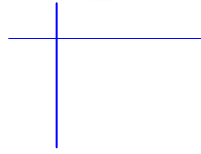




Medical Technology
Association of Australia



Submission to
Therapeutic Goods Administration
Use of Third Party Conformity Assessment Bodies
For Medical Devices Supplied in Australia
March 2009

Medical Technology for a Healthier Australia

Executive Summary

It has now been six years since a revised medical devices regulatory framework was implemented in Australia. The experience and understanding by the Therapeutic Goods Administration (TGA) and the industry has grown, not only the application of that system in Australia, but through the developments of the analogous European regulatory system which had been used as the model for the Australian legislation initiative. It is therefore opportune to move into a new phase in which the TGA can confidently implement improvements in the ways conformity assessment certification is issued to manufacturers of medical devices, and subsequently to manufacturers of in vitro diagnostic medical devices. Such changes would not only maintain the high safety standards for medical devices established by the TGA, but would assist the domestic manufacturing sector, in addition to adopting more internationally consistent requirements for the industry.

In summary, the responses by the Medical Technology Association of Australia to the questions posed in the TGA consultation paper released in December 2008 on the use of third party Conformity Assessment Bodies for medical devices supplied in Australia are as follows:

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

The TGA should not continue to be solely responsible for issuing conformity assessment certification for devices containing a designated material because:

- 1.1. The TGA should develop specific designation criteria for Conformity Assessment Bodies to issue conformity assessment certification for these products to be supplied in Australia.
- 1.2. The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity Assessment Bodies.
- 1.3. The TGA should review summary reports of the assessment of any medicines incorporated in medical devices specifically related to assessing the compliance of the medicines with the essential principles that has been carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the European Medicines Agency (EMA) for products manufactured in the European Union or the Food and Drug Administration (FDA) for products manufactured in the United States.
- 1.4. The Australian Quarantine Inspection Service (AQIS) and the TGA assess the designated materials used in certain medical devices. This duplication results in delays. MTAA suggests that efficiencies could be gained if the TGA, AQIS and industry associations collectively consider the development of one assessment protocol that AQIS would use as part of import permit assessments. The permit would then become a pre-requisite for conformity assessment certification issued by designated Conformity Assessment Bodies.
- 1.5. To assure that there is no reduction in safety requirements for these products, the TGA's designation procedures should be available for public review and comment.

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

The TGA should not be solely responsible for undertaking conformity assessments for Australian made devices intended to be supplied in Australia because:

- 2.1. The current system of mandatory TGA conformity assessments for products manufactured in Australia for supply in Australia has impeded the development of many domestic manufacturing companies and increased regulatory compliance costs.
- 2.2. The need for mandatory TGA conformity assessment certification for Australian manufacturers supplying products in Australia results in higher regulatory compliance overheads and costs which impedes companies wishing to establish manufacturing facilities in Australia.
- 2.3. TGA conformity assessment certification has not assisted Australian manufacturers to supply their products in overseas markets other than in the European Union.
- 2.4. The TGA has designated 18 Notified Bodies to issue conformity assessment certification for a range of medical devices manufactured in the European Union to be supplied in Australia. These Notified Bodies should also be permitted to certify manufacturers outside the EU and other Conformity Assessment Bodies outside the EU could also be designated by the TGA should those organisations choose to be involved.
- 2.5. Permitting Australian manufacturers to use designated Conformity Assessment Bodies would reduce the auditing overhead for those manufacturers which would be consistent with the Global Harmonisation Task Force Action Plan for 2007-2010.
- 2.6. TGA designation procedures for Conformity Assessment Bodies would overcome concerns expressed in the EU report on the operations of Notified Bodies (referenced in the Consultation Paper).
- 2.7. MTAA proposes that the TGA in consultation with industry associations develop transparent designation requirements for Conformity Assessment Bodies to certify manufacturers supplying medical devices in Australia. The designation requirements would, among other things, include processes for the regular review of the Conformity Assessment Bodies and processes for de-designation.

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

The TGA should not be solely responsible for undertaking conformity assessments for any or all classes of medical devices and TGA designated Conformity Assessment Bodies should be permitted to undertake assessments of any or all classes of medical devices because:

- 3.1. Since October 2002 the TGA has accepted CE certification as the basis for demonstrating compliance with the essential principles.
 - 3.2. The TGA has had 6 years of experience of reviewing the conformity assessment certification procedures of European Notified Bodies, especially for Class III and AIMD products.
 - 3.3. Medical devices containing designated materials are subject to full review by certain designated Notified Bodies.
 - 3.4. The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity Assessment Bodies.
 - 3.5. The TGA should review summary reports of the assessment of any medicines incorporated in medical devices specifically related to assessing the compliance of the medicines with the essential principles that has been carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the EMEA for products manufactured in the European Union or the FDA for products manufactured in the United States.
 - 3.6. This approach would be consistent with the TGA's shift in emphasis from premarket assessment to postmarket surveillance.
4. **Do you think a Conformity Assessment Body 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 the issuance of a certificate? Should the approach be the same for all classes of device?**

Except for products containing designated materials or medicines, and except for any requirements as part of the TGA's designation procedures for Conformity Assessment Bodies, a TGA designated Conformity Assessment Body should issue certificates for medical devices without the need to produce summary reports for review by the TGA as a condition of an approval to supply those products in Australia.

