AusBiotech Ltd

Submission to the Therapeutic Goods Administration (TGA) on the use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia

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AusBiotech Ltd. Level 1, 322 Glenferrie Road Malvern, VIC, 3144 Australia
Phone: (+613) 9828 1400, Fax: (+613) 9824 5188, ABN 87 006 509 726 www.ausbiotech.org

Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia

AusBiotech response to TGA Consultation Paper

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Introduction

This paper presents the AusBiotech position on the "Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia". Specific responses to the questions raised in the TGA consultation paper are included. During this consultation process, the TGA has encouraged respondents to consider the broader context of Australian medical device regulations and their international context. AusBiotech is pleased to take this opportunity to present its views on the TGA's regulatory approach to medical device approvals, how that relates to other aspects of regulation, and the opportunities for improved 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.

In the consultation paper, TGA identifies three broad areas of policy consideration to be addressed. These are reproduced below for reference:

I. *What role should the TGA have in issuing conformity assessment certificates?*
   - *Should the TGA continue to have a role in issuing conformity assessment certificates?*
   - *Should the TGA continue to have sole responsibility for issuing certificates for Australian made devices intended for supply in Australia and/or for devices containing a designated material?*
   - *Should the TGA be required to issue conformity assessment certificates for specific classes and/or types of devices, for example high-risk devices?*

II. *What requirements, if any, should apply if third party assessment was available for Australian device manufacturers intending to supply in Australia and/or for ones containing designated materials?*
   - *Should legislation specify that external bodies undertaking assessments be resident in Australia?*
   - *Should the TGA have a role in accrediting these Australian external bodies?*

III. *If external bodies are allowed to undertake assessments of Australian made devices and/or ones with a designated material, should they be permitted to issue certificates or should they provide reviews for the TGA to assess and then the TGA issue a certificate based on its review.*

Consideration of third party conformity assessment in Australia is complicated by the separate and distinct requirements that have been applied to Australian manufacturers. With regard to the question of whether to allow third party assessors to operate within Australia, in the following discussion, AusBiotech will argue strongly for the removal of this distinction and application of the same requirements to all manufacturers supplying in Australia, irrespective of their location. Should this distinction be removed, the main issues to be considered reduce to:

1. What are the specific compliance and assessment requirements that should apply to medical devices for supply in Australia (irrespective of origin), and what (if any) additional oversight may be required for specified categories of devices?
2. Should third party assessment be introduced in Australia, what should be the continuing role of TGA in medical device regulation, both in relation to oversight of the third party assessors and in relation to final approval of devices for supply by means of entry onto the ARTG?

AusBiotech has made prior submissions to the TGA on the case for implementation of third party assessment, including a detailed paper presented to the TICC committee in November 2006. In the following discussion, some of issues raised in that paper will be reviewed along with discussion of some more recent statistics and overseas experience. The introduction of third party assessment has been supported by various reviews, most notably the Productivity Commission's Banks Report and outcomes of the Medical Devices Industry Action Agenda. These are detailed in the TGA consultation paper and the previous paper to TICC from AusBiotech and will not be further reviewed here save to re-iterate AusBiotech's strong support of the views expressed in those recommendations. In summary, it is AusBiotech's view that third party assessment for Australian manufacturers is long overdue and that regulatory reform to establish third party assessment should be implemented without further delay.

Background: Current Assessment Practices of Australia and Other GHTF Members

International Practice

The Australian regulatory framework is closely modeled on that of Europe, and it is instructive to review experience in that market as the most relevant overseas experience to the current Australian conditions. The European framework was introduced in 1993 with publication of the Medical Devices Directive and has been operating for approximately fifteen (15) years. Early experience raised concerns with the competency of Notified Bodies with notable deficiencies and poor performance in several different areas. Some Notified Bodies have subsequently been de-designated or voluntarily withdrawn for the medical devices sector. In the light of this early experience, there has been extensive work done by both the Competent Authorities and Notified Bodies to improve practice. The recent revision of the European Directives corrected some deficiencies in the primary regulatory requirements – removing some classification anomalies and notably clarifying and strengthening clinical evidence requirements. In presentations from MHRA[1] during consultation seminars, the position of that agency was clear – that the current levels of oversight are generally satisfactory and that there was no reason to contemplate additional measures to strengthen medical device regulation in Europe. In particular, recent proposals by the European Commission to consider more centralised controls had not been supported.

