Australian Government
Department of Health
Therapeutic Goods Administration

Regulation impact statement

Premarket assessment requirements for Australian manufactured medical devices

OBPR Reference: 17059

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Executive summary

Title of regulatory proposal: Premarket assessment requirements for Australian manufactured medical devices

Regulatory Costs	– $6.12 million
Have offsets been provided?	Not required

RIS preferred option

Option 3, to allow third party conformity assessment for Australian medical device and IVD manufacturers, is the preferred option in this RIS.

Key points from the RIS

Australian medical device and IVD manufacturers that want to supply a device in Australia must seek conformity assessment certification from the TGA. If the same device is manufactured overseas the manufacturer can choose to either have the conformity assessment conducted by an alternative conformity assessment body or by the TGA.

Industry stakeholders have indicated that (compared to a TGA conformity assessment certification) a European notified bodies' conformity assessment certification can be completed in less time and at less expense. The preferred option will allow Australian manufacturers to choose where and how conformity assessment certification is obtained, as is the case for their overseas competitors, and to remove the disadvantages that they are currently experiencing.

Benefits

The preferred option maintains public health and safety while supporting the timely availability of medical devices and IVDs, reducing regulatory burden and associated costs and continuing Australia's commitment to promoting alignment of international medical device regulation.

Costs

The preferred option is a savings measure. Audit arrangements currently operate for overseas manufacturers to manage any public health and safety risks in manufacturers relying on overseas conformity assessment certification to on public health and safety. Where Australian manufacturers reply on overseas certification they will also be subject to these audit requirements, which will impose some additional costs (offset within the costings). These additional costs will be incurred directly by the same manufacturers who benefit overall under the preferred option.

Regulatory costs and offsets

The preferred option would save Australian manufacturers $6.12m each year by reducing the regulatory burden. Savings primarily result from the reduced delay in getting new devices to market and in the reduced administrative costs of complying with regulatory processes. Australian manufacturers would also save around $0.98m each year in reduced TGA application and assessment fees.

Stakeholder views on the preferred option

Industry stakeholders are supportive of allowing third party conformity assessment for Australian medical device and IVD manufacturers (emphatic support expressed by Australian manufacturers, and consistent support from other industry stakeholders who do not stand to benefit from the change).

Some concern was expressed from consumers, healthcare professionals and medical device procurers that this change would affect public health and safety if the level of TGA oversight of Australian medical device and IVD manufacturers is reduced. However it should be noted that the preferred option, any additional public health and safety risk is marginal and no different than that already in place for overseas manufactured products.

Other options in the RIS

Option 1 - No Change: This option fails to address the concerns which industry stakeholders have been raising since 2002. Current requirements are considered to be unreasonable and disadvantage Australian businesses compared to their overseas counterparts.

Option 2 - Allow third party conformity assessment for lower risk Australian medical device and IVD manufacturers: This option does provide a useful 'partial' change, however the depth and complexity of conformity assessment procedures increase significantly as the risk of the medical device or IVD increases. While there are many more medical devices in the lower and moderate risk classifications, the costs of conformity assessment are much more significant for higher risk medical devices. By excluding these higher risk medical devices from the change in conformity assessment requirements, more than half the benefit to Australian manufacturers is lost.

Introduction

This Regulation Impact Statement (RIS) has been prepared by the Therapeutic Goods Administration (TGA). The purpose is to assist Australian Government decision making on how to address the problems that have been identified in relation to the premarket assessment requirements for Australian manufactured medical devices. The proposal put forward in this RIS will also apply to *in vitro* diagnostic medical devices (IVDs) as they are a subset of medical devices.

A RIS, *Regulation Impact Statement: Changes to premarket assessment requirements for medical devices*, released in August 2013 outlined a number of proposed reforms to medical device regulation, including changes to the premarket assessment requirements for those manufactured in Australia.

This RIS decouples the proposal to reform the premarket assessment requirements for Australian manufactured medical devices from the other proposals in the earlier RIS. This allows the Government to further consider options for Australian manufacturers with the intention of implementing recommended reforms quickly. The other recommendations from the August 2013 RIS will be considered by Government at a later date.

This document details the problem and summarises the consultation process that has been undertaken with stakeholders to determine the best option to address the disadvantage to Australian medical device manufacturers caused by the current requirements. The RIS concludes with a recommended proposal, outlining the proposed amendments to the requirements for Government consideration.

Background

Regulation of medical devices is primarily concerned with enabling patient access to high quality, safe and effective medical devices, and restricting access to those products that are unsafe or have limited clinical effectiveness. Safety and performance are assessed through an evaluation of information that demonstrates the device is of acceptable quality, safety and performance.

Under the *Therapeutic Goods Act 1989* medical devices (including commercial IVDs[1]) must generally be included in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia. For all but the lowest risk Class I medical devices and Class 1 IVDs this includes a premarket assessment by the TGA before the device is allowed to be supplied in Australia[2]. The rigour of this assessment is based on the risk of the device.

Premarket assessment consists of two key components:

- conformity assessment – an independent check that the processes undertaken by a manufacturer ensure that a medical device complies with the regulatory requirements for quality, safety and performance; followed by
- an application (and decision) to include the medical device in the ARTG.

Note: The regulatory framework on In Vitro Diagnostic Devices -IVDs was introduced on 1 July 2010. Not all IVDs have been included in the ARTG as the transition period for implementation of the new arrangements has been extended to 30 June 2015 for commercial IVDs and 30 June 2017 for Australian laboratories that manufacture in-house IVDs.

[1] Given the low risk of Class 1 medical devices (except those which include a measuring function or are supplied sterile) conformity assessment procedures are self-assessed by the manufacturer, and on application the medical device is automatically included in the ARTG without TGA review.

Attachment A provides a more detailed outline of this premarket assessment process.

Relationship to other reform proposals

Changes to the requirements for TGA conformity assessment for Australian manufacturers of medical devices and IVDs were previously proposed in the context of a broader reform package described in The *Regulation Impact Statement: Changes to premarket assessment requirements for medical devices*, released in August 2013. That reform package also included proposals to increase the premarket scrutiny of higher risk medical devices, and improve the transparency of TGA decision making on medical devices and IVDs.

This RIS progresses options for allowing third party conformity assessment for Australian manufacturers separately from the broader reform package. The Government has asked the TGA to review the other proposals and develop a modified reform package, taking into account the Government's deregulation policy. Reforms for Australian manufacturers are being progressed now, predicated on the idea that it is inappropriate to further delay changes to current arrangements which are disadvantaging Australian manufacturers.

However some issues which the broader reform package seeks to address continue to be relevant to the proposed changes for Australian manufacturers outlined in this document. Over recent years a number of high profile issues with medical devices have resulted in pressure for increased premarket scrutiny of high risk medical devices, particularly those which are implanted. Concerns have also emerged over the variable performance of some European notified bodies and the level of evidence reviewed prior to issuing of conformity assessment certification.[3]

The options outlined below would result in Australian medical device and IVD manufacturers, in full or part, being subject to the same regulatory framework as other medical device and IVD manufacturers. Proceeding with changes for Australian manufacturers will mean that risks already present for overseas manufactured devices may also apply for those manufactured in Australia. These risks are discussed in more detail against the options below.

What's in and what's out

This document discusses options to change existing premarket assessment requirements for Australian manufacturers. The following options are all predicated on some common assumptions:

- Regulatory requirements differ somewhat between medical devices and IVDs, but are broadly comparable. The proposed options apply to both medical devices and IVDs.
- Regulatory requirements which currently apply to overseas manufacturers would apply to Australian manufacturers. There are two key elements:
  - TGA conformity assessment would continue to be required for certain kinds of high risk medical devices – those containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices.
  - Applications for inclusion on the ARTG would be subject to application audits, including mandatory audits for high risk devices and IVDs, for which an audit fee applies.

[3] These concerns were outlined in the *Regulation Impact Statement: Changes to premarket assessment requirements for medical devices* (released in August 2013), from p9 (under the heading "Performance of notified bodies and proposed European reforms")

- Conformity assessment for low risk medical devices - Class I (unless they include a measuring function or are supplied sterile) and IVDs (Class 1) - is self-certified by the manufacturer, and applications to include these devices on the ARTG are automatically included. The proposed options would not alter these arrangements.

What is the problem?

Australian market entry barriers for Australian medical device and IVD manufacturers

Australian medical device and IVD manufacturers that want to supply a device in Australia must seek conformity assessment certification from the TGA. In contrast to this, if the same device is manufactured overseas the manufacturer can choose to either have the conformity assessment conducted by an alternative conformity assessment body or by the TGA. In 2002, when the current medical devices regulatory framework commenced, the prospect of allowing third party conformity assessment was flagged[4] for future reconsideration, as global harmonisation of regulatory requirements matured.

Industry stakeholders have indicated that (compared to a TGA conformity assessment certification) a European notified bodies' conformity assessment certification can be completed in less time and at less expense. In this context Australian manufacturers consider the current requirements put them at a significant disadvantage. In the Australian market, overseas competitors may be able to supply overseas manufactured medical devices and IVDs in less time and at lower regulatory costs.

The Australian medical and surgical equipment manufacturing sector (of which medical devices comprise a large proportion, and which does not include IVDs) generates $3 billion annually in revenue.[5] Around 105 Australian manufacturers currently hold TGA conformity assessment certification, and would be directly impacted by any proposed change to current regulatory requirements. ARTG entries for devices supplied by Australian manufacturers account for around 7% of all entries, and this proportion have been consistent over recent years.

The intention of any proposed changes to the current requirements is to create a regulatory framework which allows Australian manufacturers to choose where and how conformity assessment certification is obtained, as is the case for their overseas competitors, and to remove the disadvantages that they are currently experiencing.

International market entry barriers for Australian medical device and IVD manufacturers

The requirement for TGA conformity assessment also constrains Australian manufacturers competing in international markets. While their overseas competitors can usually enter the Australian market using European certification (from a European notified body), an Australian manufacturer's TGA conformity assessment certification is not recognised for entry in the European market. Where the Australian manufacturer intends to export to Europe they may choose to seek:

Centre for Health Program Evaluation, *Technical Report 11 – An Economic Analysis of of Proposed Changes to the Conformity Assessment of Medical Devices*, May 2001.