5. **Should the TGA have a role in designating Australian Conformity Assessment Bodies?**

The TGA should have a role in designating Conformity Assessment Bodies to operate in Australia because:

- 5.1. The TGA could take positive steps to counter a number of criticisms of the EU notified body network presented in a report referenced in the TGA consultation paper.
- 5.2. The designation process should not require the Conformity Assessment Body to have a physical presence in Australia. The designation by the TGA of Notified Bodies based in the EU as part of the Europe/Australia Mutual Recognition Agreement has demonstrated that a designation process can work without the conformity assessment body being based in Australia.
- 5.3. Effective monitoring of the Conformity Assessment Bodies would be achieved through the designation process.

- 5.4. Extensive overseas experience, such as the use by the United Kingdom's MHRA of the designation handbook, could guide the implementation of the TGA designation process.
- 5.5. The use of designated Conformity Assessment Bodies will reduce the TGA's processing timeframes in assessing applications to supply medical devices as mandatory application audits would no longer be required.
- 5.6. The TGA designation procedures could be open to public review and comment to ensure that current safety standards would not be reduced.

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

MTAA proposes that the TGA retains the responsibility for making decisions to control the supply of medical and in vitro diagnostic devices in Australia through the use of the Australian Register of Therapeutic Goods (ARTG).

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

MTAA proposes that:

- 7.1. Recognition of CE certification as evidence of compliance with the essential principles should be continued by the TGA.
- 7.2. The UK MHRA and JAS-ANZ be requested to advise the TGA on the development and maintenance of a transparent designation process for Conformity Assessment Bodies to operate in Australia.
- 7.3. In assuming the role similar to a European Competent Authority, the TGA does not continue to operate as a Conformity Assessment Body.
- 7.4. The implementation program and timetable for the TGA to become a designating authority of Conformity Assessment Bodies should follow from an in-depth consultation process.
- 7.5. The conformity assessment certification and performance testing procedures of Class 4 IVDs should be analogous to the procedures for Class III medical devices and Active Implantable Medical Devices in that TGA designated Conformity Assessment Bodies should be appointed.
- 7.6. Performance testing protocols for Class 4 IVDs should be developed through a public consultation process and then recommended as a standard by a Conformity Assessment (IVD) Standards Order.
- 7.7. A maximum transition period for the TGA to assume the role as a designating authority would be 5 years to allow for the expiration of TGA issued conformity assessment certification, the adoption of any necessary legislative amendments, the development of the designation program, training of TGA staff, and the development and implementation of education and training programs for the industry.
- 7.8. The TGA and industry associations should establish a permanent consultation and review group to monitor the designation processes of the TGA and the performance measures for each TGA designated Conformity Assessment Body.
- 7.9. The TGA should adopt a similar post market role as performed by European Union Competent Authorities.

- 7.10. The TGA adopt an externally assessed and certified agency-wide quality management system.
- 7.11. The TGA work with the industry associations to develop and conduct ongoing education and training programs for the medical technology industry sector.
- 7.12. The TGA should designate Conformity Assessment Bodies to issue ISO 13485 certification to assist the domestic in vitro diagnostic industry sector.

MTAA considers that there are three fundamental components to the submissions presented in this paper. The first component is for the TGA to adopt the role as a designating authority of Conformity Assessment Bodies certifying manufacturers of all classifications of medical devices supplied in Australia. The second is maintaining the control of the supply of medical devices in Australia through the Australian Register of Therapeutic Goods. The third is to support the TGA in its move to adopt a more post market focussed role. The implementation of these fundamental components would create significant advantages for the TGA and the medical technology sector because:

1. Australia would set an example to new jurisdictions establishing medical device regulations based on GHTF principles, to encourage a similar approach to implement effective and realistic regulation of medical technology.
2. Australian manufacturers would be advantaged by a reduction in duplication of quality system audits and product conformity certification review. TGA accredited Conformity Assessment Bodies with a presence in many jurisdictions could be chosen allowing one review to be approved by all regulators. This would simplify access to a wider market without the need for bilateral or multilateral trade agreements.
3. Overseas manufacturers would have more timely access to the Australian market through TGA accredited Conformity Assessment Bodies.

