Australian Government
Department of Health
Therapeutic Goods Administration

Designation of Australian conformity assessment bodies for medical devices

Implementation

Version 1.0, November 2016

TGA Health Safety Regulation

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Introduction

This paper outlines the proposed approach to implementing a system to designate bodies to undertake conformity assessment certification of medical devices, including in vitro diagnostic medical devices (IVDs), for the Australian market.

Relevant MMDR recommendations

The proposal to designate conformity assessment certification bodies in Australia was proposed in Recommendation 15(2) of the March 2015 report of the Medicine and Medical Devices Review (MMDR)[1]. Recommendation 16 also relates to designation of Australian conformity assessment bodies.

The recommendations were accepted by Government.

Recommendation Fifteen

The Panel recommend that:

[…]

2. In order to provide timely access to devices that are safe, high quality and fit for purpose, there be multiple pathways to seek approval for the inclusion … of medical device(s) in the ARTG. Such pathways to provide for:

   Pathway One Conformity Assessment to occur within Australia by either:
   A. The Australian NRA; or
   B. A body designated by the Australian NRA to undertake Conformity Assessments of medical devices for the Australian market.
   (emphasis added)

Recommendation Sixteen

The Panel recommends that the Australian Government develop transparent criteria that it will utilise in order to designate suitably qualified bodies within Australia to undertake Conformity Assessments of medical devices [Recommendation Fifteen, Pathway 1B].

Such criteria to:

1. Include capacity to set specific requirements for different classes of medical devices; and
2. Be developed in consultation with health care consumers, health professionals, the medical devices industry and the NRA (i.e. TGA).

Scope

This document establishes a framework for designating conformity assessment bodies to operate under the Australian regulatory framework for medical devices.[2] Such bodies would

[1] Full report available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

[2] The Australian regulatory framework for medical devices is broadly outlined under Chapter 4 of the *Therapeutic Goods Act 1989*, and the Therapeutic Goods (Medical Devices) Regulations 2002.

issue conformity assessment certification under Australian law, and these certificates would be recognised only in Australia.[3]

The existing conformity assessment requirements would continue to apply, whether the certification is undertaken by the TGA or a designated conformity assessment body. Specifically this means:

- **Existing regulatory requirements:** The existing Essential Principles[4] and conformity assessment procedures[5] will be unchanged. The high risk devices specified under Regulation 4.1[6] would continue to require TGA conformity assessment certification.
- **Not subject to mandatory audit:**[7] Mandatory application audit requirements would not apply for applications for inclusion of a kind of device on the Australian Register of Therapeutic Goods (ARTG) where certification is issued by Australian conformity assessment bodies (as is already the case for TGA-issued certification):
  - Mandatory application audit requirements aim to manage the risk of relying on overseas certification issued by conformity assessment bodies for which TGA has no direct oversight or control, focusing on high risk products. Devices holding TGA conformity assessment certification are not subject to mandatory audit. Likewise devices supported by conformity assessment certification from TGA designated conformity assessment bodies would also not be subject to mandatory audits, as the risk would be managed through the designation process rather than auditing of individual applications.
  - Note that any application may be selected for discretionary audit, as is currently the case.[8]
- **Partial designation will be possible:** Individual conformity assessment bodies may seek and be designated only for certain device classifications (Class IIb and lower, etc.), and particular product groups (e.g. cardiac, orthopaedic, IVDs, etc.), based on the competency, business focus, etc. of the conformity assessment body.
- **Consideration of existing certification source will be possible:** Applications for conformity assessment submitted to an Australian notified body, where the manufacturer already holds conformity assessment certification from a European notified body, would likely be eligible for reduced assessment due to the similarity in the regulatory frameworks between Australia and Europe. It is not clear how many manufacturers would take up this option.