The regulatory assessments in Europe are supported by a large number of Notified Bodies. While there may be some isolated concerns about the smaller and more recently established assessors, the Notified Bodies are characterised as organisations that have substantial technical expertise and experience. Notably, the resource base of each of the larger Notified

[1] Higgins, Presentations to TGA consultation seminars, Sydney and Melbourne

Bodies (e.g., TUV Rheinland, TUV Sud, BSI, UL) amounts to several hundred device experts among a global staff of thousands, spread across a wide industry base. There is a very long history of technical assessment in some of these organisations, for example, TUV Rheinland has a 135 year history as an assessment body.

In Europe, the national regulators (Competent Authorities) are responsible for accrediting ("designation") and monitoring of Notified Bodies, and for oversight of postmarket regulation and of clinical trials. They have no direct or indirect involvement in the review of manufacturer conformity assessment.

In the USA, a third party assessment programme has been introduced for a large subset of 510(k) approvals – which in turn represent the great majority (approximately 98%) of devices approved in the USA. The take up of the third party option has been limited (approx 280 approvals per year out of >3,000). However this should be set in context of an alternate direct to FDA option which is well resourced, attracts low fees (of the order of $AU 3,000), and achieves average review times of approximately ninety (90) days. Overall, the third party option is about 15% faster than direct FDA review, with most benefits where there is clear device technical guidance and review is straightforward.

In Japan, there has been recent introduction of a third party assessment process for Class II devices for which there is an existing Japanese standard. The early experience has been positive, with straightforward approvals under this scheme. It is expected that the scheme will continue to grow in importance as the Japanese put effort into expanding the adoption of international standards into their domestic standards scheme. The alternate is direct application to the Japanese PMDA. That agency is under-resourced and the experience is one of very protracted review times.

In Canada, there is a model of universal third party conformity assessment of manufacturing controls under the Canadian Medical Devices Conformity Assessment Scheme (CMDCAS). A CMDCAS audit includes inspection of the manufacturers' compliance with requirements to verify and document compliance with regulations and to establish appropriate technical files. This is supplemented by a technical review by Health Canada for higher risk devices.

In summary, the third party arrangements in the other GHTF jurisdictions are all working well, with reasonable costs and review times afforded to industry and no evidence of any significant failures in regulation or unacceptable public health risks. In particular, the European experience – which is of most direct relevance to Australia – is one of a well functioning assessment regime in which there is complete devolution of assessment to third party assessors, with the regulatory agencies taking the role of oversight of the Notified Bodies, plus implementation of postmarket and clinical trials regulation. The CE mark is gaining considerable international currency as a recognition of safety and performance of medical devices. CE mark is recognised by many international jurisdictions (including TGA) as the basis for local approvals. Notably Australia imports over 60% of domestic consumption of medical devices form the USA, and in the absence of TGA recognition of US FDA approvals, almost all of those devices are approved by TGA ***on the basis of their CE certification***.

Australian Practice

The early development of Australian regulation of therapeutics was focused on the control of supply of medicines. The Therapeutic Goods Act 1989 is based on a model of review of technical data in order to make an assessment of product compliance, with successful

review leading to subsequent entry onto the ARTG as the primary point of regulatory control. The current model of devices regulation is principally based on an assessment of manufacturer competence to carry out processes of design and manufacture, with attendant consideration of risk assessment and clinical evaluation.

There is a very high level of imported devices supplied in Australia. This has resulted in a current system where the great majority of devices entered onto the ARTG are approved on the basis of review of overseas manufacturer certifications with no direct TGA review or assessment. Data from TGA consultation papers and presentations to industry from TGA during the consultation seminars[2] show that 97% of conformity assessment applications supporting device entries on ARTG are approved on the basis of review of CE certification of overseas manufacturers. Only 1.5% of conformity assessment applications relate to Australian manufacturers and these are required to undergo direct TGA assessment irrespective of any other assessments or certifications they may hold, including third party CE mark.

There has been recent experience of very lengthy delays in TGA conformity assessment associated with transition to current regulations. Given that these assessments were conducted on the very small number of conformity assessments conducted by the TGA (3% of the total certifications supporting Australian device approvals), and the very wide range of technologies required to be assessed, it raises the question as to whether the agency can be adequately resourced for a sustainable long-term role in conformity assessment.