Introduction

Discussion of an assessment scheme for manufacturers supplying medical technology in Australia needs to address a number of issues, not the least of which is the need to ensure the supply of safe and effective products. The range of medical technology products is extremely diverse ranging from simple aids, and products combining medical devices and medicines, to complex life-sustaining implants and equipment, as well as sophisticated in vitro and other diagnostic technologies.

The medical technology sector in Australia includes companies manufacturing products in Australia for supply in Australia and overseas (estimated by MTAA to represent approximately 15% of the sector), companies that are importing and supplying products manufactured by other companies based overseas (estimated by MTAA to represent approximately 10% of the sector) and companies importing their own products which have been manufactured overseas (estimated by MTAA to represent approximately 75% of the sector). Therefore a conformity assessment scheme for Australia needs to be one which assists and supports the diverse medical device sector in Australia across its range of medical devices while ensuring that the current high safety and performance standards are maintained.

As 85% to 95% of the medical technology used in Australia is imported, a conformity assessment scheme needs to recognise acceptable certification issued overseas across all classifications of medical devices. This will then reduce the regulatory costs and disincentives for companies supplying to Australia country which is only 2% of the global market.

Other factors such as

- The sustainability and growth of the diverse Australian medical device industry sector, including in vitro diagnostic medical devices;
- A sector characterised by relatively rapid development of products when compared to pharmaceutical products;
- A sector characterised by relatively short development timeframes when compared to pharmaceutical products;
- A sector impacted by relatively short periods to gain returns on investments when compared to pharmaceutical products;
- An uncertain growth potential for the sector given recent changes in the global financial environment;
- Regulation policy in general having an adverse impact on the trade in medical technology to and from Australia; and
- Ensuring the conformity assessment requirements for in vitro diagnostic medical devices are incorporated in this current proposal

are also important determinants influencing the level or type of regulatory control.

The impact of regulatory controls on the medical technology sector in Australia should be:

- Conducive to encouraging growth in the sector;
- Encourage the trade in medical technology to and from Australia; and
- Streamlined in the implementation of conformity assessment requirements.

Since 2002 the TGA has implemented a regulation policy that has had the effect of discriminating against the Australian domestic medical device manufacturing sector. It is inconceivable that this was the intention of the policy as the TGA, through the Australia/European Union Mutual Recognition Agreement (EU-MRA), has the authority to issue a CE mark for Australian manufacturers wishing to supply their products in the EU. However, some Australian-based manufacturing companies have reported that, on average, it takes twice as long at significantly higher costs for the TGA to issue conformity assessment certification or the CE mark compared to a European Notified Body. Commercial necessity required manufacturers to contract a European Notified Body to issue a CE mark for supply in Europe, undergo audits by the FDA to supply products in the United States, as well as being required to obtain conformity assessment certification from the TGA to supply in Australia.

If supplying products in both the EU and Australia, the costs of obtaining two types of certificates, one from the TGA for supply in Australia and another from an EU Notified Body to supply products in the EU, were often less than the costs of obtaining both types of certificates from the TGA under the EU-MRA. Obtaining the compulsory TGA conformity assessment certificate and a separate CE certificate from a Notified Body was also a faster way to supply Australian manufactured products in the EU for a number of companies. These delays and costs have been a significant factor in the decisions by some Australian-based manufacturers to relocate off-shore. For those manufacturers remaining in Australia it meant that they were likely to be at a competitive disadvantage as their certification compliance costs were greater than those for manufacturers based overseas. This has been supported in the Productivity Commission's *Annual Review of Regulatory Burden on Business: Manufacturing and Distributive Trades* (released in August 2008).

It should be stressed that the issue of the regulatory costs borne by the industry should not be construed as the principal decision factor facing companies when deciding whether to conduct business in Australia. The regulatory costs have to be considered in context with the total operating costs and the decision to operate a sustainable business in Australia. However it remains a challenge for both government and industry to have sufficiently accurate data to quantify the cost impact on doing business. For small companies looking for a worthwhile return on investment and a short timeframe in which to generate those returns, the regulatory costs can be a deciding factor. For some companies the regulatory costs represent a level of fixed costs which may not be offset in a relatively small market for products with limited life cycles. For other companies higher regulatory costs can be a drain on finances in a shrinking venture capital market.

An added disadvantage for Australian manufacturers is that a delay in regulatory approval to market in Australia also delays entry into third country markets requiring a Certificate of Free Sale issued by the TGA before market access is granted. A European competitor could gain CE certification more quickly and therefore gain a competitive advantage in third country markets.