European notified body conformity assessment certification is currently used as evidence to support the majority of market authorisation applications (around 92%). The high risk devices specified under Regulation 4.1[9] are an exception to this, as these require TGA conformity

[3] Stakeholders have previously indicated some countries rely on 'home market' regulatory authorisation for market entry - it is not clear how this proposal may impact such recognition.
[4] As outlined in the Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 1.
[5] As outlined in the Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3.
[6] Therapeutic Goods (Medical Devices) Regulations 2002, Part 4, Regulation 4.1 specifies that medical devices containing medicines, tissues of animal, biological or microbial origin and Class 4 IVDs must hold TGA conformity assessment certification.
[7] This would mean such applications would not be captured under Therapeutic Goods (Medical Devices) Regulations 2002, Part 5, Regulation 5.3.
[8] As outlined in the *Therapeutic Goods Act 1989*, s.41FH(1)(a).
[9] Therapeutic Goods (Medical Devices) Regulations 2002, Part 4, Regulation 4.1 specifies that medical devices containing medicines, tissues of animal, biological or microbial origin and Class 4 IVDs must hold TGA conformity assessment certification.

assessment certification. Applications for these sorts of devices, together with applications from some Australian medical device manufacturers, comprise the majority of conformity assessment applications received by the TGA.

Context for change

- **Alternative Pathways for Devices Requiring ARTG Application Audit:** The Australian medical device industry has expressed dissatisfaction at the time taken to process applications for inclusion in the ARTG when an application audit is undertaken. Conformity Assessment certification by the TGA is currently the only option for avoiding mandatory application audit.
- **Assessment evidence:** The TGA model for application audit when medical devices have EU certification was initially intended to be only an audit of the assessment undertaken for the EU. However we have found that a disappointing number of cases the clinical assessment evidence has been inadequate.
- **Small Australian market:** The Australian medical devices market is small, representing two to three percent of the global devices market.[10] This limits the feasibility of stand-alone regulatory arrangements in Australia; and so Australia chose to align its requirements with Europe when the Therapeutic Goods (Medical Devices) Regulations 2002 were implemented.
- **Alignment with Europe:** Existing Australian regulatory arrangements closely parallel those applying in Europe, with both systems aligned with the Global Harmonization Task Force (GHTF) framework.[11] Applications for marketing approval in Australia rely heavily on CE mark certification from European notified bodies (around 92% of all medical devices included on the Australian Register of Therapeutic Goods (ARTG) relying on such certification). Europe represents a much larger market, comprising around one third of the global medical devices market[12] (with the USA comprising a further 40% of the global devices market).
- **Changes in the European regulatory system:** The European regulatory system exclusively uses notified bodies, and not regulators, for medical device assessment. In recent years a number of concerns emerged about the performance of notified bodies in regards to medical device assessment, and changes to the regulatory framework have been underway over the past few years. While some changes continue to await regulatory amendments, the Europeans have also been undertaking improvements in oversight of notified bodies.[13]
  - In 2013 the European Commission commenced a program of voluntary joint assessments of notified bodies designated under the medical devices directives, which are expected to become mandatory when the revised regulatory framework is in place.
  - Over this period there has been a significant decrease in the number of notified bodies: de-designation of some and scope restrictions of others.

[10] MTAA estimates the value of the medical technology industry in Australia at AUS$10b (2012), against an estimated global market value of US$325b (2011) (http://www.mtaa.org.au/about-the-industry/industry-statistics).
[11] The GHTF was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. The GHTF was replaced by the International Medical Device Regulators Forum (IMDRF) in 2011, which is continuing international collaboration on global regulatory harmonisation.
[12] http://www.emergogroup.com/resources/market-europe
[13] For example, *Joint Assessments of medical devices Notified Bodies by Member States and Commission Experts* http://www.nbog.eu/resources/130827_NBOG_Coordination_Group_Summary_Joint_Assessment_Programme.pdf

  - Feedback from industry indicates that these changes have resulted in longer assessment timeframes and more extensive information requests from notified bodies (especially in relation to clinical evidence).

- **MDSAP:** The Medical Device Single Audit Program (MDSAP) is currently being piloted,[14] and is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of Quality Management System (QMS) requirements that apply to a medical device manufacturer in order to satisfy the relevant QMS requirements of the medical device regulatory authorities participating in the pilot program (Australia, Brazil, Canada, Japan and the USA).[15] Health Canada has committed to transition to MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements under their regulatory framework[16] by 1 January 2019. Consequently, Canadian Medical Devices Conformity Assessment System (CMDCAS) Registrars are MDSAP pilot participants. Following a successful pilot, the TGA is proposing to use MDSAP reports to provide evidence of compliance with the QMS requirements of the relevant conformity assessment procedures.

Issues to consider

- **Public health:** The TGA seeks to protect public health by ensuring that therapeutic goods available for supply in Australia, including medical devices, are safe and fit for their intended purpose. It is important that proposed changes maintain necessary public health protections.

