

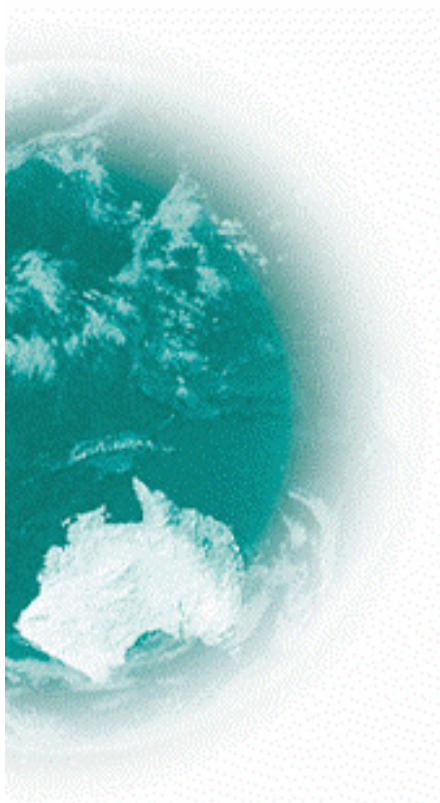


Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

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

Consultation Paper



December 2008

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

Contents

Executive Summary	3
Background.....	4
Risk Based Classification of Medical Devices	5
What are Conformity Assessment Bodies and who designates them?.....	5
What is a Conformity Assessment Body responsible for?.....	6
Operation of CABs in other jurisdictions.....	7
Proportion of inclusions into the ARTG based on certificates issued by an external CAB	9
Discussion	10
Factors to be considered.....	10
<i>a. Devices containing a designated material.....</i>	<i>10</i>
<i>b. Devices manufactured in Australia</i>	<i>11</i>
<i>c. Using the risk-based classification system to determine who is responsible for issuing conformity assessment certificates.....</i>	<i>12</i>
<i>d. Where CABs are used, what level of involvement should the TGA have in the decision to include the device in the ARTG?.....</i>	<i>12</i>
<i>e. Australian-based CABs.....</i>	<i>13</i>
<i>f. The regulatory decision.....</i>	<i>13</i>
Cost Recovery Implications	14
Other matters.....	14
The Consultation Process	15
Attachment 1: The Essential Principles.....	16
Attachment 2: The Conformity Assessment Procedures.....	17

Executive Summary

The Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic goods in Australia. The TGA's stated mission is to *safeguard public health and safety in Australia by regulating medicines, medical devices, blood, and tissues*. This is accomplished by administering the laws as defined in three key legislative instruments: the *Therapeutic Goods Act 1989*, the Therapeutic Goods (Medical Devices) Regulations 2002, and the Therapeutic Goods Regulations 1990. The requirements of medical device regulation administered by the TGA are in accordance with the framework established by the *Global Harmonization Task Force* (GHTF), the member states of which are Europe, Japan, Canada, the United States, and Australia.

In order to manufacture a device for supply to the Australian market, a manufacturer must comply with the Australian regulations. Overseas manufacturers may demonstrate compliance with Australian regulations by demonstrating compliance with the European regulations as certified by a European notified body. Notified bodies are commercial assessment bodies approved by the European Union to provide technical evaluation of the quality, safety and performance of certain medical devices.

Evidence of compliance is usually provided by means of product and/or quality management system (QMS) certificates. Both the European notified bodies and the TGA issue product and QMS certificates. These certificates are called conformity assessment certificates, as they indicate evidence of the manufacturer's conformity with the relevant regulations. Once sufficient evidence is submitted to the TGA and accepted, the medical device can then be included in the Australian Register of Therapeutic Goods (ARTG), which is a register of those therapeutic goods that may be legally supplied in Australia.

In Australia, greater than 97 per cent of applications for inclusion of medical devices in the ARTG are supported by European CE Certificates issued by one of the 78 notified bodies operating in Europe.