Any consideration of conformity assessment proposals for Australia has to ensure that the in vitro diagnostic industry sector in Australia is not adversely affected when legislation regulating that sector is enacted. The current proposal mandating TGA conformity assessment for Class 4 in vitro diagnostic devices, for example, may have the same effect as for some medical devices by disproportionately increasing the regulatory costs for supplying those products in the Australian market. This has the strong potential to reduce the

accessibility of new diagnostic tests in the Australian market in the same way that the USA lags well behind other parts of the world in adopting state of the art testing due to the high regulatory burden imposed on these types of assays.

There are three fundamental components to the submissions presented in this paper. The first component is for the TGA to adopt the role as a designating authority of Conformity Assessment Bodies certifying manufacturers of all classifications of medical devices supplied in Australia. The second is maintaining the control of the supply of medical devices in Australia through the Australian Register of Therapeutic Goods. The third is to support the TGA in its move to adopt a more post market focussed role. The implementation of these fundamental components would create significant advantages for the TGA and the medical technology sector because:

1. Australia would set an example to new jurisdictions establishing medical device regulations based on GHTF principles, to encourage a similar approach to implement effective and realistic regulation of medical technology.
2. Australian manufacturers would be advantaged by a reduction in duplication of quality system audits and product conformity certification review. TGA accredited Conformity Assessment Bodies with a presence in many jurisdictions could be chosen allowing one review to be approved by all regulators. This would simplify access to a wider market without the need for bilateral or multilateral trade agreements.
3. Overseas manufacturers would have more timely access to the Australian market through TGA accredited Conformity Assessment Bodies.

Responses to the Questions Posed in the TGA Discussion Paper

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

MTAA proposes that the TGA should not be solely responsible for issuing conformity assessment certification for devices containing a designated material for the following reasons:

- 1.1. The revised medical devices regulations applying from October 2002 require the TGA to continue to assess applications for the supply of medical devices containing designated materials, as required under the previous legislation. The justification for the continuation of this requirement was not well communicated by the TGA at that time. MTAA is not aware of any products containing designated materials that have been assessed and accepted by European Conformity Assessment Bodies that have been rejected by the TGA's conformity assessment procedures, and the TGA now has 6 years' experience with assessing such products. The fact that the TGA permitted many abridged conformity assessment audits towards 4 October 2007 at the conclusion of the transition period would appear to indicate that the TGA accepted the assessment and certification work of a number of overseas Conformity Assessment Bodies.
- 1.2. Where a manufacturer chooses to use a Conformity Assessment Body that is not designated by TGA to assess designated materials, the TGA should offer a process for assessing the quality and safety of the designated material (rather than conformity assessment of the whole product). The TGA need only have the role of assessing those aspects of the product that have not been assessed by the Conformity Assessment Body.
- 1.3. The TGA should review summary reports of the assessment of any medicines incorporated in medical devices carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the EMEA for products manufactured in the European Union or the FDA for products manufactured in the United States.
- 1.4. The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity Assessment Bodies.
- 1.5. For materials of animal or other biological origin it is the risk of a number of infections, including transmissible spongiform encephalopathies, which are of concern. A Conformity Assessment Body can be designated to undertake assessment of those safety risks if it is assessed to have the expertise to do so. As in Europe, guidance documents, such as MEDDEV 2.11/1 could be adopted by the TGA to assess such risks.

- 1.6. The Australian Quarantine Inspection Service (AQIS) and the TGA assess the designated materials used in certain medical devices. This duplication results in delays. MTAA suggests that efficiencies could be gained if the TGA, AQIS and industry associations collectively consider the development of one assessment protocol that AQIS would use as part of import permit assessments. The permit would then become a pre-requisite for conformity assessment certification issued by designated Conformity Assessment Bodies.
- 1.7. Even though the overseas Conformity Assessment Bodies designated by the TGA under the EU-MRA have not been able to undertake this work on behalf of the TGA, some of these bodies do have the expertise to certify these goods, and are designated to certify these products for supply within the EU.
- 1.8. If the TGA has concerns about either the designation procedures by European Competent Authorities for the Conformity Assessment Bodies deemed competent to assess these products, or their individual competence, the TGA should develop and implement specific designation procedures for Conformity Assessment Bodies wishing to undertake this work.
- 1.9. The TGA designation procedures for Conformity Assessment Bodies should be open to public scrutiny and review to ensure the effectiveness and transparency of the process. The TGA's increased emphasis on post market surveillance complement oversight of the safety of these products.

In summary, as far as undertaking conformity assessments for devices that contain a designated material is concerned, MTAA proposes that:

- The TGA, acting in a similar way to a European Competent Authority, would designate Conformity Assessment Bodies as acceptable to assess medical devices containing designated materials.
- Where a manufacturer chooses to use a Conformity Assessment Body that has not been designated by the TGA to assess designated materials, the TGA could provide a service to assess the compliance of the designated material with the essential principles.
- The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity Assessment Bodies.
- The TGA should review summary reports of the assessment of any medicines incorporated in medical devices specifically related to assessing the compliance of the medicines with the essential principles that has been carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the EMEA for products manufactured in the European Union or the FDA for products manufactured in the United States.