  Of the International Medical Device Regulator Forum (IMDRF) members (Australia, Brazil, Canada, China, European Union, Japan and Russia) only the Europeans fully outsource medical device assessment, including high risk devices, for market approval.[17] Some IMDRF members utilise third party assessments for low-medium risk devices. The TGA accepts European notified body certification for low risk devices, without a requirement for mandatory application audit.

- **Industry development:** Designation of Australian conformity assessment bodies provides for the establishment of a potential new industry in Australia. However, conformity assessment of medical devices, especially high risk medical devices including implants, is a very complex process requiring significant levels of expertise and a collaborative approach between relevant areas when assessing a device. Assessment bodies should have the relevant expertise in house, and while this expertise is in short supply in Australia, larger pool of expertise would be available to l notified bodies that work globally.

- **Viability:** Impacts of designating conformity assessment bodies within the sector include:

  - Applicants whose devices are subject to mandatory application audit may seek certification from a TGA designated third party in order to expedite the time taken for an

[14] The pilot runs for three years (2014-2016) – for more details see http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/

[15] Regulators in the USA, Canada, Brazil, Japan and Australia are participating in the MDSAP pilot. The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union are Official Observers

[16] See Health Canada *Notice: Transition Plan for Medical Device Single Audit Program (MDSAP)* at http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/mdsap-trans-notice-avis-eng.php

[17] The use of third party conformity assessment bodies can result in different regulatory outcomes increasing risk for consumers in some jurisdictions. For example: Thomas J Hwang et al, *Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study*, BMJ 2016;353:i3323; *Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US*, May 2012, document produced by the FDA, *Notified Bodies, Are they fit for purpose*, BMJ 2012:345:e7177.

ARTG application for inclusion. This would be an attractive option if the designated third party assessment times were more expeditious than TGA mandatory application audit times; and the cost for certification was in line with the costs for application audit (sales during the otherwise audit delayed period could offset a higher certification fee).

- TGA currently receives around 300 applications requiring mandatory application audit per year. This would be the potential scale of work that would be undertaken by TGA designated third party conformity assessment bodies. To carry out this work there is a need for an extensive breadth and depth of clinical and technical expertise.
- Given the need for extensive clinical and technical expertise and economies of scale the most likely candidates to be attracted to enter the Australian market are those organisations already undertaking conformity assessment certification in this area, such as European notified bodies.

· **Capacity: Development of a new certification process in Australia will be influenced by:**

- *The availability of expertise in bodies undertaking conformity assessment certification*: Two technical experts are typically required for each discipline required to undertake an assessment, to ensure that decision makers are not reviewing their own work. At least one of these resources are typically required to be in-house under both European notified body designation procedures and MDSAP recognition requirements to enable appropriate oversight of work and avoid conflicts.[18] A minimum of two experts provide for appropriate technical oversight of technical assessments.
- Specialised expertise will also be required by the TGA as the designation authority to allow effective oversight of certification bodies conducting assessment of high risk medical devices.

· **Funding the Designation of Australian Notified Bodies:** TGA operations are fully cost recovered from industry. The cost recovery of TGA operations in designating third parties and the ongoing monitoring and oversight of these certification bodies may include:

- TGA charging certification bodies directly for designation activities, or
- funding the regulatory overhead cost from the annual charges currently applicable to ARTG entries.

Commercially based cost recovery is expected to be used by the designated authorities established under this pathway. Conformity assessment certification costs (assessment and audit fees etc.) would be a commercial matter between the Australian certification body and their client, as is the case for European notified bodies, introducing competition for these costs.

[18] For example, NBOG, *Designating Authorities Handbook*, Assessment of applicant's proposed use of subcontractors (pp 29-30 – 4.13) notes that notified bodies must have sufficient in-house expertise to assess the expertise and control the work of sub-contractors, and may not subcontract the final decision to issue a certificate of conformity. IMDRF *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition* outlines the MDSAP requirement for independent review and approval of work (p12 - 6.1.7) and that those personnel responsible for final review and decision-making are employees (p14 – 7.2.1)

Scope

- Should designated Australian conformity assessment bodies (subject to capability etc.) be able to provide conformity assessment certification for all medical device applications? Should some device types or classes continue to be required to hold TGA conformity assessment certification?
- Does your organisation market devices to countries relying on 'home market' regulatory approval? How would this proposal impact on this?