[2] IBIS*World* Medical and Surgical Equipment Manufacturing in Australian: Market Research Report

- conformity assessment certification from a European notified body in parallel to the TGA conformity assessment process, thus minimising delays in gaining market entry to the European market but incurring the cost of two regulatory assessments; or
- additional certification, from the TGA, to allow the medical device entry into the European market under a Mutual Recognition Agreement (MRA) with the European Union. However these manufacturers would still experience similar delays and further expense.[6]

It should be noted that overseas regulatory charges and related compliance costs for Australian manufacturers are outside the scope of this RIS, however these do have an significant impact on Australian businesses who trade internationally.

Why is government action needed?

The Government recognises that the current arrangements impose an unreasonable burden on Australian manufacturers of medical devices that is not shared by overseas competitors. The existing regulatory requirement to seek conformity assessment certification from the TGA puts Australian businesses at a disadvantage when supplying medical devices in both Australian and overseas markets.

The TGA's exclusive role in issuing conformity assessment certificates to Australian medical device manufacturers has frequently been questioned. Previous consultation[7] on removing the requirement for a TGA conformity assessment for Australian medical device manufacturers received very strong support from industry.

In practice, certification issued by European notified bodies is used for over 90 per cent of applications for inclusion of medical devices and IVDs in the ARTG where independent conformity assessment certification is required.

While not compromising public health and safety, the objective of the proposed change is to:

- support the timely availability of Australian manufactured medical devices and IVDs to the Australian public
- minimise unnecessary regulatory burden and associated costs on the Australian medical device and IVD industries
- continue Australia's commitment to promoting alignment of international medical device regulation.

The MRA does not cover IVDs. The only option for Australian IVD manufacturers wanting to supply in Europe is to seek a second certification from a European notified body. The MRA also does not cover medical devices incorporating tissues of animal origin (unless the tissues are only intended to come in contact with intact skin). Under current arrangements all Class III and AIMD medical devices are also temporarily excluded from MRA arrangements until 'confidence building' has been undertaken.

[3] As outlined in the "Previous consultation" section below, numerous rounds of consultation on third party conformity assessment have been undertaken, with strong and consistent responses from industry stakeholders supporting removing the requirement for TGA conformity assessment.

What policy options are being considered?

Option 1: No change

No changes would be made to the TGA's existing premarket assessment requirements. As outlined in Attachment A - Regulation of Medical Devices, current regulations require a conformity assessment that is appropriate to the risk level of the medical device to be certified, prior to seeking inclusion in the ARTG. Australian medical device manufacturers would continue to be required to seek a conformity assessment from the TGA.

Option 2: Allow third party conformity assessment for lower risk Australian medical device and IVD manufacturers

This proposal removes the requirement for Australian manufacturers to have TGA conformity assessment for lower and moderate risk medical devices and IVDs.

Under this proposal, Australian manufacturers of lower and moderate risk medical devices and IVDs[8] could choose to have their conformity assessment certification provided either by a third party conformity assessment body with the necessary expertise to undertake the certification or by the TGA. In practice, for Australian manufacturers of lower classification medical devices, this would allow the acceptance of conformity assessment certificates issued by a European notified body. For Australian manufacturers of Class 2 and Class 3 IVDs this would mean the acceptance of third party evidence of conformity assessment that is consistent with that currently accepted for overseas manufacturers.

This would ensure that Australian manufacturers of lower and moderate risk medical devices and IVDs are not disadvantaged compared to their overseas counterparts. Applications for high risk devices (such as AIMD and Class III medical devices[9]) would continue to be required to seek TGA conformity assessment. The European Commission is currently seeking to amend regulation of medical devices, including governance of notified bodies. In addition, confidence building for notified bodies under the MRA needs to be undertaken prior to allowing certification issued under the MRA to be accepted for Class III and AIMD medical devices. Extending the removal of the requirement for Australian manufacturers to seek TGA conformity assessment for all medical devices (rather than only those lower risk medical devices) would be considered as the changes to strengthen European regulatory arrangements and processes have progressed.

Applications relying on TGA conformity assessment are not subject to mandatory audit requirements when applying for inclusion in the ARTG. Once the requirement for TGA conformity assessment is removed, applications for inclusion for some low and moderate risk medical devices and IVDs[10] relying on third party conformity assessment would be subject to

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Lower and moderate risk device include Class I medical devices which are supplied sterile or include a measuring function, Class IIa and Class IIb medical devices and Class 2 and Class 3 IVDs. Medical device and IVD classifications and examples are provided at Attachment B – Glossary.

[4] In addition the highest risk medical devices and IVDs will also be required to seek TGA conformity assessment (medical devices containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices) under both Option 2 and Option 3.

[5] Medical devices (classified as Class IIb or lower) currently subject to mandatory audit include devices such as barrier and implantable contraceptives, implantable intra-ocular lenses, intra-ocular visco-elastic fluids. A range of IVDs (classified Class 3 or lower) are also currently subject to mandatory technical file review including self-testing and point of care tests, and IVDs for testing of notifiable diseases.

audit requirements when applying for ARTG inclusion (including an audit fee). Conformity assessment certification also may not be accepted for some applications where the third party conformity assessment is insufficient, such as when the classification of a device differs in Australia. These requirements already apply sponsors of the same classification of devices and IVDs manufactured overseas seeking to gain market entry to the Australian market, so this change would put Australian manufactured devices on the same footing as those manufactured overseas.

Option 3: Allow third party conformity assessment for Australian medical device and IVD manufacturers

This proposal removes the requirement for Australian manufacturers to have TGA conformity assessment for the majority of medical devices and IVDs.

Under this proposal, most Australian medical device manufacturers could choose to have their conformity assessment certification provided either by a third party conformity assessment body with the necessary expertise to undertake the certification or by the TGA. As under option 2, in practice, for Australian manufacturers this would enable acceptance of conformity assessment certificates issued by a European notified body for medical devices, and third party evidence of conformity assessment that is consistent with that currently accepted for overseas manufacturers for Class 2 and Class 3 IVDS.

This would ensure that Australian manufacturers are not disadvantaged compared to their overseas counterparts. TGA conformity assessment would continue to be required for specified kinds of high risk medical devices – those containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices. This is already the case for such devices manufactured overseas, so all manufacturers would be on a level playing field.

Applications for the higher risk devices (such as AIMD and Class III medical devices and many Class 3 IVDs, in addition to selected Class IIb devices) relying on third party conformity assessment would be subject to audit requirements when applying for ARTG inclusion. Conformity assessment certification may not be accepted where the third party conformity assessment is insufficient, such as when the classification of a device differs in Australia. These requirements already apply to sponsors of the same classification of devices and IVDs manufactured overseas seeking to gain market entry to the Australian market, so this change would also put Australian manufactured devices on the same footing as those manufactured overseas.

What is the likely net benefit of each option?

The stakeholder group affected by changes to premarket assessment requirements for medical devices is primarily the Australian medical device industry (sponsors and manufacturers). The changes may have a flow on effect for healthcare professionals and consumers. More broadly there are also stakeholders that rely on the TGA's assurance that medical devices available for supply in Australia are safe and perform as intended, such as private health insurers, hospitals and other healthcare providers.

Changes to requirements may impact these stakeholders in a variety of ways:

- **Public health and safety:** Changes to the risks and benefits of using medical devices
- **Costs:** Financial impacts likely to be experienced, whether indirect (relating to implementation or compliance) or direct (fees and charges, etc.)

- **Timeliness:** Impacts from efficiency of the regulatory processes, such as the speed of medical devices gaining market entry to the Australian market
- **Access:** Impacts on the availability of medical devices in Australia
- **Other:** Such as the impacts of international harmonisation

This section discusses the benefits and risks for the various stakeholders and provides a costing of the option, including the direct regulatory costs and regulatory burden.

Direct regulatory costs

This is of particular relevance for this RIS as the TGA operates on a cost recovery basis, funded through a mixture of fees (which relate to the assessment service provided by the TGA) and charges (which are 'cost recovery' taxes, and fund the TGA's post market regulatory activities). Fees are charged for TGA's premarket assessment activities, so if the TGA is no longer undertaking this work the related fees will not be payable. Charges, such as the annual charge for each ARTG entry, would continue to be payable.

Under the following options these direct regulatory costs have been calculated based on TGA administrative data on the fees paid for applications and their assessment during the 2012-13 financial year. These direct regulatory costs are not included in the regulatory burden calculations outlined below, in line with advice from OBPR.

Regulatory burden and cost offset estimate table

Under the Government's new deregulatory requirements, outlined in *The Australian Government Guide to Regulation*, regulatory compliance burdens are calculated, by considering compliance burdens and other regulatory costs such as opportunity costs, indirect costs (and benefits) and the costs (or savings) to the Government of administering new (or eliminating old) regulation.

The costs of the regulatory burden on the industry for the following options have been calculated in conjunction with Deloitte Australia, who provided regulatory burden baseline costings. They provided two baseline costings:

- Compliance to therapeutic regulations by Australian manufacturers of medical devices.
- Compliance to therapeutic regulations by Australian sponsors of medical devices manufactured overseas (as these are the regulatory requirements which would apply for Australian manufacturers if they are no longer required to seek TGA conformity assessment).

The baseline costing provided by Deloittes Australia is based on:

- **Direct industry input:** Industry was consulted to provide key inputs. This involved two workshop sessions, facilitated by Deloitte Australia, with TGA and a number of medical device companies operating in the Australian market. This was followed up with information provided confidentially by participants directly to Deloitte Australia, given the commercially sensitive nature of some information required for costings. Key inputs from industry include:
  - ***Preparation time taken to complete conformity assessment activities and applications.*** Preparation of the dossier to support a conformity assessment application is a significant cost. Actual costs vary based on the risk of the device, but this is estimated on average to be around $128,000 per conformity assessment application. Recertifications are less onerous, with an average of around $5,700 per application. As outlined above, these estimates do not include TGA's direct fees and charges.

  - ***Revenue and profit margins*** provided in confidence by industry stakeholders to Deloittes Australia (given the commercially sensitive nature of this information).

- **Other inputs:** Deloitte Australia used IBIS*World* data, together with feedback from industry stakeholders, to underpin revenue and profit margin estimates. Industry responses regarding revenue varied and were not considered reflective of the entire market, and IBIS*World* was recommended by Deloitte Australia as a reputable source of industry information. It reports that the Australian medical devices manufacturing industry is worth $3.5billion per year and manufacturers earn approximately 15.7% profit. The report noted that some devices were used for veterinary services; these costs were deducted as TGA only regulates medical devices used in humans.

TGA then used the administrative data for Australian manufacturers each year to multiply these estimated industry costs (based on a 10 year average), including:

- ***Conformity assessment applications.*** The number of conformity assessments completed - split between new products (an average of 18.5 per annum) and recertifications and significant changes (an average of 50 per annum).