Finally, the European model of regulation is fundamentally based on a separation of powers, with Competent Authorities responsible for the oversight, accreditation, and integrity of the Notified Body third party assessors. The current Australian model in which TGA assumes both roles presents a clear conflict of interest. It is noted that in European experience, this situation occurs in only a small number of Member States and, where it does occur, the Notified Bodies which combine a competent authority role are some of the weakest.

Mandatory TGA Assessment of Australian Manufacturers

The domestic manufacturing sector exports most of its product and needs to obtain regulatory approvals in multiple markets. Third party assessment bodies are frequently accredited in multiple jurisdictions, and by judicious choice of assessor, a manufacturer may achieve certification in multiple markets from a single assessment body. However, for supply in the Australian market, the only route to approval is by direct TGA review of manufacturer conformity assessment. Australia is unique in the world in requiring a more restricted, costly, and onerous regulatory review for its domestic manufacturers compared to importers. Given the very small size of the Australian market and past TGA history in lengthy assessment times, many domestic manufacturers have chosen to give priority to a direct assessment by a Notified Body and supply to export markets, ahead of seeking approval to supply the domestic market.

AusBiotech is not aware of any evidence that Australian manufacturers are of a lesser standard to overseas manufacturers or that devices from Australian manufacturers present a higher safety risk or perform less adequately than those manufactured overseas. However,

[2] Flood, M. Presentations to TGA consultation seminars, Sydney and Melbourne

the current mandatory TGA assessment requirement places a very substantial impost on Australian manufacturers which has no basis in any public health concerns.

An important component of both the Australian and European regulatory models is postmarket review. In Europe, this aspect of regulation is overseen by the Competent Authorities, and AusBiotech strongly supports the continuation of the TGA's responsibilities in this area and a further strengthening of the TGA's postmarket regulatory role. For reasons of more immediate access to manufacturers and their facilities, postmarket monitoring of Australian domestic manufacturers by the TGA is more straightforward and likely to be more effective than postmarket monitoring of manufacturers located offshore. This reduces the risks associated with Australian sourced devices and is a further argument for the removal of direct conformity assessment requirements for Australian manufacturers.

Finally, a matter often overlooked in requiring direct TGA assessment is that many overseas markets, especially those in Asia and South America, base their approvals on the medical device being approved for supply in its home market. Given that TGA does not recognise CE certification for local manufacturers, this means that Australian manufacturers must undergo TGA assessment to access many of these markets even if they have gained CE mark.

Possible Models for Third Party Assessment for Australian Manufacturers

Introduction

In developing a model for third party assessment in Australia, several issues must be considered:

- The controls on assessment bodies and the means by which they are accredited and monitored;
- The range of devices which may be subject to third party assessment; and
- The continuing role of TGA should third party assessment be made available to Australian manufacturers.

Control of third party Assessors

It is noted that the TGA currently accepts conformity assessment certificates from any of the seventy-eight (78) Notified Bodies operating in Europe. There has been no direct TGA assessment of these Notified Bodies and the acceptance is based on a reliance on European Competent Authority oversight. The TGA also accepts direct certification to Australian requirements from a more limited range of Notified Bodies under the EC-Australia Mutual Recognition Agreement (MRA), although it is understood that the actual number of MRA certificates presented to TGA is very low.

Given that the TGA currently accepts such overseas third party certifications for 97% of all conformity assessment reviews, and that a large majority of those certifications will relate to manufacturers located outside of Europe, it could be argued that TGA should allow any of these bodies to conduct conformity assessments of Australian manufacturers. However, given the concerns about the differences in capabilities of Notified Bodies, and the difficulties of tracking changes in capabilities and currency of European designations, it would be prudent to implement an accreditation and monitoring arrangement for third party assessors who wish to operate in Australia. Presentations from MHRA at the TGA consultation seminars highlighted the extensive work conducted in Europe on codifying the practices of

monitoring and accreditation of Notified Bodies in Europe and the production of a Designation Handbook. It is understood that the TGA is aware of this work and guidance and this would appear the obvious model to consider for implementing a designation scheme in Australia. This would allow the TGA to adopt the role of Competent Authority, which is in keeping with the regulatory model as applied in Europe.

The approach taken by the TGA with respect to the regulatory requirements for Australian manufacturers of medical devices is at odds with the policy initiative of the Australian Government to promote Australian manufacturers and reduce barriers to trade. In fact, the requirements for Australian manufacturers places them at a significant disadvantage compared to their overseas competitors.