Certain specified high-risk devices (those containing a medicinal component or one of biological origin) must be assessed by the TGA, regardless of whether the manufacturer holds CE certification or not. Additionally, all Australian medical device manufacturers intending to supply their devices in Australia must be assessed by the TGA.

Certificates for Australian manufacturers make up about 1.5 per cent of the conformity assessment certificates that support device inclusions in the ARTG, with the remaining 1.5 per cent being for devices classified higher in Australia than in Europe, for the specified high-risk devices, and for those manufacturers that do not hold CE certificates.

The TGA's exclusive role in issuing certificates to Australian manufacturers has been questioned over a number of years by the medical devices industry sector, which sees it as an unfair restriction on Australian manufacturers, relative to overseas manufacturers.

The present paper invites discussion and comment on the use of third-party bodies for the assessment of devices or of manufacturers and to determine an appropriate balance of regulatory involvement in the process to ensure the timely availability of safe and effective medical devices to the Australian community.

Background

Australia regulates the quality, safety and performance of medical devices in accordance with the framework established by the GHTF for the regulation of medical devices. The fundamental components of the framework are:

- a classification system for medical devices based on the risk the device presents to the user, the patient and the environment;
- a set of Essential Principles¹ setting out requirements for safety and performance of a medical device;
- a set of conformity assessment procedures² used by the manufacturer of a medical device to demonstrate the device is in compliance with the Essential Principles of safety and performance;
- assessment of the application of those procedures by an appropriately authorised body, including initial and on-going surveillance audits of the manufacturer's quality management system;
- inclusion as a 'kind of medical device' on the ARTG.

Inclusion in the ARTG allows a medical device to be legally supplied in, or exported from, Australia. To be included in the ARTG the TGA requires applicants to hold, or have access to, evidence that the conformity assessment procedures applied by the device manufacturer demonstrate compliance with the Essential Principles, including evidence that the manufacturer's quality system has been accredited to an acceptable standard. The evidence is produced in a form termed a conformity assessment certificate and the body issuing the certificate is referred to as a Conformity Assessment Body (CAB).

The *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002* specify that the TGA is responsible for issuing conformity assessment certificates for devices in two circumstances:

- where the device contains a medicinal component and/or materials of animal, biological or microbial origin or recombinant equivalents of these substances – referred to collectively in this paper as 'designated materials',³ and
- where the device is manufactured in Australia (other than 'low risk' or Class I devices).

Where the device is not made in Australia and it does not contain a designated material then bodies other than the TGA may issue conformity assessment certificates. These certificates are provided to the TGA as evidence to support the inclusion of the device in the ARTG. The TGA's exclusive role in issuing certificates to Australian manufacturers has been questioned over a number years by the medical devices industry sector, which sees this

¹ Refer to Attachment 1 for details of the medical devices Essential Principles.

² Refer to Attachment 2 for an explanation of conformity assessment procedures.

³ Division 4.1 of Part 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* requires TGA to issue Conformity Assessment Certificates for medical devices that contain tissues of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only); medical devices that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body; medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device; medical devices that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device.

requirement as an unfair restriction on Australian manufacturers relative to overseas manufacturers. This position has been articulated most recently in the Productivity Commission's *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*, which was released in August 2008.⁴

The TGA's role in issuing conformity assessment certificates to Australian manufacturers was to have been considered as part of the establishment of the Australia New Zealand Therapeutic Products Agency (ANZTPA). Although the establishment of ANZTPA has been postponed, the Government has flagged its intentions to discuss options for enabling bodies other than the TGA to issue conformity assessment certificates for those devices required by current legislation to have TGA-issued certificates.

The present paper outlines the principal issues to be considered in relation to use of third party conformity assessment bodies for assessment of medical devices or manufacturers.

Risk Based Classification of Medical Devices

The Australian regulatory framework adopts a classification system to categorise medical devices based on the risk the device presents to the patient, the user and the environment. The system uses a set of classification rules based on:

- the manufacturer's intended use for the device
- the level of risk presented by use of the device, and
- the degree of invasiveness in the human body.