- ***ARTG inclusion applications.*** The number of applications for ARTG inclusion from Australian manufacturers (an average of 57.6 per year) and the expected proportion of these applications which would be subject to application audit (12.7 audits, or around 22% of applications for lower and moderate risk devices (Option 2), or 17.3 audits, or around 30% of applications for all devices (Option 3)).

- ***Delay to market resulting from TGA conformity assessment timeframes.*** TGA administrative data on completed applications to calculate this costing of an average of 245.5 calendar days to finalise a conformity assessment applications for lower and moderate risk devices (Option 2) and 256.5 calendar days for all devices (Option 3). These figures were then reduced by 12 weeks (84 days) to 161.5 calendar days (Option 2) and 172.5 calendar days (Option 3), to provide for the delay manufacturers will experience in seeking conformity assessment certification from a European notified body (based on industry feedback).

  The maximum statutory timeframe for making a decision on a conformity assessment application is 255 TGA working days. The figures above are annualised to calendar days, so include non-working days and time when the applicant was seeking further information, which 'stops the clock' on TGA working days. The average time taken to complete conformity assessments was calculated for all conformity assessment applications completed in 2012-13 and 2013-14. A total of 488 applications were completed in this time period (including new conformity assessments, recertifications and changes), with 137 of those for Australian manufacturers. Actual timeframes can vary widely, with several of the applications included in the 2012-13 and 2013-14 sample taking up to 3 years to complete, while some other applications were completed in only a few days.

  These delay to market figures are also significantly lower than the estimate provided by industry stakeholders to Deloitte Australia, as the average completion time dropped significantly in 2013-14 (from 307.8 calendar days for applications from Australian manufacturers completed in 2012-13 to 220.9 calendar days for applications completed in 2013-14) as business process re-engineering activities by the TGA came into effect.

It should be noted that the costings for regulatory burden (including annual costs and savings, number of conformity assessments and the number of applications for ARTG inclusion) are annual averages projected across 10 years (as required under the Office of Best Practice Regulation (OBPR) business cost calculator). The 10 year projection for conformity assessment, application for ARTG inclusion and audits includes a forecast growth factor of 4% per annum, reflective of the Medical Technology Association of Australia (MTAA)'s forecast growth of the

entire devices industry. Projected fees include no growth factor, in line with OBPR business cost calculator requirements.

The costings for each option include two key components:

- Administrative costs of complying with regulatory processes (submitting applications and gathering related evidence, responding to queries as part of the assessment process, etc.)
- Cost of delay (TGA processing times delay the product to market).

The following Regulatory Burden and Cost Offset Estimate Table provides cost calculations for the two reform options outlined in this RIS.

Regulatory Burden and Cost Offset Estimate Table

Average Annual Regulatory Costs (from Business as usual)*				
Change in costs	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Option 1 (no change)	$0m			$0m
Option 2 (low and moderate risk devices)	-$1.92m	-	-	-$1.92m
Option 3 (low, moderate and high risk devices)	-$6.12m	-	-	-$6.12m
Cost offset	**Business**	**Community Organisations**	**Individuals**	**Total by Source**
Option 1 (no change)	-	-	-	-
Option 2 (low and moderate risk devices)	-	-	-	-
Option 3 (low, moderate and high risk devices)	-	-	-	-
Are all new costs offset? D yes, costs are offset D no, costs are not offset O deregulatory, no offsets required				
Total (Change in costs - Cost offset) ($million): Option 1 (no change) $0.00m; Option 2 (low and moderate risk devices) -$1.92m; Option 3 (low, moderate and high risk devices) -$6.12m				

* Does not include any increased regulatory burden incurred overseas.

These figures include the costs of offsets of the regulatory burden in Australia. However the fees, administrative costs and delays to manufacturers associated with seeking conformity assessment overseas are commercial arrangements which have not been included here. Feedback from industry stakeholders indicates that the overseas conformity assessment bodies, which typically perform a large number of assessments for a wide range of clients, provide assessment at costs and times less than those in Australia. The notified body costs and timeframes are commercial arrangements and not publicly available. In practice however costs incurred overseas will reduce the net impact of the savings for Australian manufacturers outlined in this document. It should be noted however that many Australian manufacturers already incur the overseas costs in seeking duplicate conformity assessment from a European notified body to support their market entry in Europe. For these manufacturers regulatory costs incurred overseas would be part of their existing business practice. For these manufacturers a reduction in Australian regulatory compliance costs reduces regulatory duplication rather than simply shifting costs overseas.

The calculation of these costs is explored in more detail under each of the options below.

Option 1: No change

There is little support from industry stakeholders to retain the current conformity assessment requirements for Australian manufacturers of medical devices and IVDs as the current requirements are considered to be unreasonable and disadvantage Australian businesses compared to their overseas counterparts.

The existing provisions requiring Australian medical device manufacturers to seek TGA conformity assessment were introduced when the current medical devices regulatory framework commenced in 2002, and in the IVD amendments introduced in 2010. At that time the regulatory framework was initially introduced it was already being suggested this requirement should be reconsidered. A May 2001 report by the Centre for Health Program Evaluation[11] recommended that the prospects for a regulated competition model for third party conformity assessment be reviewed in the future when there is more evidence on the performance of the European notified body model, MRA arrangements and global harmonisation of regulatory requirements. While there are continuing concerns about the way the notified body scheme operated in Europe, and with the performance of some European notified bodies in particular, these are being managed through the TGA's current confidence building program, and through the European Commission's program for increased oversight of and proposed reforms to the European regulatory framework (currently before the European Parliament).[12]

Industry stakeholders strongly support change given that, in practice, the current requirements result in additional burden for Australian manufacturers.

Consumers, healthcare professionals and procurers of medical devices would support retaining current regulatory requirements. They have expressed concern about whether appropriate Government oversight can be achieved should third party conformity assessment be permitted for Australian manufacturers, as this would remove direct oversight by the TGA of these manufacturers. While these issues can be managed in other ways (and already are for overseas manufacturers) existing arrangements do provide more direct oversight of Australian manufacturers. This direct oversight includes the regulatory power to enter the premises of the manufacturer where concerns arise, the capacity to include specific conditions on conformity assessment certificates and the capacity to influence and correct design parameters for devices

Centre for Health Program Evaluation, *Technical Report 11 – An Economic Analysis of of Proposed Changes to the Conformity Assessment of Medical Devices*, May 2001.

[6] See discussion of TGA's confidence building program and concerns about European notified body performance at Attachment A - Regulation of Medical Devices.

designed in Australia. Where conformity assessment certificates are not issued by TGA, these powers are held and exercised by the third party assessment body.

Quantification of cost to business, community and/or individuals

Direct regulatory costs

Under this proposal there would be no change to the direct regulatory costs of those affected by the current conformity assessment requirements for Australian manufactured medical device. Australian manufacturers would continue to pay for a TGA conformity assessment certification and would not be subject to audit provisions (and fee) when applying for inclusion in the ARTG.

Regulatory burden and cost offsets

Under this option there would be no change to current arrangements. The cost of existing regulatory requirements for Australian manufacturers has been calculated at $28.33m, including two key components:

- Administrative costs of complying with regulatory processes of $3.41m (submitting applications and gathering related evidence, responding to queries as part of the assessment process, etc)
- Cost of delay of $24.92m (TGA processing times delay the product to market)

Option 2: Allow third party conformity assessment for lower risk Australian medical device and IVD manufacturers

Option 2 will reduce the regulatory burden for Australian manufacturers of lower risk medical devices and IVDs as it will no longer be mandatory for Australian manufacturers to seek TGA conformity assessment services for those lower risk devices. High risk (AIMD and Class III) devices manufactured in Australia will still require TGA conformity assessment certification. However retaining mandatory TGA certification continues to negate the need for mandatory audit of applications for these high risk (AIMD and Class III) devices for inclusion on the ARTG.

Australian medical device and IVD manufacturers will be the primary beneficiaries of this proposal. In response to previous consultation on this proposal[13] industry stakeholders were supportive of allowing third party conformity assessment for Australian manufacturers, and advocated strongly for this proposal to be broadened to also include high risk medical devices. Health professionals and consumers were less supportive of this change. Both Australian and overseas manufacturers will also continue to have the option of seeking conformity assessment from the TGA.

This option provides a staged approach to allowing third party conformity assessment for Australian manufacturers. It enables this change to be made immediately for manufacturers of lower and moderate risk medical devices. It could then be extended to apply for higher risk Australian manufactured medical devices as part of the broader modified reform package. That package is intended to include measures to address the current concerns with European notified body arrangements, and for confidence building activities to mature.

It should also be noted that proceeding with this change for Australian manufacturers in advance of the broader reform package does create some transitional issues (discussed in the "How will you implement and evaluate the chosen option?" section below).

[7] August 2103 RIS and other consultations

Public health and safety

This proposal would change the level of direct scrutiny by the TGA over lower and moderate risk medical devices and IVDs manufactured in Australia. Where a manufacturer chooses to use a European notified body the Australian Government would lose direct oversight of local manufacturing of these products which is achieved through the current TGA conformity assessment process. The direct controls over the manufacturer (i.e. the right of entry to the manufacturer's premises), that issuing a TGA conformity assessment certificate gives to the TGA, would no longer exist. Additionally post market controls over the manufacturer could not be enforced (e.g. the TGA could not suspend or revoke a conformity assessment certificate which the TGA did not itself issue). Any post market issues with the manufacturer would need to be managed through interaction with the notified body that issued the conformity assessment certificate or the European regulatory authority responsible for that notified body, as is the case now for overseas manufactured devices.

While this is a change for Australian manufactured medical devices and IVDs, any additional risk is no greater than that already in place for overseas manufactured products. Any regulatory action needed within Australia would be through the Australian sponsor, based upon continuing supply through the ARTG entry. This is already the case for overseas manufactured products and the sponsor of Australian manufactured medical device or IVD is generally the manufacturer so in practice any additional risk may be marginal.

Most consumers, healthcare professionals and medical device procurers have little or no knowledge of the TGA regulatory process, leading to some misunderstanding that this proposal may increase the public health and safety risks associated with Australian manufactured medical devices. However if this proposed change to the requirements for Australian manufacturers is adopted the requirements will become identical to those which are already in place for comparable low and moderate risk devices manufactured overseas that are supplied in Australia It should be noted that, if concerns arise for devices , any dealings with the Australian manufacturer would be led by the European notified body over which the Australian Government has no direct oversight and control. The TGA would also have no regulatory power to enter the premises of the manufacturer in such a situation.