The Commonwealth Department of Foreign Affairs and Trade states that the "Government is committed to creating a more productive economy" by "cutting the regulatory burden faced by business". Despite this policy initiative, Australian manufacturers (compared to their overseas counterparts) are severely disadvantaged by the requirements imposed upon them by the TGA via the Therapeutic Goods Act 1989 and face a much greater regulatory burden in their own country. This is completely at odds with the Commonwealth's policy of "creating a more productive economy" by "cutting the regulatory burden faced by business".

Range of devices to be subjected to third party assessment

Direct assessment by TGA is currently required for devices containing designated materials or integral medicinal components, irrespective of location of the manufacturer or of any other certifications held. These requirements were included at the outset of the current regulatory framework as a safeguard against potential higher risks from some of these devices, and also when new devices emerged (e.g., drug-eluting coronary stents) that other jurisdictions such as Europe had not yet had much experience assessing.

Experience to date in both Europe and Australia indicates that there has not been any significant public health issues associated with this subset of devices. It is notable that there is no obvious difference in experience between Australia and Europe, where there is no additional competent authority review of such devices. In the case of the UK MHRA, arguably one of the most credible and conservative of the European Competent Authorities, the only instance of competent authority review of conformity assessment occurs in the case of devices where there is a potential for transmission of prions responsible for Transmissible Spongiform Encephalopathy (TSE). The additional review is limited to assessment of a summary report forwarded to MHRA by the Notified Body.

Fundamentally, any requirement for additional review of specified device categories should be related to the risk associated with the device. Considering the classes of materials currently required to undergo direct TGA assessment, the following observations relate to the risk profile of these devices.

Inactivated Animal Origin Materials

The safety profile of animal origin biomaterials is very well established. Such materials have been supplied for many years, notably devices such as porcine tissue heart valves. Furthermore, there has been development of a set of consensus international standards for risk management of such products (EN ISO 12442 Parts 1-3 *Animal tissues and their derivatives utilized in the manufacture of medical devices*). Australia (including representatives from the TGA) had direct input into development of these documents

and they have been adopted into the Australian regulatory framework through Conformity Assessment Standards Order No. 2. These standards have similarly been adopted into all other GHTF regulatory frameworks. They address the full range of risks in animal origin devices including matters such as quality controls, viral and other pathogen inactivation, and donor selection and traceability. Devices containing inactivated animal tissues are regulated as Class III devices in most jurisdictions and are subject to concomitantly rigorous conformity assessment review, including Notified Body design dossier evaluation. With the exception of the additional review of Notified Body summary reports in the case of TSE risk, discussed above, there are no special or additional controls applied to such devices in Europe.

Recombinant and Microbial Origin Materials

Production of materials by means of microbial fermentation with or without the use of recombinant technology is a very well established practice. The materials so produced are highly refined, with low risks, and these products are generally regulated as Class II devices in the rest of the World.

Devices Containing an Integral Medicine

Devices containing an integral medicine cover a very wide range of risk profiles, for example, these devices include medicated dressings, condoms with spermicide, and drug-eluting stents. These are all regulated as Class III devices, usually including Notified Body design dossier evaluation. Furthermore, such devices are also subject to a medicines evaluation which will vary in rigour according to the nature of the medicinal component – which is the appropriate way to manage risks of medicated devices.

A need to retain specific TGA assessment of devices containing such "designated materials" would imply either

- an elevated level of risk which is not adequately managed through existing classification based Conformity Assessment procedures, or
- inadequate capabilities of third party assessors to review such devices or, alternately, a comparatively enhanced capability of TGA to conduct the reviews.

AusBiotech is not aware of any evidence to suggest that any of these circumstances apply. Given the well understood risk profiles for devices containing materials of animal, microbial or recombinant origin, or integral medicines and the already well established risk-based procedures governing review of such devices, there appears little justification for reserving such devices for special review by the TGA. At most, there may be a case for providing extra controls where there is a uniquely Australian quarantine requirement (such as a TSE risk). However, this should be able to be quite adequately managed through existing AQIS regulation and controls on imports.

Role of the TGA in the context of third party assessment

Should third party review of Conformity Assessment be implemented in Australia, the question arises as to the continuing role of the TGA (if any) in such assessments.

As discussed above there are inherent conflicts of interest in TGA assuming the role of both Competent Authority and Conformity Assessment Body under the current regulatory model. It would be more appropriate for the TGA to exit the role of conformity assessment review and instead to focus on the Competent Authority role of designating and monitoring the

activity of third party assessors. This would also allow the TGA to redeploy its resources and, in particular, to allow the strengthening of its postmarket monitoring capabilities.