The five classes of medical devices, starting with the lowest designated level of risk are:

- Class I (low risk)
 - Class I supplied sterile (Class Is)
 - Class I with a measuring function (Class Im)
- Class IIa (low - medium risk)
- Class IIb (medium – high risk)
- Class III (high risk)
- Active Implantable Medical Devices (AIMD)

Further information on device classification can be found in TGA's *Guidance Document 25 – Classification of Medical Devices*, <http://www.tga.gov.au/docs/html/devguid25.htm>

What are Conformity Assessment Bodies and who designates them?

The implementation of the GHTF regulatory model requires appointment of an assessment body (or bodies), independent of the manufacturer, to verify the manufacturer has correctly applied and documented an appropriate conformity assessment procedure to the device and, depending on the outcome of the review of the manufacturer's activity, will issue the relevant certificates. These organisations, referred to as 'CABs', are given various titles in the different GHTF jurisdictions:

- Europe Notified Body
- USA Authorized Person
- Canada Registrar

⁴ Productivity Commission 2008, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*, Research Report, Canberra.

- Japan Registered Certification Bodies.

The appointment or designation of these assessment bodies is undertaken by the Government regulatory agency in each jurisdiction. In some jurisdictions the regulatory agency performing the designation task is also the one responsible for assessments; in others it is a commercial organisation appointed by the regulatory agency; and in other jurisdictions it is a combination of both the regulatory agency and commercial organisations.

What is a Conformity Assessment Body responsible for?

Conformity assessment is composed of a number of elements. Firstly, it is the responsibility of the medical device manufacturer to correctly choose and apply a conformity assessment procedure⁵ relevant to the classification of the medical device.

Secondly, it is the correct application of the selected procedure, or procedures, by the manufacturer that is reviewed by the CAB. On successful review, a certificate will be issued appropriate to the procedure(s) used. That certificate will be supported by a report detailing the findings and conclusions of the assessment body.

Titled a 'Conformity Assessment Certificate', the certificate will also be subtitled, where appropriate, as follows

Design Examination – This relates to where the manufacturer has implemented an appropriate control process to ensure the specification for the manufacture of the device produced at the end of the design process is verified as meeting the original design requirements, including compliance with the Essential Principles. The assessment body will examine the documented Design Dossier describing the process and the product and will issue a Design Examination Certificate.

Type Examination – This relates to where the manufacturer has submitted technical documentation relating to the device, and a representative sample of the device, for type examination. The assessment body reviews the information provided, and examines the device against an appropriate safety and performance standard. When satisfied the device is in compliance with the applied standard, the assessment body will issue a Type Examination Certificate.

Quality Assurance Procedures – These are where the manufacturer has implemented an appropriate Quality Management System (QMS) covering production, installation and service of medical devices and the design, development and provision of related services. Class III and AIMD devices also require that the QMS encompass control over design and development procedures for the device. The assessment body may issue either a Full Quality Assurance Procedure certificate where the QMS incorporates design control, or a Production Quality Assurance Procedure certificate where design control is not an element of the QMS.

Verification Procedures – These are where the manufacturer has implemented a process to ensure the devices are produced in accordance with an approved type or with technical documentation defining the device, and the assessment body examines every individual product, or a statistically relevant sample from each batch of product, and has carried out such tests as to show conformity of the device with the approved/documented design. When satisfied the device, or samples of the device conform with the

⁵ Refer to Attachment 2 for an explanation of conformity assessment procedures.

approved/documented design, the assessment body will issue a Verification Procedures certificate.

Product Verification Procedures – These are where the manufacturer has implemented a QMS covering final inspection and testing of finished product to ensure the device is made in accordance with an approved type or approved/documented specification, and the assessment body has examined the implementation of the QMS. When satisfied the QMS is in place and the functions and procedures employed in the manufacturing of the medical device are in compliance with the documented QMS, the assessment body will issue a Product Quality Assurance Procedures certificate.

