concern being that there is an assumption that the performance of subsequent devices to that which was assessed by MSAC would be the same, provide the same clinical accuracy, benefit, and health economic outcomes. The assumption is based on no data, and no review process whatsoever.

A similar disparity of lack of comparative review seems to be in existence to notified bodies for non-Australian manufactured products to those which are domestically manufactured.

AusBiotech will be responding to the announced consultation on proposals for changes to the Medical Services Advisory Committee (MSAC) processes for submissions for public funding in 2011 and looks forward to providing input to reforms in this area and the proposed subcommittees such as the Protocol Advisory Sub Committee (PASC). AusBiotech recognises that there is need for Industry to be more engaged in these processes and that we can draw upon a

number of highly qualified and experienced individuals willing to make significant contributions. AusBiotech is pleased to see the greater level of improved coordination between the TGA and the Department of Health and Ageing following the recommendations of the HTA Review especially in taking steps to ensure the timely assessment and appraisal of co-dependent and hybrid technologies and the single point of entry proposals.

References

[1] Medical and Surgical Equipment Manufacturing in Australia, IBISWorld, November 2010

[2] Medical and Scientific Equipment Wholesaling in Australia, IBISWorld, July 2010

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[4] Rethinking Regulation, (the "Banks Review") January 2006

[5] Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades (August 2008)

[6] Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia (December 2008)

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[8] Review of Health Technology Assessment in Australia (HTA Review), February 2010

[9] AusBiotech Ltd Submission to the Commonwealth Department of Health and Ageing on the Review of Health Technology Assessment in Australia (HTA Review) May 2009 www.ausbiotech.org

[10] Australian Orthopaedic Association National Joint Replacement Registry 2010 Annual Report for Hip and Knee Arthroplasty (replacement) , Lay Summary, October 2010

[11] AusBiotech submission to the TGA on the Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia, December 2008 www.ausbiotech.org