TGA currently offers Conformity Assessment review for European approval (CE marking). Such services are separately contracted under MRA arrangements. This could theoretically be continued post the implementation of domestic third party assessment. However, it would be expected that demand for such services would likely reduce with time in the presence of third party assessors who may be able to offer a wider range of international accreditations than is possible via the TGA. Retention of an assessment role under MRA may prove difficult in a TGA which has realigned to act as a designating authority with responsibilities to oversee third party assessors. Therefore, in these circumstances it would appear to be appropriate for the TGA to exit this activity. Transitional arrangements would be required for transfer of current clients to accredited third party assessors.

The role of the ARTG as the primary point of control for device approvals in Australia is supported. TGA should continue to maintain device entries onto the ARTG. This would be analogous to similar registers established in some European states and planned for implementation as a pan – European database. It is noted that most of the current European device registers are intended for notification only. Entry onto the register is administrative only and involves no product review. In some cases, the entry may be retrospective to initial supply of product.

In Europe, with the sole exception of devices with risks of TSE transmission discussed above, there is no additional review of conformity assessment conducted by Competent Authorities for any class of device. AusBiotech believes that the TGA's role in maintaining the devices section of the ARTG should similarly be limited to ensuring the collection of complete device and manufacturer information. This can be achieved through the e-Business portal. It is noted that this is already accomplished for Class I devices and this approach could be extended to all devices.

Proposed new conformity assessment arrangements for IVDs

It is noted that the TGA is currently proceeding to implement new regulatory arrangements for in vitro diagnostic devices, with conformity assessment requirements modelled on the European IVDD. The regulatory model proposed by the TGA will duplicate the regulatory arrangements currently applied to medical devices, in particular, mandatory TGA assessment for certain types of IVD devices and for all Australian manufacturers. For the reasons set out above, AusBiotech argues strongly that the implementation of those IVD devices regulations should not include any differential treatment of Australian manufacturers and should only place additional direct assessment requirements where there is demonstrable public health risk which cannot be adequately managed by third party conformity assessment review, as is currently conducted in Europe and elsewhere for such devices.

Specific Responses to the TGA Consultation Questions

Based on the above discussion, the following specific responses are provided to the questions raised in the TGA consultation paper.

1. **Do you think TGA should continue to be solely responsible for undertaking conformity assessments for devices that contain a designated material?**

   The classification of these devices as Class II (for recombinant or microbial origin materials) and Class IIII for those containing animal origin materials or integral medicines adequately addresses the respective risk profiles of devices containing such materials.

   There does not appear to be any evidence that supports concerns relating to patient safety where third party assessors conduct reviews of such devices, nor any substantial data or evidence of failures or unacceptably high risk that supports the TGA continuing being solely responsible.

   It is therefore AusBiotech's view that there is no apparent justification for the TGA to continue to be solely responsible for undertaking review of conformity assessments for devices that contain a designated material.

2. **Do you think TGA should continue to be solely responsible for undertaking conformity assessments for Australian made devices intended to be supplied in Australia?**

   It is difficult to understand why the 1.5% of all conformity assessment applications which are submitted to the TGA from domestic manufacturers need to be treated differently to the 97% of applications related to overseas manufacturers for which certification from one of seventy-eight (78) European Notified Bodies is accepted. There is no evidence at all that Australian manufacturers are less capable or produce devices of higher risk compared to overseas manufacturers. Furthermore, the local presence means that postmarket supervision by the TGA of Australian manufacturers can be more effectively implemented than for overseas manufacturers. Given this absence of any additional risk, these significantly increased and unfair regulatory burdens on Australian manufacturers cannot be justified and should be removed as a matter of urgency.

   Therefore, it is AusBiotech's view that the TGA should not continue to be solely responsible for undertaking conformity assessments for Australian-made devices intended to be supplied in Australia.

3. **Do you think TGA should be solely responsible for undertaking conformity assessments for any or all classes of medical device? Should CABs be permitted to undertake assessments of any or all classes of medical device?**

   The fundamental principle which should guide the means of assessment for any kind of medical device is the risk related to that device, including those devices containing the current designated materials or integral medicines. The evidence is clear that despite some early difficulties in implementing third party assessment in Europe, that system now works very effectively and there are no grounds for believing that there is a general absence of competence of third party assessors in relation to any specific type or category of device, nor any enhanced capabilities of TGA in the same regard.