There are, however, other regulatory powers available to TGA. For example, the TGA can undertake a post market assessment of the safety and performance of a medical device, independently of the notified body, for any device included on the ARTG. The TGA may also cancel the ARTG inclusion for any device on safety and performance grounds, and so cease the marketing approval for the device in Australia.

The Consumer Health Forum has also expressed concern generally about the reliability of notified body conformity assessments in their responses to previous consultation. Under this proposal high risk medical devices[14] manufactured in Australia will still require TGA conformity assessment. Additionally, as previously discussed, the TGA addresses the issue of assuring the performance of notified bodies conformity assessments through TGA's ongoing relationship with other regulators, through participation in harmonisation initiatives of international regulator organisations including IMDRF's MDSAP program and undertaking its own 'confidence building' activities with European regulatory authorities (as outlined under 'Use of EU conformity assessment certification' in Attachment A - Regulation of Medical Devices). The European Commission is itself undertaking review of notified body regulation and pursuing regulatory reforms.

Costs and timeliness

This proposal will provide a reduction in the direct costs Australian manufacturers currently pay to the TGA (i.e. the fees and charges). It will also reduce Australian manufacturers'

[8] Class III, AIMD and Class 4 IVDs will continue to require TGA conformity assessment.

administrative costs in complying with one element of the Government's regulatory requirements and it is may decrease the time to market for locally manufactured medical devices. These costs are quantified below.

Access

This proposal would directly benefit the Australian medical technology industry in terms of costs and timeliness of market entry, which would be expected to have flow on effects for patient and healthcare professions who use these devices in terms of cost and the speed of these devices gaining entry the Australian market.

Other

This proposal will result in the TGA being increasingly reliant on overseas bodies, further increasing the need to ensure international cooperation and harmonisation. As outlined above the TGA is already actively engaged in managing these issues, including through the current confidence building process.

This option also increases the level of international harmonisation, to the particular advantage of Australian medical device and IVD manufacturers of lower and moderate risk medical devices and IVDs who are competing in the international market.

Quantification of cost to business, community and/or individuals

Direct regulatory costs

It should be noted that under this option Australian medical device manufacturers will continue to be required to hold an appropriate conformity assessment certification. If this is not sought from the TGA no fees will be payable to the TGA for the certification or related assessments. While conformity assessment fees will be payable, these will be commercial set fees paid to overseas notified bodies. These fees are not publicly available and have not been included here. This option does enable manufacturers to shop around overseas conformity assessment bodies for the best price and value service to meet their needs.

In the 2014-15 TGA revenue forecast for conformity assessment for Australian manufacturers is estimated at $0.53m. While these lower and moderate risk medical devices and IVDs account for 70% of all ARTG entries requiring conformity assessment certification, it is estimated that they account for around 53% of conformity assessment activity.[15] Of the total TGA conformity assessment forecast revenue of $5.0m, it is estimated 20% relates to Australian manufacturers.

Once conformity assessment has been certified, Australian manufacturers are also required to apply for inclusion on the ARTG. Under this option application fees for ARTG inclusion would continue to apply. Australian manufacturers may be newly subject to audit fees in relation to some of those applications.

There were 48 applications for ARTG inclusion from Australian manufacturers in 2013. While any application for inclusion may be audited, the majority of applications for inclusion for lower and moderate risk medical devices and IVDs are not subject to mandatory audit or technical file

This is because the complexity of the conformity assessment procedure increases in line with the risk associated with a medical device ie while there are fewer high risk devices assessed (about 30%) their conformity assessment takes longer and cost more

review (for which an audit fee applies).[16] A maximum audit fee of $6,500 would apply for any audited application.

Annual charges would continue to be collected for each medical device ARTG inclusion, to fund TGA's post market surveillance and compliance activity.

Regulatory burden and cost offsets

This change is estimated to reduce the regulatory burden for Australian manufacturers by $1.92m. This includes the costs of the regulatory burden saved in Australia, but has not been offset by the administrative and delay costs associated with seeking conformity assessment certification overseas. As with fees, the administrative costs and delays to manufacturers associated with seeking conformity assessment overseas are commercial arrangements which have not been included here. Feedback from industry stakeholders indicates that the commercial nature of the overseas conformity assessment bodies results in assessment costs and times being less than those occurring in Australia. In practice, however costs incurred overseas will reduce the net impact of the savings for Australian manufacturers outlined in this document.

The savings associated with removing the requirement for TGA conformity assessment for Australian manufacturers is estimated at $8.59m includes two key components:

- Administrative costs of complying with regulatory processes of $1.48m (submitting applications and gathering related evidence, responding to queries as part of the assessment process, etc.)
- Cost of delay of $7.11m (TGA processing times delay the product to market)

While the administrative costs of compliance are a significant expense, the cost of delay in gaining market entry is the most significant cost for Australian manufacturers. This aligns with feedback from Australian manufacturers, who express most concern about the impacts of delays and the reduction in their competitiveness in the market relative to their overseas competitors, rather than more direct administrative compliance costs.

These significant savings are offset by the additional cost of application audits some Australian manufacturers may be newly subject to in relation to some of their applications for ARTG inclusion. Around 22% of applications are subject to discretionary audit,[17] which results in both administrative and delay costs of applicants estimated at $6.67m (comprised of administrative costs of around $0.34m and delay costs of $6.33m).

This costing assumes all Australian manufacturers, when given the choice, would choose not to seek conformity assessment from the TGA. This assumption is based on the significant costs outlined above and the strongly expressed support of Australian manufacturers for this change. However this will be a business decision for individual Australian manufacturers, and they will continue to have the option to seek conformity assessment from TGA. Some manufacturers may opt to wait until their existing conformity assessment certification expires before changing conformity assessment bodies. As most conformity assessment certificates are valid for 5 years it may be that long before the full impact of this change is known.

Medical devices (classified as Class IIb or lower) currently subject to mandatory audit include devices such as barrier and implantable contraceptives, implantable intra-ocular lenses, intra-ocular visco-elastic fluids. A range of IVDs (classified Class 3 or lower) are also currently subject to mandatory technical file review including self-testing and point of care tests, and IVDs for testing of notifiable diseases.

[9] Devices in this option are unlikely to be subject to mandatory audit, which are targeted to high risk devices.

Option 3: Allow third party conformity assessment for Australian medical device and IVD manufacturers

Option 3 will reduce the regulatory burden for Australian manufacturers of medical devices and IVDs as it will no longer be mandatory for Australian manufacturers to seek TGA conformity assessment services.

Australian medical device manufacturers will be the primary beneficiaries of this proposal and are very supportive of allowing third party conformity assessment for Australian manufacturers. They consider that the proposal will allow them to choose the conformity assessment body to provide their medical device's conformity assessment certification. Both Australian and overseas manufacturers will also continue to have the option of seeking conformity assessment from the TGA. It should be noted that in previous consultations industry stakeholders strongly advocated for this option, while health professionals and consumers were generally not supportive.

In the previous *Regulation Impact Statement: Changes to premarket assessment requirements for medical devices*, this proposal to allow third party conformity assessment for Australian manufacturers was presented in the content of a broader reform package. In that package a measure to increase premarket scrutiny of conformity assessment for higher risk medical devices as part of mandatory application audits prior to ARTG inclusion was included to manage the risk of relying on third party conformity assessment certification for higher risk medical devices. Work is ongoing to also progress those reforms, however this option progresses the change for Australian manufacturers in advance of that broader package.

It should also be noted that proceeding with this change for Australian manufacturers in advance of the broader reform package does create some transitional issues (discussed in the "How will you implement and evaluate the chosen option" section below).

Public health and safety

As outlined above for Option 2, this proposal would change the level of direct scrutiny by the TGA over medical devices and IVDs manufactured in Australia. As is already the case for overseas manufacturers relying on conformity assessment certification not issued by the TGA, the Australian Government would lose direct oversight of local manufacturing of the majority of Australian manufactured medical devices and IVDs. Any post market issues with the manufacturer would need to be managed through the responsible notified body. Existing post market actions and sanctions against the sponsor of the product would continue to apply. The key difference for this option over Option 2 is that this would additionally apply for high risk medical devices and IVDs.[18]

Just as for Option 2, this change for Australian manufactured products would not result in any greater risk than that which already exists for overseas manufactured products, and regulatory action needed within Australia would be pursued through the Australian sponsor, based upon continuing supply through the ARTG entry. This is already the case for overseas manufactured products and the sponsor of Australian manufactured medical device or IVD is generally the manufacturer so in practice any additional risk may be marginal.

The concerns of consumers, healthcare professionals and medical device procurers are likely to be heightened by the inclusion of high risk devices in this proposal. However, as for Option 2, if this proposed change to the requirements for Australian manufacturers is adopted the requirements will become identical to those which are already in place for overseas manufactured devices supplied in Australia (more than 90% of all medical devices and IVDs).

With the exception of certain kinds of high risk medical devices – those containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices. These devices require TGA conformity assessment irrespective of the country of manufacture.

It was also noted under Option 2 that Consumer Health Forum has expressed concern about the reliability of notified body conformity assessments. This concern will be heightened given conformity assessment for AIMD and Class III medical devices are included in this option. The increased concern is because the complexity of the conformity assessment process is significantly greater for these high risk medical devices. However, these risks in using conformity assessment certification are already managed under current application audit arrangements, with AIMD, Class III and select Class IIb medical devices and many Class 3 IVDs subject to mandatory audit requirements when seeking inclusion on the ARTG, unless they hold certification issued directly under the Australian regulatory framework (i.e. TGA or appropriately accredited MRA certification). The highest risk medical devices[19] (whether manufactured in Australia or overseas) will also still require TGA conformity assessment. As noted previously, concern about the reliability of notified body conformity assessments is also mitigated by TGA's ongoing relationship with other regulators, through participation in harmonisation initiatives of international regulator organisations including IMDRF's MDSAP program and undertaking its own 'confidence building' activities (as outlined under 'Use of EU conformity assessment certification' in Attachment A - Regulation of Medical Devices) and regulatory review and reform activities being undertaken by the European Commission.

Costs and timeliness

This proposal will provide a reduction in the direct costs Australian manufacturers currently pay to the TGA (i.e. the fees and charges). It will also reduce Australian manufacturers' administrative costs in complying with one element of the Government's regulatory requirements and it may decrease the time to market for locally manufactured medical devices. These costs are quantified below.