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

MTAA proposes that the TGA is not solely responsible for undertaking conformity assessments for Australian made medical devices intended for supply in Australia for the following reasons:

- 2.1. The current system of mandatory TGA conformity assessments for products manufactured in Australia for supply in Australia has impeded the development of many domestic manufacturing companies and increased regulatory compliance costs.
- 2.2. The need for mandatory TGA conformity assessment certification for Australian manufacturers supplying products in Australia results in higher regulatory compliance overheads and costs which impedes companies wishing to establish manufacturing facilities in Australia.
- 2.3. TGA conformity assessment certification has not assisted Australian manufacturers supply their products in overseas markets other than in the European Union.
- 2.4. The decision of some companies to relocate off-shore in order to supply their products back in to Australia to reduce the regulatory costs related to supplying their products in Australia. This cost reduction was achieved by undergoing only one type of conformity assessment certification (CE mark) which is acceptable for the European market and Australia. While the regulatory costs may not be the principal financial factor, when considered in context with the total operating costs and the decision to operate a sustainable business in Australia, the relative impact may not be able to be adequately offset during the life cycle of the manufacturer's products.
- 2.5. Under the current arrangements the required oversight of Australian manufacturers by the TGA provides a barrier to transfer manufacturing operations from overseas to Australia due to the burden and additional cost incurred, therefore reducing opportunities to expand Australian manufacturing operations locally.
- 2.6. The TGA has designated 18 Notified Bodies to issue conformity assessment certification for a range of medical devices manufactured in the European Union to be supplied in Australia. These Notified Bodies should also be permitted to certify manufacturers outside the EU and other Conformity Assessment Bodies outside the EU could also be designated by the TGA should those organisations choose to be involved.
- 2.7. The continuation of programs of multiple audits by different regulatory authorities is in conflict with the GHTF Action Plan for 2007-2010: Path Forward for the Global Harmonisation Task Force, April 2007 which recommends that single audits are used for multiple jurisdictions (p.2).

- 2.8.** In becoming a designating authority for Conformity Assessment Bodies to operate within Australia, in a similar way to European Competent Authorities, the TGA could eliminate some criticism noted in a report from the European Commission, ie *“Generally speaking, most respondents confirmed that the current legal framework for medical devices left some room for improvement to strengthen the regulatory system. There was broad support for the view that some weaknesses which the Commission had highlighted in the questionnaire eg inconsistent oversight of notified bodies, no uniform level of expertise in notified bodies, lack of regulation of certain products) needed to be addressed. Also, further elements of centralisation were considered useful, ...”* (page 2 of the European Commission’s Report on the Recast of the Medical Devices Directives – Summary of Responses to the Public Consultation)
- 2.9.** Given that the TGA designated a number of European Conformity Assessment Bodies through the MRA, MTAA cannot see any reason why the same recognition could not be offered to any suitable Conformity Assessment Body wishing to undertake conformity assessment certification activities on behalf of the TGA and meet the TGA’s criteria for designation. The TGA would need to determine the criteria for suitability as it did under the EU-MRA.
- 2.10.** Given that TGA designated a number of European Conformity Assessment Bodies through the EU-MRA, MTAA maintains that the TGA should now have confidence in the work of those Conformity Assessment Bodies and consequently accept their certification activities in relation to Australian regulations on behalf of manufacturers outside the EU as well as those within the EU.
- 2.11.** MTAA proposes that the TGA and industry associations collectively develop transparent designation requirements for Conformity Assessment Bodies to certify manufacturers supplying medical devices in Australia. The designation requirements would, among other things, include processes for the regular review of the Conformity Assessment Bodies and processes for de-designation.

In summary, as far as the TGA continuing to be solely responsible for undertaking conformity assessments for Australian made devices intended to be supplied in Australia is concerned, the MTAA proposes that:

- The TGA becomes a designating authority for suitably qualified Conformity Assessment Bodies to assess and certify manufacturers based in Australia that supply their products in Australia
- The TGA ceases to operate as a Conformity Assessment Body as this would give rise to conflicts in performing the role of a Competent Authority. This especially valid when a Competent Authority has to consider the performance of a Conformity Assessment Body it has designated.