The possibility of specific risks arising relating to uniquely Australian issues of quarantine has been raised in consultation discussions. There are already well-established and adequate quarantine controls administered by AQIS and AusBiotech sees no reason to depart from or add to those controls, which are the appropriate mechanism for management of such risks.

Should the situation arise that there are concerns about unacceptable risk associated with a particular category of devices, then it may be appropriate to implement additional controls. These would not necessarily involve direct assessment by the TGA. A more appropriate approach would be to add specific measures to the third party assessment process to address the identified risk This could be done, for example, by development of a specific Conformity Assessment Order specifying additional compliance requirements. Whatever the chosen course of action, the reasoning behind such a perceived risk should be justified. AusBiotech is not aware of any current categories of devices where additional controls above and beyond the existing risk-based conformity assessment procedures are necessary.

Therefore, for these reasons, it is AusBiotech's view that there are no significant grounds for the TGA retention of sole responsibility for assessment of any particular category of medical devices.

4. **Do you think a CAB should issue certificates for acceptance, or otherwise, by the TGA or should they produce a report of their findings for the TGA to consider prior to issuance of a certificate? Should the approach be the same for all classes of device?**

   The TGA currently accepts CAB certification for 97% of all conformity assessment applications covering all device classes except Class I, for which there is no CAB or TGA review. There are no apparent grounds for not continuing this practice. Furthermore, given the absence of any special concerns or risks associated with Australian manufacturers, the TGA should also accept certification as primary conformity assessment evidence for Australian manufacturers.

5. **Should TGA have a role in designating Australian CABs?**

   The Australian model is based on that of Europe where there is almost universal separation of Competent Authorities and the Notified Bodies which they designate. The combination of the role of assessor and designating body into one organisation presents clear conflicts of interest. For this reason, it is argued that the correct path would be for the TGA to assume the role of Competent Authority and to oversee Australian third party assessors.

   Currently, European Notified Bodies satisfactorily conduct assessment operations worldwide for award of CE mark and the TGA already accepts certification from all Notified Bodies without direct review of their competence. The TGA effectively relies on the oversight of European Notified Bodies by the Competent Authorities. However, the possibility exists that other organisations may wish to become accredited as third party assessors and it would be logical for the TGA to introduce mechanisms for such accreditation. AusBiotech recommends that the TGA should consult widely on the approaches to accreditation and monitoring of third party assessors, and in particular should involve JASANZ in those consultations.

With regard to the question of any requirement for Australian domicile of third party assessors, there do not appear to be strong arguments for or against, particularly given the current practice of acceptance of certifications from the seventy-eight (78) European Notified Bodies, of which less than ten (10) have local office presence or corporate entities in Australia. It would appear that quite adequate controls could be implemented by issue of appropriate accreditations or licenses to overseas-based assessors.

6. Should TGA retain responsibility for making the final decision to allow supply of a medical device into the Australian marketplace?

The current European model is based on the final decision for approval being the prerogative of the Notified Body. There are requirements for registration on national device databases in several European countries and development of a pan European database is in progress. However, entry onto these registries is an administrative step, in some cases retrospective to initial supply. The primary function of such registers is to support postmarket regulation and ,in particular, identification of suppliers and manufacturers of approved devices. AusBiotech therefore supports the role of the TGA in being responsible for the final entry onto the ARTG but this role should be carried out based on the provision of certification evidence from third party assessors and should not involve any additional review of summary reports or other non certification evidence.

The current legislative requirement for entry onto the ARTG to be able to legally supply a therapeutic good in Australia would continue to provide adequate safeguards in the form of a ready means for the TGA to withdraw or suspend a specific device should particular safety or performance concerns arise.

7. Are there other matters you wish to be considered in relation to conformity assessment for medical devices?

AusBiotech is particularly concerned that the proposed new regulatory framework for in vitro diagnostics (IVDs), which is being implemented in parallel with this current consultation on third party assessment, may duplicate the current conformity assessment requirements applied to medical devices. In particular, it is noted that the proposals for IVD devices regulation would implement mandatory TGA assessment for Australian IVD device manufacturers and for Class IV IVD devices. AusBiotech is strongly of the view that the manifestly inequitable treatment of Australian manufacturers in requiring direct TGA assessment should not be repeated for IVD device manufacturers. Rather, the TGA should seek to conclude the implementation of regulatory reform with relation to third party assessment in concert with the implementation of the new IVD devices regulatory framework.