Access

This proposal would directly benefit the Australian medical technology industry in terms of costs and timeliness of market entry, which would be expected to have flow on effects for patient and healthcare professions who use these devices in terms of cost and the speed of these devices gaining entry the Australian market.

Other

As for Option 2, this proposal will result in the TGA being increasingly reliant on overseas bodies, further increasing the need to ensure international cooperation and harmonisation. As outlined above the TGA is already actively engaged in managing these issues, including through the current confidence building process.

This option also increases the level of international harmonisation, to the particular advantage of Australian medical device and IVD manufacturers who are competing in the international market.

Quantification of cost to business, community and/or individuals

Direct regulatory costs

It should be noted that under this option Australian medical device manufacturers will continue to be required to hold an appropriate conformity assessment certification. If this is not sought from the TGA no fees will be payable to the TGA for the certification or related assessments. Conformity assessment fees will be payable, however these will be commercial set fees paid to

[10] Only TGA conformity assessment certification is accepted for any medical device containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices.

overseas notified bodies. These fees are not publicly available and have not been included here. This option does enable manufacturers to shop around overseas conformity assessment bodies for the best price and value service to meet their needs.

In the 2014-15 forecast TGA revenue for conformity assessment for Australian manufacturers is estimated at $1.0m (of the total TGA conformity assessment forecast revenue of $5.0m, it is estimated 20% relates to Australian manufacturers).

Some Australian manufacturers will still be required to seek TGA conformity assessment for those specified highest risk medical devices (i.e. medical devices containing medicines or tissues of animal, biological or microbial origin, or Class 4 IVD medical devices.) Conformity assessment fees will continue to be payable for these situations. A review of conformity assessment applications from Australian manufacturers indicates that in 2012-13 this would have affected only 2 applications, however given the very low numbers this figure may vary widely between years.

Once conformity assessment has been certified, Australian manufacturers are also required to apply for inclusion on the ARTG. Under this option application fees for ARTG inclusion would continue to apply. Australian manufacturers may be newly subject to audit fees in relation to some of those applications.

There were 48 applications for ARTG inclusion from Australian manufacturers in 2013. On average 8% of applications for inclusion are subject to mandatory audit (for which an audit fee applies), which would result in an approximate additional regulatory cost of $24,960 (a maximum of $6,500 for each affected applicant).

Annual charges would continue to be collected for each medical device ARTG inclusion, to fund TGA's post market surveillance and compliance activity.

Regulatory burden and cost offsets

The table below outlines the costs and savings of allowing third party conformity assessment for Australian manufacturers. This change is estimated to reduce the regulatory burden for Australian manufacturers by $6.12m. As for Option 2, this includes the costs of the regulatory burden saved in Australia, but has not been offset by the administrative and delay costs associated with seeking conformity assessment certification overseas. In practice, these overseas costs will reduce the net impact of the savings for Australian manufacturers outlined in this document.

The savings associated with removing the requirement for TGA conformity assessment for Australian manufacturers is estimated at $15.83m includes two key components:

- Administrative costs of complying with regulatory processes of $2.80m (submitting applications and gathering related evidence, responding to queries as part of the assessment process, etc.)
- Cost of delay of $13.03m (TGA processing times delay the product to market)

While the administrative costs of compliance are a significant expense, the cost of delay in gaining market entry is the most significant cost for Australian manufacturers. This aligns with feedback from Australian manufacturers, who express most concern about the impacts of delays and the reduction in their competitiveness in the market relative to their overseas competitors, rather than more direct administrative compliance costs.

These significant savings are offset by the additional cost of application audits some Australian manufacturers may be newly subject to in relation to some of their applications for ARTG inclusion. Around 30% of applications are subject to audit (both mandatory (8%) and discretionary (22%)), which results in both administrative and delay costs of applicants

estimated at $9.71m (comprised of administrative costs of around $0.46m and delay costs of $9.25m).

As for Option 2, this costing assumes all Australian manufacturers, when given the choice, would choose not to seek conformity assessment from the TGA.

Who was consulted about the options and how?

Changes to premarket assessment requirements for medical devices: Regulation Impact Statement

Consultation on changes to premarket assessment requirements for medical devices was undertaken between January and March 2013 and again between May and June 2013. A summary of both these consultations is included in the 26 July 2013 RIS, *Changes to premarket assessment requirements for medical devices* (Attachments F and G).

The response from stakeholders in both these rounds of consultation was consistent:

- industry stakeholders are supportive of allowing third party conformity assessment for Australian medical device and IVD manufacturers (emphatic support expressed by Australian manufacturers, and consistent support from other industry stakeholders who do not stand to benefit from the change)
- some concern expressed from consumers, healthcare professionals and medical device procurers that this change would affect public health and safety if the level of TGA oversight of Australian medical device and IVD manufacturers is reduced.

The proposal to allow third party conformity assessment for Australian medical device and IVD manufacturers was previously linked to other reform elements and the industry response was to suggest this be 'decoupled' and proceed more quickly, on the basis of the disadvantage currently experienced by Australian medical device and IVD manufacturers.

In the first round of consultation (January and March 2013) it was suggested that third party conformity assessment for Australian medical device and IVD manufacturers be limited to lower risk devices (as proposed in Option 2). Feedback from industry stakeholders strongly supported expanding any changes to cover all Australian manufactured medical devices and IVDs to create a level playing field for Australian manufacturers with their overseas competitors (as proposed in Option 3). While under Option 3 some very high risk products will still require TGA conformity assessment, this is based on the risk of the device rather than the country of manufacturer, and applies equally to all manufacturers seeking to enter the Australian market.

Previous consultation

The proposals outlined in this RIS also build on consultation, inquiries and reports prior to the 26 July 2013 RIS. Proposals to allow the use of third party conformity assessment bodies by Australian manufacturers have a long history, with various previous rounds of consultation:

- *Use of third party conformity assessment bodies for medical devices supplied in Australia* – consultation December 2008 to March 2009
- *Review of Health Technology Assessment in Australia* – released December 2009
- Included in *Reforms in the medical devices regulatory framework* – consultation October to December 2010

- Included in Senate Standing Committee on Community Affairs Inquiry (reported 22 November 2011) on *The regulatory standards for the approval of medical devices in Australia*
- *Proposal Paper: Changes to premarket assessment requirements for medical devices* – consultation January to March 2013
- *Regulation Impact Statement exposure draft: Changes to premarket assessment requirements for medical devices* – consultation from May to June 2013

A number of these consultations also explored other reforms, which are being progressed separately.

Once Government policy approval is in place further communication will be required to support implementation of the chosen option. A stakeholder engagement and communication strategy has been prepared. The arrangements outlined in that strategy are summarised the section below titled "How will you implement and evaluate the chosen option?"

What is the best option from those considered?

Option 1 – No change

This option is not recommended. It fails to address the concerns which industry stakeholders have been raising prior to the current arrangements coming into place in 2002.

Option 2 - Allow third party conformity assessment for lower risk Australian medical device and IVD manufacturers

Option 2 provides deregulatory savings for Australian manufacturers, although more significant savings are delivered by Option 3.

There are some risks in allowing third party conformity assessment for Australian manufacturers, but these are no greater than those which already exist for medical devices and IVDs manufactured overseas (which comprise more than 90% of all medical devices available in Australia), and the risks can be managed using existing arrangements.

This option does provide a useful 'partial' change, if the risks associated with allowing third party conformity assessment for Australian manufacturers of higher risk devices are considered too great to allow Option 3 to proceed, or to provide stepped or phased approach to implementing this change while other medical device reforms are progressed.

However the depth and complexity of conformity assessment procedures increase significantly as the risk of the medical device or IVD increases. While there are many more medical devices in the lower and moderate risk classifications, the costs of conformity assessment are much more significant for higher risk medical devices. By excluding these higher risk medical devices from the change in conformity assessment requirements, nearly half the benefit to Australian manufacturers is lost.

Option 3 - Allow third party conformity assessment for Australian medical device and IVD manufacturers

This option achieves the objectives for the proposed change – maintaining public health and safety while supporting the timely availability of medical devices and IVDs, minimising unnecessary regulatory burden and associated costs and continuing Australia's commitment to promoting alignment of international medical device regulation. For this reason it is the preferred option. It provides a significant deregulatory improvement for Australian medical device and IVD manufacturers.

While a range of mitigation arrangements are in operation to manage the potential impact on public health and safety, which are already used in respect of overseas manufacturers, proceeding with allowing third party conformity assessment for all Australian manufacturers does pre-empt the modified medical device reform package currently being developed.

This option delivers significant savings to the regulated industry, with a $6.12m reduction in the regulatory burden to industry, and around $0.98m savings in application and assessment fees, with minimal additional risk to public health and safety.

It is considered that, on balance, existing premarket risk management mechanisms (such as application audits and confidence building) are sufficient to mitigate any marginal additional risk for public health and safety while other medical device reforms are progressed. The benefits arising from the Australian Government having direct oversight of Australian medical device manufacturers is insufficient to justify continuing the disadvantage caused to Australian manufacturers in requiring a TGA conformity assessment.

How will you implement and evaluate the chosen option?

Implementation

Implementation of this change will require amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). The key change will be to remove Regulation 4.1(1), which requires Australian manufacturers of medical devices to seek conformity assessment from the TGA. There are a number of incidental changes also required, to allow provisions which currently apply for medical devices manufactured overseas to also apply to those manufactured in Australia. It is anticipated that these amendments will be straightforward, and drafting of the changes can commence as soon as Government policy approval for this change is in place.

The amendments to the Regulations will be drafted to come into effect the day following their inclusion on the Federal Register of Legislative Instruments (FRLI). A start date could be specified, but there is no operational reason to delay the start of this ch*a*nge.

Advice on the change will need to be provided to affected stakeholders. This would involve:

- Communication directly with the 105 Australian manufacturers who currently hold conformity assessment certification with the TGA
- Communication with peak bodies representing affected stakeholders (the MTAA, AusBiotech, IVD Australia, the Australian Dental Industry Association and the Association of Therapeutic Goods Consultants)

- A web statement on the TGA website outlining the change and updates to TGA guidance on conformity assessment requirements (on the TGA website and included in the Australian Regulatory Guidelines on Medical Devices)

In addition, guidance on the change will be provided to TGA staff, including updates to standard operating procedures.

This change will also be communicated to other stakeholders who interact with TGA or have an interest in this change, such as health professional bodies, consumer groups, the Departments of Industry and Australian Customs and Border Protection, as well as state and territory health departments.