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

MTAA proposes that the TGA is not solely responsible for undertaking conformity assessments for any or all classes of medical device and Conformity Assessment Bodies should be permitted to undertake assessments of any or all classes of medical device for the following reasons:

- 3.1.** Since enactment of the new regulations in 2002, the TGA has gathered extensive experience working with European Notified Bodies in various ways. The TGA has accepted EC Quality Management System certification and CE Certification for medical devices as the basis for TGA approval.
- 3.2.** Through the EU-MRA, the TGA has accepted the evaluation of Design Dossiers for Class III devices manufactured in the EU without undertaking any further evaluation thereby demonstrating its confidence in the processes and procedures undertaken by 18 designated Conformity Assessment Bodies. As experience with other Class III and AIMD devices has increased, the TGA has recently reduced the requirements for Level 2 Application Audits to a minimal level.
- 3.3.** The TGA initially justified the requirement for mandatory application audits for Class III and AIMD products which were already CE Marked as a confidence building process. The TGA now has more than 6 years experience working with overseas Conformity Assessment Bodies. MTAA experience supports the acceptance of conformity assessment by recognised overseas Conformity Assessment Bodies. MTAA also considers that the regulatory burden of additional TGA evaluation is not justified in protecting the safety and welfare of the Australian public when compared with the other regulatory jurisdictions.
- 3.4.** Medical devices that contain designated materials are subjected to full evaluation by certain designated Notified Bodies which have demonstrated expertise with devices incorporating medicines or materials of animal, human or microbial origin. The TGA could also designate these Notified Bodies if they met the criteria determined by the TGA and wanted to be involved in the program.
- 3.5.** The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials or medicines with the essential principles for devices incorporating medicines or materials of animal, human or microbial origin that has been undertaken by TGA designated Conformity Assessment Bodies.
- 3.6.** The approach of accepting conformity assessment by overseas Conformity Assessment Bodies for any and all medical devices is consistent with the TGA's stated shift in emphasis from premarket assessment to postmarket

surveillance.

- 3.7.** The TGA could also designate regulatory agencies in other jurisdictions which seek to extend their services and meet the designation criteria. This could also advance the GHTF's quest in improving mutual recognition of regulatory requirements between regulatory authorities.

In summary, as far as the TGA being solely responsible for undertaking conformity assessments for any or all classes of medical device and Conformity Assessment Bodies being permitted to undertake assessments of any or all classes of medical device are concerned, MTAA proposes that:

- The TGA becomes a designating authority for suitably qualified Conformity Assessment Bodies to assess and certify manufacturers of all classifications of medical and in vitro diagnostic devices.
- The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity Assessment Bodies.
- For medical devices manufactured overseas and containing medicines the TGA should review summary reports of the assessment of any medicines incorporated in medical devices specifically related to assessing the compliance of the medicines with the essential principles that has been carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the EMEA for products manufactured in the European Union or the FDA for products manufactured in the United States.
- The TGA does not operate as a Conformity Assessment Body as this would give rise to conflicts in performing the role of a Competent Authority. This is especially valid when a Competent Authority has to consider the performance of a Conformity Assessment Body it has designated

4. Do you think a Conformity Assessment Body 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 the issuance of a certificate? Should the approach be the same for all classes of device?

MTAA proposes that certification issued by TGA designated Conformity Assessment Bodies for all classifications of medical devices, except for those devices described below and in vitro diagnostic products described in the reply to Question 7, should be accepted by the TGA without the added requirement of producing a report of their findings.

- 4.1. The TGA has already designated 18 Conformity Assessment Bodies under the EU-MRA and currently accepts the certification issued by those Notified Bodies without further review or examination. This system has been successfully utilised by the TGA without the need to review reports of the findings. There has been no evidence of any diminution in safety of the products supplied under those certifications.
- 4.2. Further to this, the TGA has recognised and accepted that its own designation procedures under the EU-MRA have obviated the need for application audits for products manufactured in the European Union.
- 4.3. Imposing a requirement to review the reports relating to certification issued by a TGA-approved Conformity Assessment Body would unnecessarily complicate and delay the introduction of medical technology into Australia.
- 4.4. The penalty of withdrawing the accreditation of a TGA-approved Conformity Assessment Body would be an effective control, in conjunction with the ARTG, to ensure the safety and quality of products supplied in Australia.
- 4.5. Pre-market activities are a snapshot in time. Post-market monitoring of medical and in vitro diagnostic medical devices in Australia would be more efficient and an effective way of monitoring ongoing safety and performance.

In summary, as to the need for a Conformity Assessment Body to issue certificates for acceptance, or otherwise, by the TGA or produce a report of their findings for the TGA to consider prior to the issuance of a certificate, and whether the approach should be the same for all classes of device are concerned, MTAA proposes that:

- The TGA becomes a designating authority for suitably qualified Conformity Assessment Bodies to assess and certify manufacturers of all classifications of medical and in vitro diagnostic devices
- For medical devices that do not contain designated materials or medicines, the TGA should accept, without further review, the conformity assessment evidence issued by TGA designated Conformity Assessment Bodies
- The TGA should review summary reports of the conformity assessment certification processes specifically related to assessing the compliance of designated materials with the essential principles that has been undertaken by TGA designated Conformity

Assessment Bodies.