Operation of CABs in other jurisdictions

Table 1 highlights the different approaches to the use of CABs in the different GHTF jurisdictions of Europe, USA, Canada and Japan. It also compares these with the current regulatory framework in operation in Australia for overseas manufactured devices.

The regulatory authorities in the United States, Japan and Canada⁶ are exclusively responsible for the assessment and approval of all medical devices except ones classed as low risk, in which case a CAB may undertake the assessment, but not the final approval, of the device. In the European Union all device assessments and approvals are currently⁷ undertaken by CABs irrespective of the risk classification.

TGA makes significant use of the reports issued by the CABs used in Europe to approve medical devices for entry into the European markets. The role of European CABs (Notified Bodies), as well as the wider medical devices regulatory system in Europe, is currently being assessed by the European authorities with a view to simplifying and strengthening the present arrangements. The European Commission has published a summary of comments received in response to their consultation but is yet to determine what actions will be taken in response to these comments.

The following extract from the summary of comments received by the European Commission expresses their general concerns relating to CABs:

“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 (e.g. 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, although the suggestion to expand the role of the European Medicines Agency (EMA) to include medical devices was rejected by a majority of respondents.”

⁶ As indicated in the Table Canada allows external assessment of a manufacturer’s quality system but retains responsibility for assessment of the device.

⁷ http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm. Responses to the consultation are reported at http://ec.europa.eu/enterprise/medical_devices/recast_docs_2008/responses/responses_public%20consultation_recast.pdf

Table 1 Summary and comparison of roles performed by international CABs

	Device types *	CAB	Designation of the CAB	Regulatory decision to approve/reject the device is by
European Union	All	Notified Body	Regulatory Authority	Notified Body
United States	Only designated (US) class II and III intended for export as well as local consumption	Regulatory Authority - FDA, OR Designated 3 rd Party	Regulatory Authority (FDA) – Third Party Review Board	Regulatory Authority (FDA)
	All others	Regulatory Authority - FDA	Regulatory Authority (FDA)	Regulatory Authority (FDA)
Canada	Quality Management System assessment for all devices	Registrar	Health Canada, based on recommendation of the Standards Council of Canada	Regulatory Authority (Health Canada)
	Device (product) Assessment	Regulatory Authority – Health Canada	-	Regulatory Authority (Health Canada)
Japan	Class II, but limited to availability of a Japanese standard	Pharmaceutical and medical Devices Agency (A Government Agency separate to the responsible ministry, MHLW)	Regulatory Authority (Ministry of Health Labour and Welfare, MHLW)	Regulatory Authority (MHLW)
	Class II, III and IV	Registered Certification Body	MHLW	Regulatory Authority (MHLW)
Australia	Low Risk classification	TGA accepts evidence of 3 rd party assessments	-	Regulatory Authority (TGA)
	High Risk classification	TGA reviews reports generated in 3 rd party assessments	-	Regulatory Authority (TGA)
	Australian manufacturers and products containing designated materials	Regulatory Authority – TGA – but taking into account reports generated in 3 rd party assessments where possible	-	Regulatory Authority (TGA)

* The system used to classify medical devices based on risk is not the same in each jurisdiction. Thus, for example, Class II in USA is not equivalent to Class II in Japan or Australia.

Specific criticisms were made in relation to the operation of CABs (Notified Bodies) under the European system:

“There was unanimous support for improving the way in which Notified Bodies currently work. Most respondents believed that this should be done first of all by tightening up the designation and monitoring of Notified Bodies to ensure a uniform high level of competence. Many respondents, including the Notified Bodies themselves, supported central oversight of their designation by Member States. In this context, it was often mentioned that NBOG [Notified Body Operations Group] should be given legal status to adopt binding measures (e.g. the NBOG Handbook).”