Transitional arrangements

Specific transitional arrangements are not required for this change. However, it should be noted that under the previously proposed reform package outlined in the August 2013 RIS, there would have been a 12 to 18 month delay in implementing this change for Australian manufacturers while related reforms were put in place. This would have provided Australian manufacturers with significant notice of this change coming into effect. Proceeding with this change separately to the rest of the reform package outlined in the previous RIS means the implementation of this policy will be comparatively rapid. It will take a few months from the time Government policy approval is in place until the changes come into effect.

Undertaking a conformity assessment process with the TGA or any other body is a significant investment both in terms of time and funds. Processing of conformity assessment applications takes a significant period to complete, with TGA conformity assessments completed for Australian manufacturers taking an average of 256.5 calendar days during the past two financial years (2012-13 and 2013-14). In addition, gaining conformity assessment certification is effectively a longer term commitment for Australian manufacturers (to the TGA as their conformity assessment body), given conformity assessment certification typically is valid for five years.

Whether Australian manufacturers continue to use the TGA as their conformity assessment body will be a business decision for each manufacturer. Australian manufacturers who already have a TGA conformity assessment process underway may be frustrated by the changes in existing rules, where they may have decided to engage a different conformity assessment body (a European notified body) had the choice been available to them at the time they lodged their application. The TGA will seek to finalise existing applications as soon as practicable to minimise transitional concerns, however it is anticipated that some individual manufacturers may choose to withdraw from existing conformity assessment processes. As the TGA is a cost recovered organisation there is no provision for the TGA to refund assessment fees where the assessment work is underway.

Given the five year duration of conformity assessment certification, it is also expected that most manufacturers will continue to rely on existing TGA certification until their current certification expires or significant changes require reassessment. Again, it will be a business decision for individual Australian manufacturers to continue with the TGA as their conformity assessment body or change to a suitable European notified body.

It is anticipated that TGA will receive fewer conformity assessment applications as a result of this change. However as this change has a long timeframe to take effect, Australian manufacturers are only a proportion of the TGA's conformity assessment workload and this change will result in an increase in application audits, so the TGA will need to maintain its existing skills.

Evaluation

This measure will be evaluated by monitoring the choices Australian manufacturers make in selecting conformity assessment bodies (whether TGA or a European notified body). Given the duration of most conformity assessment certification, it is expected that it will be five years before the full effects of this change are apparent.

Attachments

Attachment A - Regulation of medical devices

Under the *Therapeutic Goods Act 1989* medical devices (including commercial IVDs[20]) must generally be included in the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia. For all but the lowest risk Class I medical devices and Class 1 IVDs this includes a premarket assessment by the TGA before the device is allowed to be supplied in Australia[21]. The rigour of this assessment is based on the risk of the device.

Premarket assessment consists of two key components: conformity assessment followed by an application (and decision) to include the medical device in the ARTG.

Conformity assessment of medical devices and IVDs

To be included in the ARTG an appropriate conformity assessment procedure must have been applied to the medical device or IVD. Conformity assessment procedures are the processes undertaken by a manufacturer to ensure that a medical device complies with the regulatory requirements for quality, safety and performance (as set out in the Essential Principles). The conformity assessment procedures are set out in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).

A person seeking to include a medical device or IVD in the ARTG must be able to substantiate the application of those conformity assessment procedures to the device, usually relying on certification issued by a conformity assessment body.

Currently the TGA is the only body that can provide conformity assessment certification for Australian manufacturers of medical devices.

For medical devices manufactured outside Australia, manufacturers are required to hold TGA conformity assessment certification in relation to the highest risk medical devices. These are those medical devices that contain medicines or tissues of animal, biological or microbiological origin, or Class 4 IVDs.

For other medical devices and IVDs that have been manufactured overseas, the TGA may accept certification from certain other conformity assessment bodies as evidence of an appropriate conformity assessment procedure. In practice conformity assessment certification is generally accepted from European notified bodies for medical devices under the European Medical Device Directives[22], given the close parallels between the European and Australian regulatory frameworks. IVD conformity assessment certification is generally accepted from European notified bodies under the IVD Directive[23], or ISO 13485 certification European notified bodies, Registrars recognised by the Canadian Medical Devices Conformity Assessment System or certification bodies accredited under International Accreditation Forum Multilateral Recognition Arrangement to perform ISO 13485 certification.

Note: The regulatory framework on IVDs was introduced on 1 July 2010. Not all IVDs have been included in the ARTG as the transition period for implementation of the new arrangements has been extended to 30 June 2015 for commercial IVDs and 30 June 2017 for Australian laboratories that manufacturer in-house IVDs.

[11] Given the low risk of Class 1 medical devices (except those which include a measuring function or are supplied sterile) conformity assessment procedures are self-assessed by the manufacturer, and on application the medical device is automatically included in the ARTG without TGA review.

[12] European Directive 93/42/EEC on Medical Devices or Directive 90/385/EEC on Active Implantable Medical Devices

[13] European Directive 98/79/EC on In Vitro Diagnostic Devices

Inclusion of medical devices and IVDs on the ARTG

For all but Class I medical devices and Class 1 IVDs, once conformity assessment certification is obtained from an appropriate conformity assessment body, an application to include the medical device in the ARTG can be made.

The degree of rigour of the assessment conducted by the TGA at the point of application for ARTG inclusion depends on the risk classification of the device and the source of the conformity assessment certification. The TGA may approve the inclusion of a device in the ARTG based solely on the application received, or may audit the application through a desk top review of information such as the labelling, instructions for use and the clinical evidence for the device.

The scope of any audit will depend largely on the issues identified by the TGA as requiring further scrutiny. In most cases high risk devices (Class III and active implantable medical devices (AIMDs)) are subject to mandatory application audits where the conformity assessment body is a European notified body. In practice many Class 3 IVDs, such as those for self–testing, point of care testing and IVDs to monitor patients diagnosed with Human immunodeficiency virus (HIV), are selected for mandatory audit. The TGA is able to select any application for audit; however audit fees ($3,545 or $6,500 for medical devices and $6,330 for IVDs) are only payable for mandatory application audits required under Regulation 5.3.

Use of EU conformity assessment certification

In the EU, there are a large number (around 75 at present) notified bodies. These bodies undertake conformity assessment of medical devices under the European regulatory framework. Assessment of medical devices in Australia is based on Essential Principles relating to safety and performance (rather than a prescriptive framework), and the European regulatory framework is based on a similar set of Essential Requirements. The risk classification for medical devices is also similar and most devices have the same risk classification.

Given these parallels between the Australian and European regulatory frameworks conformity assessment certification from European notified bodies is generally accepted as evidence of conformity assessment procedures to support the inclusion of many overseas manufactured medical device in the ARTG. There are some instances, such as where a device has a higher classification in Australia, where the notified body certification will be insufficient to satisfy Australian regulatory requirements. As outlined above, this option to rely on conformity assessment evidence from European notified bodies is not available to Australian medical device manufacturers.

As outlined above, for lower risk IVDs that have been manufactured overseas conformity assessment may be under the European IVD Directive, or relying on ISO 13485 certification from European notified bodies, Registrars recognised by the Canadian Medical Devices Conformity Assessment System or other International Accreditation Forum Multilateral Recognition Arrangement bodies accredited to perform ISO 13485 certification.

The key concern in accepting certifications such as European notified body and ISO 13485 certification is that these are assessed in relation to the regulatory frameworks of other countries, and do not provide assurance that the specific requirements of the Australian regulatory framework have been met. Risks arising from this are managed through the targeted use of application audit arrangements for higher risk devices (such as AIMD and Class III medical device and IVDs for self-testing or point of care).

In addition the TGA is currently undertaking ‘confidence building’ activities in liaison with European regulatory authorities. The TGA will establish confidence in the outputs of selected European notified bodies through a program of observed audits and desk audits, leveraging off the joint assessments being conducted in Europe and the International Medical Device Regulators Forum (IMDRF)’s Medical Devices Single Audit Program (MDSAP), a program to

develop a standard set of requirements for auditing organisations performing regulatory audits of medical device manufacturers' quality management systems. Once confidence is established, a program to maintain confidence in the future will be developed. Confidence building seeks to gain assurance on the appropriateness of the control a regulatory authority within a jurisdiction in Europe has on one or more of its notified bodies and the quality of the work conducted by individual notified bodies. The purpose of the TGA confidence building process is to develop and publish, by the end of 2014, a list of European notified bodies in which TGA has 'confidence'. Benefits to industry will be represented by reduced audit requirements, waived fees and faster access to market.

Performance of notified bodies and proposed European reforms

As outlined in the previous *Regulation Impact Statement: Changes to premarket assessment requirements for medical devices* (released in August 2013) there is significant international concern over the performance of some European notified bodies and the level of evidence reviewed prior to issuing the certification which enables the device to be approved for marketing in the European Union.

These issues are highlighted in a series of articles published in the British Medical Journal about medical device regulation.[24] Some of the key issues highlighted in the articles include the influence of financial or trade facilitation considerations in the granting of marketing approvals, a lack of transparency about the basis for marketing approval, and concerns about the level of evidence to support the marketing approval of many higher risk devices is insufficient to allow safe widespread use.

On 26 September 2012, the European Union announced a package of reforms to provide for more stringent regulation of medical devices with the European Union to ensure a high level of protection of human health and safety. The European Union intends to reform the operation of notified bodies to ensure the legal requirements concerning the premarket evaluation of medical devices are applied and implemented effectively in all member states, including ensuring notified bodies follow the same high standards and criteria when they undertake conformity assessments. This is because of reported variations in the quality and depth of conformity assessment performed by notified bodies which could lead to variations in the level of protection of patient and user safety. The proposed changes are summarised in Attachment C to the previous RIS.

For example: Deborah Cohen, Out of Joint, 21 May 2011, BMJ 2011;342:d2905; Deborah Cohen, EU approval system leaves door open for dangerous Devices, 24 October 2012, BMJ 2012;345:e7173; Philipp Storz-Pfennig et al, Trials are needed before new devices are used in routine practice in Europe, 11 May 2013, BMJ 2013;346:f1646

Attachment B – Stakeholder engagement and communication plan

Consultation strategy overview

A Regulation Impact Statement (RIS) has been developed to assist with Australian Government decision making on how to address the problems that have been identified in relation to the premarket assessment requirements for Australian manufacturers of medical devices. This document has been prepared by the Therapeutic Goods Administration (TGA) to outline the stakeholder engagement strategy for those proposed changes.