- The TGA should review summary reports of the assessment of any medicines incorporated in medical devices specifically related to assessing the compliance of the medicines with the essential principles that has been carried out by authorities through agreements developed with the TGA. These authorities could include, for example, the EMEA for products manufactured in the European Union or the FDA for products manufactured in the United States.

5. Should the TGA have a role in designating Australian Conformity Assessment Bodies?

MTAA proposes that the TGA assume a similar role in Australia as a Competent Authority in the European Union, in terms of designating and monitoring Conformity Assessment Bodies for the following reasons:

- 5.1.** In becoming a designating authority for Conformity Assessment Bodies, the TGA could take positive steps to counter a number of criticisms of the EU notified body network described in a report from the European Commission which has been referenced on page 7 of the TGA consultation paper. These issues included the inconsistent oversight of notified bodies, no uniform level of expertise, and a lack of regulation of certain products.
- 5.2.** The designation criteria should not require the Conformity Assessment Bodies to have a physical presence in Australia if this has been proposed as a form of control. There are two ways to control the supply of products in Australia by adopting the recommendations in this paper. The first is through the conditions of Inclusion in the ARTG. The second is by withdrawing the designation of the Conformity Assessment Body.
- 5.3.** Given that the TGA already permits 18 European Notified Bodies to undertake conformity assessment certification on its behalf under the EU-MRA, there is no reason why the same recognition could not be extended to any Conformity Assessment Body, in Australia or overseas, which met the designation criteria established by the TGA.
- 5.4.** The TGA has demonstrated its confidence in the designation process available through the EU-MRA over the past 6 years, and consequently should now accept the certification activities of those Conformity Assessment Bodies on behalf of manufacturers outside the EU as well as those within the EU.
- 5.5.** By designating Conformity Assessment Bodies the TGA could remove the requirement for mandatory TGA application audits. This would reduce the time taken to process applications to supply medical devices.
- 5.6.** In assuming the role of a designating authority, the industry expects that the legislation regarding the conditions of inclusion on the ARTG will be amended to ensure that any joint audits of a manufacturer's facilities by the TGA and Conformity Assessment Bodies would be only undertaken as part of the TGA

designation procedures of those Conformity Assessment Bodies, *and not* as part of the conformity assessment certification procedures of the manufacturer by the Conformity Assessment Body.

- 5.7. Extensive experience (including periods of confidence building) and established guidelines (such as those developed by the Notified Body Operations Group and the “Designating Authorities Handbook”) have resulted from the work of Competent Authorities. The TGA can benefit from this experience, and is in an ideal position to act as a designating authority for Conformity Assessment Bodies.
- 5.8. The TGA designation procedures should be open to public scrutiny and review to ensure the safety of products. A transparent designation process for Conformity Assessment Bodies certifying products supplied in Australia would be an effective way for the TGA to reinforce its, and consequently, the Australian public’s confidence in those bodies.

In summary, as far as the TGA having a role in designating Australian Conformity Assessment Bodies, MTAA proposes that:

- The TGA should assume responsibility for designating Conformity Assessment Bodies, and therefore discontinue its role as a Conformity Assessment Body.
- Conformity Assessment Bodies designated by the TGA would not be required to have a physical presence in Australia.
- The same Conformity Assessment Body will be able to provide approval in multiple jurisdictions.
- The TGA designation procedures should be open to public scrutiny and review to ensure the effectiveness and transparency of the process.

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

MTAA proposes that the TGA retains the responsibility for making decisions to allow the supply of medical and in vitro diagnostic devices in Australia through the use of the ARTG. This would be further strengthened by implementing those parts of the postponed ANZTPA legislation concerned with the product licence scheme.

Despite Conformity Assessment Bodies being based overseas, all products supplied in Australia would still be controlled through regulation of the Sponsor and the conditions of Inclusion in the ARTG, exactly as currently applies to therapeutic goods manufactured overseas.