Proportion of inclusions into the ARTG based on certificates issued by an external CAB

In Australia greater than 97 per cent of applications for inclusion of medical devices in the ARTG, are supported by EC Certificates issued by one of the 78 Notified Bodies operating in Europe, or by MRA Certificates issued by one of the 18 CABs in Europe approved for the purposes of the Australia-European Union Mutual Recognition Agreement.

The TGA has issued 156 conformity assessment certificates to 102 Australian manufacturers since October 2002, of which 127 certificates are for low-medium risk devices. Certificates for 21 new Australian manufacturers are currently under review. Certificates for Australian manufacturers make up 1.5 per cent of the conformity assessment certificates that support device inclusions in the ARTG.

In all cases approval for inclusion in the ARTG is considered when the sponsor supplies the necessary certificates to the TGA.

Discussion

The issues to be considered fall into three broad categories. These are:

- 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.

Factors to be considered

a. Devices containing a designated material

Medical devices that contain a medicinal component, such as a drug-eluting stent, and ones that contain a material of animal or other biological origin, such as collagen implants, are required to be assessed by the TGA. They are regarded as high risk medical devices.

Where a medical device contains a medicinal component this component is often one that would be classed as a prescription medicine, for example, antibiotics, steroids and hormones. Assuring the quality and safety of these drugs is essential for the welfare of the patient.

Materials of animal or other biological origin require specialised assessment to ensure the absence of transmissible substances such as viruses and prions, which could infect the recipient.

The TGA has adopted international standards for ensuring the quality and safety of medicinal substances and for ones of animal and other biological origin. When presented in medicinal form, the TGA undertakes a full assessment of the substance for compliance with these

standards. Similarly, the TGA undertakes the assessment of devices containing these designated materials to determine that requirements applied to the substance ensure its quality and safety and to ensure that the standards applied are the same as those applied when the substance is used in other therapeutic goods assessed by the TGA.

The TGA has therefore sought to apply a uniform approach to controlling the quality and safety of these substances irrespective of whether they are used in a medicine or as a component of a medical device.

1. Do you think TGA should continue to be solely responsible for undertaking conformity assessments for devices that contain a designated material? If so, why? If not, who should do this?

b. Devices manufactured in Australia

Australian medical device manufacturers intending to supply their product in Australia (excluding Class I) are required to apply to the TGA for a conformity assessment certificate. The TGA's role in authorising the supply of medical devices in Australia and for export purposes from Australia has been considered valuable for protecting the reputation of Australian manufacturers and therefore for enhancing exports opportunities.

However, since more than 95 per cent of the medical devices supplied in Australia are imported, mainly from jurisdictions where use of CABs is recognised, albeit to different extents, it has been argued that Australian manufacturers intending to supply product in Australia should also be allowed to use CABs. Arguments made in support of this approach have pointed to potential reduction in duplication of regulatory requirements for those Australian manufacturers wishing to export products, and potential reduction in timeframes and costs to achieve conformity certification.

An advantage in retaining the current status is that there is a high level of accountability for the quality and performance of the TGA undertaking the conformity assessments. There is international confidence in the competence of the TGA as an assessment body and the flow on is confidence in the quality, safety and performance of devices manufactured in Australia. It also has the perceived benefit of maintaining the high standing of Australian manufacturers in overseas markets, as well as locally, by virtue of the fact that the TGA has direct responsibility for the oversight of their products.

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? If so, why? If not, who should do this?

c. Using the risk-based classification system to determine who is responsible for issuing conformity assessment certificates

Table 1 above highlights the different approaches to the use of CABs taken by the different GHTF jurisdictions. The regulatory authorities in the United States, Japan and Canada (see footnote 6) are responsible for the assessment and approval of all medical devices except ones classed as low risk, in which case a CAB may undertake the assessment, but not the final approval, of the device. On the other hand, in the European Union all device assessments and approvals are currently undertaken by CABs irrespective of the risk classification.

A review of the European medical devices regulatory system is currently underway (see footnote 7). One of the proposals under discussion is transfer of responsibility for conformity assessments for higher risk devices from CABs to a supra-national authority and for the latter to make recommendations for consideration by the various national regulators, similar to the approach used for medicines.