The TGA has been consulting on possible changes to premarket assessment requirements for Australian manufacturers of medical devices, including several previous rounds of full public consultation. This document includes an outline of previous consultation, as well as anticipated future communications about implementation and transition of any agreed changes.

Background

Australian medical device and IVD manufacturers that want to supply a device in Australia must seek conformity assessment certification from the TGA. In contrast to this, if the same device is manufactured overseas the manufacturer can choose to either have the conformity assessment conducted by an alternative conformity assessment body or by the TGA. Industry stakeholders have indicated that (compared to a TGA conformity assessment certification) a European notified bodies' conformity assessment certification can be completed in less time and at less expense. In this context Australian manufacturers consider the current requirements put them at a significant disadvantage.

The intention of any proposed changes to the current requirements is to create a regulatory framework which allows Australian manufacturers to choose where and how conformity assessment certification is obtained, as is the case for their overseas competitors, and to remove the disadvantages that they are currently experiencing. The RIS outlines three policy options:

- No change (status quo)
- Allow third party conformity assessment for lower risk Australian medical device and IVD manufacturers
- Allow third party conformity assessment for Australian medical device and IVD manufacturers

Consultation

Previous RIS on changes to premarket assessment requirements for medical devices

Consultation on changes to premarket assessment requirements for medical devices was undertaken between January and March 2013 and again between May and June 2013.
A summary of both these consultations is included in a previous RIS, *Changes to premarket assessment requirements for medical devices* (at Attachments F and G).

The response from stakeholders in both these rounds of consultation was consistent:

- industry stakeholders are supportive of allowing third party conformity assessment for Australian medical device and IVD manufacturers (emphatic support expressed by Australian manufacturers, and consistent support from other industry stakeholders who do not stand to benefit from the change)

- some concern expressed from consumers, healthcare professionals and medical device procurers that this change would affect public health and safety if the level of TGA oversight of Australian medical device and IVD manufacturers is reduced.

The proposal to allow third party conformity assessment for Australian medical device and IVD manufacturers was previously linked to other reform elements and the industry response was to suggest this be 'decoupled' and proceed more quickly, on the basis of the disadvantage currently experienced by Australian medical device and IVD manufacturers.

In the first round of consultation (January and March 2013) it was suggested that third party conformity assessment for Australian medical device and IVD manufacturers be limited to lower risk devices (as proposed in Option 2). Feedback from industry stakeholders strongly supported expanding any changes to cover all Australian manufactured medical devices and IVDs to create a level playing field for Australian manufacturers with their overseas competitors (as proposed in Option 3). While under Option 3 some very high risk products will still require TGA conformity assessment, this is based on the risk of the device rather than the country of manufacturer, and applies equally to all manufacturers seeking to enter the Australian market.

Previous consultation

The proposals outlined in this RIS also build on consultation, inquiries and reports prior to the 26 July 2013 RIS. Proposals to allow the use of third party conformity assessment bodies by Australian manufacturers have a long history, with various previous rounds of consultation:

- Use of third party conformity assessment bodies for medical devices supplied in Australia – consultation December 2008 to March 2009
- Review of Health Technology Assessment in Australia – released December 2009
- Included in Reforms in the medical devices regulatory framework – consultation October to December 2010
- Included in Senate Standing Committee on Community Affairs Inquiry (reported 22 November 2011) on The regulatory standards for the approval of medical devices in Australia
- Proposal Paper: Changes to premarket assessment requirements for medical devices – consultation January to March 2013
- Regulation Impact Statement exposure draft: Changes to premarket assessment requirements for medical devices – consultation from May to June 2013

A number of these consultations also explored other reforms, which are being progressed separately.

Issues

Stakeholder opinion on the proposed change has been clearly established by previous consultation. Future communication activity will be required to address:

- Implementation of regulatory changes and implications for stakeholders
- Transitional arrangements for managing the change in regulatory change
- Evaluation of the changes

Stakeholders

Likely views/attitudes and reactions of stakeholders

The following table lists stakeholders affected by organisation with a possible interest in this proposed change. It includes an assessment of the nature of their interest, and possible points of concern.

Stakeholder organisations	View represented
Australian manufacturers of medical devices and IVDs	Very supportive of change Interest in implementation and transition arrangements
Medical devices industry associations • Medical Technology Association Australia (MTAA) • AusBiotech • IVD Australia • Australian Dental Industry Association (ADIA) • Australasian Health Manufacturers And Development Association (AHMADA)	Supportive of change Interest in implementation and transition arrangements
Medical devices industry • Regulatory consultants • European notified bodies	Interest in change of requirements Interest in implementation and transition arrangements
Health professionals • Associations such as Australian Medical Association, Royal Colleges, etc. • Universities and research organisations (e.g. CSIRO)	For information Possible concern that change will lead to reduced assurance in health and safety of medical devices For information Changes to requirements to commercialise medical technology research in Australia may be of interest
Health sector • State health departments • Private health providers • Private health insurers	For information Does not alter requirements for market access (i.e. ARTG inclusion of the device)

Stakeholder organisations	View represented
Government organisations	
• Department of Industry	Policy interest in medical technology sector
• Customs and Border Protection	For information TGA relies on Customs Service for enforcement of a range of compliance mechanisms. These are unaffected by this change.
• Health Technology Assessment areas (Prostheses List Advisory Committee, Medical Benefits Advisory Committee)	For information HTA arrangements generally conditional on ARTG inclusion. Change does not alter requirements for market access
• TGA (internal)	Operational changes for affected staff
International medical device regulators	For information
• European regulators (European Commission and regulators in European member states)	
• Other regulators, e.g. MedSafe (New Zealand), FDA (USA), Health Canada, etc.	
Consumers	For information
• Consumer Health Forum	Possible concern that change will lead to reduced assurance in health and safety of medical devices

Activity overview

Implementation

Implementation of this change will require amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). The key change will be to remove Regulation 4.1(1), which requires Australian manufacturers of medical devices to seek conformity assessment from the TGA. There are a number of incidental changes also required, to allow provisions which currently apply for medical devices manufactured overseas to also apply to those manufactured in Australia. It is anticipated that these amendments will be straightforward, and drafting of the changes can commence as soon as Government policy approval for this change is in place.

The amendments to the Regulations will be drafted to come into effect the day following their inclusion on the Federal Register of Legislative Instruments (FRLI). A start date could be specified, but there is no operational reason to delay the start of this change.

Advice on the change will need to be provided to affected stakeholders. This would involve:

- Communication directly with the 105 Australian manufacturers who currently hold conformity assessment certification with the TGA, or who have applied and have a conformity assessment application in progress
- Communication with peak bodies representing affected stakeholders (the MTAA, AusBiotech, IVD Australia, the Australian Dental Industry Association and the Association of Therapeutic Goods Consultants)
- A web statement on the TGA website outlining the change and updates to TGA guidance on conformity assessment requirements (on the TGA website and included in the Australian Regulatory Guidelines on Medical Devices)

In addition, guidance on the change will be provided to TGA staff, including updates to standard operating procedures.

This change will also be communicated to other stakeholders who interact with TGA or have an interest in this change, such as health professional bodies, consumer groups, the Departments of Industry and Australian Customs and Border Protection, as well as state and territory health departments.

Transition

Specific transitional arrangements are not required for this change. However, it should be noted that under the previously proposed reform package outlined in the RIS released in August 2013, there would have been a 12 to 18 month delay in implementing this change for Australian manufacturers while related reforms were put in place. This would have provided Australian manufacturers with significant notice of this change coming into effect. Proceeding with this change separately to the rest of the reform package outlined in the previous RIS means the implementation of this policy will be comparatively rapid. It will take a few months from the time Government policy approval is in place until the changes come into effect.

Undertaking a conformity assessment process with the TGA or any other body is a significant investment both in terms of time and funds. Processing of conformity assessment applications takes a significant period to complete, with TGA conformity assessments completed for Australian manufacturers taking an average of 256 calendar days during the past two financial years (2012-13 and 2013-14). In addition, gaining conformity assessment certification is effectively a longer term commitment for Australian manufacturers (to the TGA as their conformity assessment body), given conformity assessment certification typically lasts five years.

Whether Australian manufacturers continue to use the TGA as their conformity assessment body will be a business decision for each manufacturer. Australian manufacturers who already have a TGA conformity assessment process underway may be frustrated by the changes in existing rules, where they may have decided to engage a different conformity assessment body (a European notified body) had the choice been available to them at the time they lodged their application. The TGA will seek to finalise existing applications as soon as practicable to minimise transitional concerns, however it is anticipated that some individual manufacturers may choose to withdraw from existing conformity assessment processes. As the TGA is a cost recovered organisation there is no provision for the TGA to refund assessment fees where the assessment work is underway.

Given the five year duration of conformity assessment certification, it is also expected that most manufacturers will continue to rely on existing TGA certification until their current certification expires or significant changes require reassessment. Again, it will be a business decision for individual Australian manufacturers to continue with the TGA as their conformity assessment body or change to a suitable European notified body.

It is anticipated that TGA will receive fewer conformity assessment applications as a result of this change. However as this change has a long timeframe to take effect, Australian manufacturers are only a proportion of the TGA's conformity assessment workload and this change will result in an increase in application audits, so the TGA will need to maintain its existing skills.

Summary of communication activities

Activity	Stakeholders	Issues	Channel
Web statement	All	Advice of change and reference to further information / guidance	TGA website
Direct communication	Australian manufacturers of medical devices and IVDs Courtesy copies to: • Medical devices industry associations • Regulatory consultants	Advice of change and reference to further information / guidance	Email distribution
	Health professional associations Consumers (CHF)	Advice of change, including: • content addressing any concerns about health and safety • reference to further information	Email distribution
	Government organisations Health sector	Advice of change, including: • note of nature of impact on organisation • reference to further information	Email distribution
Update guidance	TGA staff Australian manufacturers of medical devices and IVDs Regulatory consultants Medical devices industry associations	Operational implications of change Develop guidance in consultation with medical devices industry associations	TGA web site
Telephone support	Any – anticipated to be primarily Australian manufacturers TGA staff	Telephone script to be developed, including FAQs and reference to further info (web)	TGA medical devices and IVD helpline (1800 141 144) TGA Public Contact Team (1800 020 653)

The resources to support these activities (web statement, emails, guidance, etc) will need to be prepared in advance of consideration of the regulatory amendment by the Executive Council meeting. This will enable their release to coordinate with the changes coming into effect once the regulatory amendments are registered with FRLI (and come into effect the following day).