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

- 7.1.** A feature of the current regulation practices for medical devices introduced in October 2002 was provided through Regulation 3.5 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. This regulation allowed the Secretary of the Department to accept conformity assessment certification in the form of CE certificates issued by European Notified Bodies. So far as MTAA is aware, during the past 6 years the TGA, while indicating some lack of confidence about some aspects of the CE certification processes undertaken by some Notified Bodies, has not raised any objections at a formal level with the European Commission, nor has the TGA ceased to recognise the authority or expertise of any Notified Body. Given that this has been an evolving regulatory process during the past 6 years during which experience has been gained by both the industry and the regulators, MTAA considers that the fundamentals of the practice whereby the TGA recognises and accepts CE certification remain sound and should be continued.
- 7.2.** MTAA recommends that the TGA seeks advice from suitably credentialed organisations which have been involved in establishing designation programs and services to help the TGA develop and maintain a transparent designation process for Conformity Assessment Bodies. Overseas regulators such as Health Canada, the US FDA, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the Joint Accreditation System of Australian and New Zealand (JAS-ANZ) should be able to provide the necessary advice and guidance to complement the TGA's experience gained over the past 6 years and implement a new phase in the TGA's regulatory programs and oversight.
- 7.3.** The MHRA, during the public seminars held in Sydney and Melbourne during March 2009, indicated that it has worked well in Europe to have the functions and operations of Competent Authorities and Notified Bodies undertaken by separate organisations, while allowing for the designation and monitoring roles of the Competent Authorities over the Notified Bodies. This practice is a practical and realistic measure to avoid real or potential conflicts of interest. For example, the MHRA's Guidance Note 6 explains the duty of a designating authority to withdraw the designation of a notified body if that notified body fails to meet certain auditing criteria.

In advocating that the TGA assumes the role of a competent authority MTAA therefore recommends that the TGA does not continue to operate as a Conformity Assessment Body.

- 7.4.** It should be noted that there is an analogy between the conformity assessment certification requirements for medical devices containing a designated material and proposals to assess Class 4 IVDs. MTAA recommends that the TGA should not be solely responsible for undertaking conformity assessments, including performance testing, of Class 4 IVDs. The TGA should develop publically reviewable designation and monitoring criteria for Conformity Assessment Bodies or laboratories which have the capabilities and expertise to

perform these roles. The TGA could then review the summary reports of the conformity assessment procedures and the performance testing reports before approving the supply of the IVDs being assessed. This process then becomes analogous to the MTAA recommendations for Class III medical devices and active implantable medical devices.

As Australia is likely to be the first jurisdiction to implement IVD regulations, and with other jurisdictions likely to assess the impacts and effectiveness of the program, MTAA considers that the strategy of designating conformity assessment and performance testing organisations should minimise the time it will take to place these IVDs on markets, not only in Australia but in other jurisdictions.

MTAA considers that a strategy in which designation criteria, conformity assessment protocols and the adoption of a Conformity Assessment (IVD) Standards Order for performance testing for Class 4 IVDs be developed for Australia (while ensuring it is consistent with the conformity assessment procedures which have been adopted in the European Union through the IVD Directives), will assist IVDs to be supplied in Australia. Without this strategy it may not be viable to supply products in Australia due to unique regulatory requirements or the relatively small market.

- 7.5.** MTAA recommends that a performance testing protocol for Class 4 IVDs should be developed through a consultation process between the TGA, the industry and users of that class of IVDs and then proposed as a recommended performance standard by a Conformity Assessment (IVD) Standards Order.
- 7.6.** There should be a maximum transition period of five years for the TGA to assume the role as a designating authority. This would allow for the expiration of TGA issued conformity assessment certification, thereby maximising the returns that could be gained from any TGA certification, the adoption of any necessary legislative amendments, the development of the designation program, training of TGA staff, and the development and implementation of education and training programs.
- 7.7.** MTAA considers that a TGA designation scheme for Conformity Assessment Bodies will provide more certification options for manufacturers, based in Australia or overseas, when balancing contractual arrangements with Conformity Assessment Bodies and the legislative requirements in the markets in which the manufacturers elect to supply their products.
- 7.8.** MTAA recommends that the implementation program and timetable for the TGA to become a designating authority of Conformity Assessment Bodies will follow from in-depth consultation with all industry associations, Commonwealth Government departments, State government departments, health authorities and professional healthcare bodies.
- 7.9.** MTAA recommends that the TGA and industry associations establish a permanent consultation and review group to monitor the designation activities of the TGA and the performance measures for each Conformity Assessment

Body.

- 7.10.** The TGA should adopt a similar post market surveillance role as performed by the Competent Authorities in the EU. In so doing it would complement the designation scheme for Conformity Assessment Bodies operating on behalf of the TGA.
- 7.11.** MTAA encourages the TGA to implement an agency wide quality management system which is externally assessed and certified.
- 7.12.** MTAA recommends that the TGA develops and conducts ongoing education and training programs to help all medical technology companies doing business in Australia understand the regulatory requirements. Experience has demonstrated that ad-hoc training, for example at the introduction of new legislation or guidance documents, does not assist with ongoing issues. This could be undertaken as a collaborative exercise with the industry associations.
- 7.13.** An additional advantage of having the TGA designate Conformity Assessment Bodies is that it would be expected that those Conformity Assessment Bodies would have also have been accredited to issue ISO 13485 certification. This would help the domestic IVD industry sector overcome the current problem whereby the TGA cannot issue internationally recognised ISO certification.