If Australia were to align the use of CABs with its classification system then a decision would be required as to which classes of devices would be eligible for assessment by a CAB. This decision could be informed by the arrangements followed in other jurisdictions (see Table 1).

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?

d. Where CABs are used, what level of involvement should the TGA have in the decision to include the device in the ARTG?

Under the current regulatory arrangements the TGA has the following involvement with CABs:

- For Australian-made devices intended for supply in Australia and ones containing a designated material the TGA coordinates and/or undertakes all aspects of the assessment and makes the final decision regarding inclusion in the ARTG, making use where possible of work undertaken by CABs.
- For other devices, except Class I, the TGA reviews declarations provided by applicants prior to making a decision as to whether or not the device should be included in the ARTG. The declarations include statements that appropriate conformity assessment certificates are available. For certain types of devices these certificates are also reviewed. The certificates are generated for the device manufacturer by a CAB. When required, the TGA will also review the CAB's reports that were created in support of the assessment certificates.
- For Class I (excluding Class I supplied sterile and Class I with a measuring function) inclusion into the ARTG is based on the applicant's declaration that the device meets all of the TGA's requirements for Class I devices. Reviews of evidence used to support the declaration, including certificates issued by CABs, may be undertaken once the device has been included in the ARTG.

Where a CAB is used, possible arrangements for the TGA, prior to making a decision to include/not include a device in the ARTG, are to:

- accept a declaration by the applicant that a certificate has been issued, and/or
- require the certificate be provided for review, and/or
- require the certificate and the CAB report be provided for review.

These requirements could vary depending on the type and class of medical device.

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?

e. Australian-based CABs

Where CABs are used in overseas jurisdictions they are required to be designated as such by the regulatory authority (refer to Table 1). Designation is achieved when the CAB can demonstrate that it complies with the requirements of an international standard for conformity assessment bodies. Compliance can be assessed by the regulatory authority or by a suitable accreditation authority.

If the TGA were to be the designating body for Australian-based CABs there would need to be a set of agreed principles that would be used by the TGA in making a decision on whether or not a body would receive designation status. Factors that could be considered include that the CAB be a legal entity in Australia; that it be subject to TGA audits and agree to TGA staff undertaking joint assessments when required. These and other criteria would be subject to further discussion.

5. Should TGA have a role in designating Australian CABs? If yes, why? If not, who should perform this function?

f. The regulatory decision

The decision to authorise a medical device for supply is the responsibility of the regulatory authority in each GHTF jurisdiction except the EU. In the EU the issuing of a CE mark by a CAB is the authority to supply the medical device within the EU. The advantage of the regulatory authority being the final decision maker is that it allows for a uniform approach to be taken to regulatory decisions and it enables the authority to hold all relevant information

about a device in the event that problems arise when the device is in the marketplace and there is a need to undertake product recall.

Arguments for allowing market entry to be determined by a commercial assessment body include faster time to market entry and greater consistency in international access to market.

6. Should TGA retain responsibility for making the final decision to allow supply of a medical device into the Australian marketplace? If yes, why? If not, who should hold this responsibility?

Cost Recovery Implications

The TGA is required to operate within a full cost recovery budget therefore the changes discussed above would need to be considered in the context of the current fees and charges model. Given the range of options canvassed in this paper and the interdependency of some options on the outcomes from others no attempt has been made to date to develop costings.

Other matters

This paper has tried to identify and raise for discussion some of the key points related to conformity assessment. The TGA is interested in receiving input on any other matters of relevance to conformity assessment for medical devices.

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

The Consultation Process

Relevant industry sectors, professional and consumer groups are invited to provide comment and input to the consideration of a proposal to use third party conformity assessment bodies for medical devices supplied in Australia.

The TGA intends to hold a workshop on this matter as part of the consultation process.

The TGA is inviting submissions, views and input from all interested parties by close of business on **Friday 27 March 2009**. All interested parties are welcome to provide input to this consultation process.