Evaluation

This measure will be evaluated by monitoring the choices Australian manufacturers make in selecting conformity assessment bodies (whether TGA or a European notified body). Given the duration of most conformity assessment certification, it is expected that it will be five years before the full effects of this change are apparent.

Attachment C - Glossary

Australian Register of Therapeutic Goods (ARTG)	The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia. All medical devices, including Class I, must be included in the ARTG before supply in Australia. There are limited exceptions to this requirement specified in the legislation, including for clinical trials and custom made medical devices.
Application audit	The TGA has established two levels of application audit, Level 1 and Level 2: *Level 1*: Targeted for completion within 30 days The TGA will consider: • the original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity • Copy of the latest and current conformity assessment evidence for the medical device • Information about the device, including copies of the: – Label – Instructions for use – Advertising material such as brochures, web pages and advertisements. *Level 2:* Targeted for completion within 60 days In addition to all of documentation considered in a Level 1 audit, the TGA will also consider: • the risk management report • the clinical evaluation report • efficacy and performance data for medical devices that disinfect including those that sterilise other medical devices. *IVD audit:* In addition to the documentation considered for a Level 1 or Level 2 medical device audit the TGA will also consider: • the technical file validating the performance of the IVD Regulation 5.3 prescribes certain kinds of applications that must be selected for audit by the Secretary, including AIMD, most Class III medical devices and certain of IVDs (eg IVDs for self-testing). The Secretary may also select any other application for auditing under section 41FH of the Act.

Confidence building	Confidence building is the process where the TGA can gain assurance on the appropriateness of the control a regulatory authority within a jurisdiction in Europe has on one or more of its notified bodies and the quality of the work conducted by individual notified bodies through a sampling exercise initially, followed by an ongoing maintenance

program.

Conformity assessment	Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles. In Australia this means that the manufacturer must be able to demonstrate that both the medical device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation, including compliance with the Essential Principles. It provides objective evidence of the safety, performance, benefits and risks for a specified medical device and also enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements.
Conformity assessment procedures	Conformity assessment procedures are the processes undertaken by a manufacturer to ensure that a medical device complies with the Essential Principles and a Quality Management System (QMS), and so is safe and performs as intended. Manufacturers can choose the appropriate procedures to use, depending on the classification of the device. The level of assessment is commensurate with the level and nature of the risks posed by the device to the patient, ranging from manufacturer self-assessment for low risk devices through to full conformity assessment for the highest risk devices. Options available to manufacturers are outlined in Schedule 3 of the Regulations. The following table summarises the usual conformity assessment procedure for each class of medical device: There are also some additional conformity assessments procedures which can be used in place of those above, however these are not commonly used as they are generally more expensive for manufacturers.

The following table summarises the usual conformity assessment procedure for each class of IVD:

Class	Most commonly used conformity assessment procedure	Regulations Reference
Class I	Self-assessment by the manufacturer	Schedule 3, Part 6, clause 6.6
Class I (measuring) and Class IIa (non-sterile)	Self-assessment by the manufacturer *AND* Product Quality Assurance Procedures	Schedule 3, Part 6, clause 6.6 Part 5
Class I (sterile) and	Self-assessment by the manufacturer	Schedule 3, Part 6, clause 6.6

Class	Most commonly used conformity assessment procedure	Regulations Reference
Class IIa (sterile)	*AND* Production Quality Assurance Procedures	Part 4
Class IIb	Full Quality Assurance Procedures	Schedule 3, Part 1 clause 1.8
Class III and Class AIMD	Full Quality Assurance Procedures *AND* Examination of Design	Schedule 3, Part 1 clause 1.8 Clause 1.6
Systems or Procedure Packs	Procedures for Medical Devices Used for a Special Purpose	Schedule 3, Part 7, clause 7.5

Conformity assessment body	Conformity assessment body means an organisation that conducts conformity assessment activities and includes test facilities and certification bodies. Conformity assessment bodies include regulators such as the TGA which may directly assesses conformity, or third party conformity assessment is where assessment and/or testing are undertaken by an independent organisation. The TGA and European notified bodies are conformity assessment bodies.
Conformity assessment certificate	A certificate issued by a conformity assessment body to demonstrate a manufacturer has been assessed and has the appropriate systems in place to manufacture the devices. Assessment processes will vary according to the conformity assessment procedures selected by the manufacturer, but include: • confirming that the conformity assessment procedures are appropriate for the classification of the device and have been applied correctly • systematic examination of the documentation provided and procedures undertaken by the manufacturer • may include an on-site audit of the manufacturing premises • re-certification of conformity assessment evidence that is due to expire
Declaration of conformity	Once the manufacturer has obtained evidence of conformity assessment (typically a conformity assessment certificate), they must make a Declaration of Conformity (DoC). This involves preparing technical documentation for a medical device and establishing a post-market

monitoring system for Australia. The DoC declares that the device complies with:

- the applicable provisions of the Essential Principles
- the classification rules
- an appropriate conformity assessment procedure

If requested, the TGA must be provided with a copy of the DoC, and the DoC must be maintained and updated when appropriate.

Essential Principles

The Essential Principles provide the measures for safety and performance and are set out in the Regulations. For a medical device to be supplied in Australia, it must be demonstrated that the relevant Essential Principles have been met. The Essential Principles are:

General principles that apply to all devices

1. Medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction that apply depending on the kind of device

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence

Additional essential principle for IVDs only

15. Principles applying to IVD medical devices only (this includes 7 principles relating specifically to the safety and performance of IVD medical devices).

European designating authority

A designating authority designates notified bodies to conduct conformity assessment procedures specified in the various directives – in the European Union these are the regulators in the Member States, such as the Medicines & Healthcare products Regulatory Agency (MHRA) on the

	UK.
European notified body	A notified body, in the European Union, is an organisation that has been accredited by a Member State (by the appropriate designating authority) to assess whether a product meets certain preordained standards. Assessment can include inspection and examination of a product, its design and manufacture. For medical devices, a notified body may designate that a medical device conforms to the European Directive 93/42/EEC on Medical Devices, the Directive 90/385/EEC on Active Implantable Medical Devices and/or the Directive 98/79/EC on In Vitro Diagnostic Devices.
Examination of Design	Involves an examination of the design dossier (the technical documentation) for the medical device to assess the compliance of the device with the Essential Principles. Note that the manufacturer must also apply a QMS conformity assessment procedure.
In-vitro diagnostic device (IVD)	A medical device is an IVD if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures. The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured and are not sold or presented for use specifically as an IVD.
Kind of medical device	A single entry in the ARTG may cover a range of products that are of the same kind rather than individual devices. At present, medical devices (with the exception of Class III and Active Implantable Devices (AIMDs) and Class 4 IVDs and Class 4 in-house IVDs) are included as a group in the ARTG under a single entry if they: have the same sponsor; have the same manufacturer; have the same medical device classification; have the same nomenclature system code (GMDN) code.
Manufacturer	A manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations. Refer to section 41BG of the Act for remainder of definition.
Medical device	A medical device is: (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: – diagnosis, prevention, monitoring, treatment or alleviation of disease

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A)

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B)

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).

Refer to section 41BD of the Act for remainder of definition.

Medical device classifications

Medical devices are classified by the manufacturer according to the intended purpose of the medical device and the degree of risk involved for the patient and user. The device classifications are determined using a set of rules contained in the Regulations that take into account the degree of invasiveness in the human body, the duration and location of use and whether the device relies on a source of energy other than the body or gravity. There are two sets of classifications, for medical devices and IVDs.

Medical devices (other than IVD medical devices):

Class	Risk	Examples
Class I	Low risk	Surgical retractors, tongue depressors
Class I – supplied sterile Class I – incorporating a measuring function	Low-medium risk	Sterile bandages, drainage bags
Class IIa		Hypodermic needles, suction unit
Class IIb	Medium-high risk	Lung ventilator, hip, knee and shoulder joint implants
Class III	High risk	Heart valves
AIMD (Active Implantable Medical Devices)		Implantable defibrillator

IVD medical devices:

Class	Risk	Examples
Class 1 IVD	No public health risk or low personal risk	Instrumentation and analysers (e.g., glucose meter). Microbiological culture media.
Class 2 IVD	Low public health risk or moderate personal risk	Pregnancy self-testing kit. Liver function tests.
Class 3 IVD	Moderate public health risk or high personal risk	Test to detect the presence or exposure to a sexually transmitted agent such as C. trachomatis or N. gonorrhoea.
Class 4 IVD	High public health risk	Assay intended for the clinical diagnosis of HIV. Assay intended for screening blood donations for Hepatitis C virus.

Medical Devices Single Audit Program (MDSAP)	A project of the International Medical Device Regulators Forum (IMDRF) to develop, manage and oversee a single audit program that will allow a single regulatory audit of a medical device manufacturer's quality management system to satisfy the needs of multiple regulatory jurisdictions.
Quality assurance procedures	Quality assurance procedures involve the manufacturer implementing an appropriate quality management system and arranging for the quality management system to be audited by an appropriate conformity assessment body. Australian regulatory requirements for quality assurance procedures vary based on the risk of the device, and include: • Full quality management system ie all clauses of ISO 13485 including clauses 7.3 and 7.5.2. Assessment will include the manufacturer's technical documentation for the medical devices, including clinical evidence. • Product quality management system ie ISO 13485 excluding clauses 7.3 and 7.5.2. This is a quality management system encompassing the final inspection and testing of a medical device. Assessment will include review of a sample of the manufacturer's technical documentation for the devices. • Production quality management system i.e. all clauses of ISO 13485 excluding clause 7.3 but including clause 7.5.2. This is a quality management system encompassing the production and final inspection of a medical device. Assessment will include review of a sample of the manufacturer's technical documentation for the devices.
Quality	A quality management system for medical devices is a collection of

Management System (QMS)	business processes focused on assuring product safety and efficacy and customer satisfaction. ISO 13485 is an International Organization for Standardization (ISO) standard for a comprehensive quality management system for the design and manufacture of medical devices. Compliance with this standard demonstrates an organisation's ability to provide medical devices and related services that consistently meet regulatory and customer requirements applicable to medical devices and related services.
Sponsor	Under Section 7 of the Act a Sponsor, in relation to therapeutic goods, means: (a) a person who exports, or arranges the exportation of, the goods from Australia; or (b) a person who imports, or arranges the importation of, the goods into Australia; or (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who: (d) exports, imports or manufactures the goods; or (e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

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Reference/Publication #