The TGA will use the submissions and input received to help inform future regulatory directions.

Once the consultation period has closed, the TGA will continue to work with stakeholders in formulating the final direction in relation to the use of third party external assessment bodies for conformity assessment of medical devices supplied in Australia.

Please forward all consultation feedback to:

Parliamentary and Management Group
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or Parliamentary and Management Group
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Or via **email** to: ODBTConsult@tga.gov.au

Please note:

This document is intended to be a consultation document and should therefore not be relied upon for advice regarding the regulation of medical devices.

Attachment 1: The Essential Principles

The Essential Principles (EP's) set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with medical device standards is not mandatory, but is one mechanism under the framework for a manufacturer to establish compliance with the EP's.

The essential principles may define, for example, results to be achieved, performance levels, hazards to be addressed, or issues to be considered, but do not specify how the principles can be satisfied or complied with.

This provides flexibility for a manufacturer and caters for technology advances and changes in the application of medical devices.

The Essential Principles can be divided into two main types:

- general principles - which always apply to all medical devices; and
- particular principles - which only apply to some medical devices.

It should be noted that **both** the general principles **and** the relevant particular principles have to be met in order to meet the requirements of the Essential Principles for all medical devices. Compliance with only the relevant particular principles does **not** ensure compliance with the general principles.

It is the responsibility of a manufacturer to demonstrate the medical device is in compliance with the applicable Essential Principles.

Further information on the Essential Principles can be found in TGA's *Guidance Document 22 – The Essential Principles for medical devices*,
<http://www.tga.gov.au/docs/html/devguid22.htm>

Attachment 2: The Conformity Assessment Procedures

A manufacturer, either in Australia or elsewhere, must use a conformity assessment procedure to demonstrate a medical device conforms to the Essential Principles.

Depending on the procedure chosen, assessment of the final design, the controls implemented for production and the manufacturer's courses of action may have to be assessed by the TGA or another appropriate conformity assessment body.

The conformity assessment procedures are defined in Parts 1 to 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Figure 1 is a schematic diagram illustrating these procedures and which classes of medical devices are appropriate for each procedure.

The flowchart illustrates a number of possible 'pathways' a manufacturer may follow in applying an appropriate conformity assessment procedure for a particular class of medical device. Restricted only by the classification of the medical device, it is the responsibility of the manufacturer to choose a 'pathway' appropriate to his circumstances where more than one option is available.

Figure 1 The Conformity Assessment Procedures

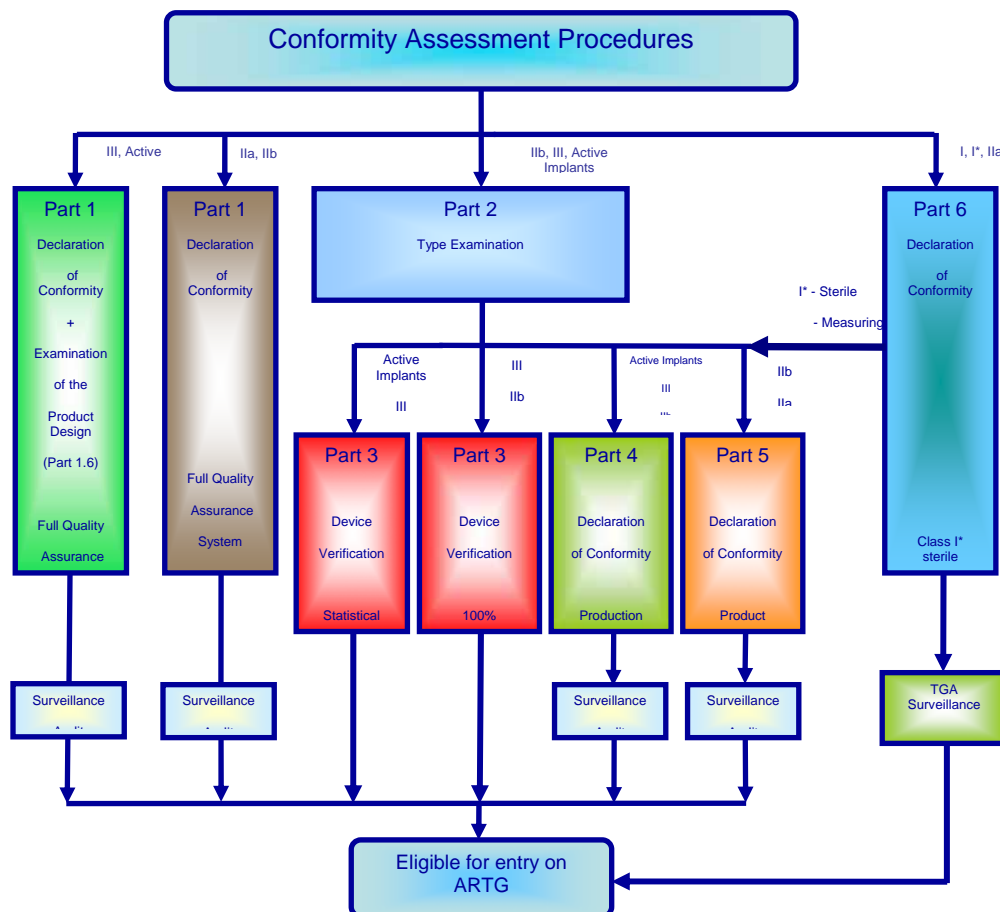


Table A1 – Eligible Conformity Assessment Procedures by Device Class

Classification of Medical Device	Minimum Conformity Assessment Options	Conditions or Options
Class I	Part 6	
Class I Sterile	Part 6 + Part 4	Declaration of conformity to Part 6
Class I Measure	Part 6 + Part 3, or	Declaration of conformity to Part 6
	Part 6 + Part 4, or	Declaration of conformity to Part 6
	Part 6 + Part 5	Declaration of conformity to Part 6
Class IIa	Part 1 excluding Clause 1.6 (Design examination), or	
	Part 6 + Part 3, or	Not for sterile medical devices Declaration of conformity to Part 6
	Part 6 + Part 4, or	Declaration of conformity to Part 6
	Part 6 + Part 5	Not for sterile medical device Declaration of conformity to Part 6
Class IIb	Part 1 excluding Clause 1.6 (Design examination), or	
	Part 2 + Part 3, or	Not for sterile medical devices
	Part 2 + Part 4, or	
	Part 2 + Part 5	Not for sterile medical devices
Class III	Part 1, or	
	Part 2 + Part 3, or	Not for sterile medical devices
	Part 2 + Part 4	
Class AIMD	Part 1, or	
	Part 2 + Part 3, or	for non sterile devices
	Part 2 + Part 4	

Further information on these conformity assessment procedures can be found in TGA's *Guidance Document 3 – Conformity Assessment Procedures*, available at <http://www.tga.gov.au/docs/html/devguid3.htm>

The conformity assessment procedures described in Parts 7 and 8 of Schedule 3 are respectively –

Part 7 – Procedures for medical devices used for a special purpose describing specific procedures which can be followed for manufacturers of either medical devices custom made for a specific individual, or systems and procedure packs where multiple medical devices are 'bundled' and supplied either as a system as is typically the case with capital equipment, or as a procedure pack, where multiple devices are pre-packaged for convenience in undertaking a clinical procedure.

Separate guidance is in preparation for custom made medical device and procedure pack manufacturers.

Part 8 – Procedures open to a manufacturer to obtain and evaluate clinical evidence to determine compliance with Essential Principle 14 – Clinical Evidence.

Separate guidance on clinical evidence requirements can be found in TGA's *Guidance Document 4 – Clinical Evidence Requirements for inclusion of medical devices in the ARTG*, available at <http://www.tga.gov.au/docs/html/devguid4.htm>.