Context

- Are there other key issues which should be considered in developing this proposal?

Designating authority[19]

Roles and responsibilities

As the designating authority, TGA would have four main responsibilities:

- **Designate:** Ensure that certification bodies applying for designation meet the Australian regulatory requirements. This will require that the applicant certification bodies:
  - to have the necessary technical, scientific and medical competence and facilities to carry out the conformity assessment certifications for the particular conformity assessment procedures, dictated by device classifications, the certification body is seeking authorisation to certify under Australian regulations
  - can demonstrate the necessary levels of independence, impartiality and integrity to be acting on behalf of government within the regulatory scheme.
- **Monitor:** Ensure that designated certification bodies continue to comply with Australian regulatory requirements, through regular and structured surveillance of their activities.
- **Control:** Act on the findings of monitoring assessments of certification bodies, including:
  - communicating to the certification body the details of any concerns about its performance
  - on the basis of these concerns agree or impose actions (such as supervision of activities including additional reporting, recruitment of specific expertise, etc.) for the certification body to address the concerns and monitor compliance with those agreed actions
  - where necessary, adjust the scope of the designation for the certification body (i.e. no new clients, lower risk devices only, etc.) or de-designate the body
  - exercise enforcement powers where appropriate (such as civil or criminal penalties, etc.)
- **Maintain:** In addition the designating authority may also be required to:
  - assist in maintaining the regulatory framework, including participation in international forums, input to regulatory improvements, etc.
  - comply with relevant sector standards and guidance available for accreditation bodies (such as ISO/IEC 17011:2004).

Composition

In order to undertake its function, the TGA as the designating authority will need to be appropriately resourced, particularly in having suitably trained and experienced staff to execute its responsibilities.

Key personnel will be the designation assessors. A sufficient number of assessors would be required to provide diversity of expertise and experience, flexibility in scheduling, ensure backup, oversight and professional support, avoid regulatory capture through overfamiliarity

[19] Note that this section was informed by the Notified Body Operations Group (NBOG) *Designating Authorities Handbook*, reflecting existing European arrangements (available at http://www.nbog.eu/2.html).

and management of any actual or perceived conflicts of interest (such as prior work history with particular organisations).

The skills and training of designation assessors will also be critical, with required skills and expertise to include but not be limited to:

- Comprehensive knowledge of the regulatory framework for medical devices in Australia.
- Detailed understanding of the designation process and regulatory framework established for this purpose in Australia.
- Expertise in third party oversight including audit skills.
- Demonstrated impartiality and integrity.
- Knowledge and experience of medical device (including AIMDs and IVDs) manufacturing and familiarity with relevant standards, to enable the assessors to conduct meaningful, thorough and appropriate assessment against specified criteria.

Accessing the required range of expertise and experience through TGA's in-house assessors may be difficult, and some contracting for particular expertise may be required on occasion to balance workloads and expertise requirements.

Structure

TGA will continue to conduct conformity assessments in response to applications received, to ensure ongoing availability of a full scope of conformity assessment capability to the industry.

TGA's regulatory role and responsibility will be expanded to include those of a designating authority.

Cost recovery

TGA operations are cost recovered from industry, and it is expected that the costs of the new designation function would also be cost recovered. For existing TGA operations assessment and evaluation costs are recovered as fees from applicants (based on the cost of the assessment function) while post market monitoring and surveillance are recovered as a cost recovery levy, in the form of annual charges.

Under the Australian Government Cost Recovery Guidelines key considerations in assessing the form of cost recovery include the nature of the activity, who might be charged, impact on competition, innovation and financial viability of those paying the charges, efficiency, and impacts on policy outcomes, other governments policies and Australia's international treaty obligations.

The identifiable beneficiaries of the designation activity would be the conformity assessment bodies, in that through designation they will be able to offer (and charge for) government recognised certification functions. However it may be that the overhead costs (TGA staffing and operational costs), apportioned across a small number of applicants, mean seeking designation as a certification body would not be cost effective. In setting designation fees consideration will need to be given to alternative cost recovery avenues.

Competitive neutrality

Compliance with the Commonwealth's competitive neutrality requirements will impact aspects of TGA's new designation role. Administrative separation of TGA's designation and conformity assessment functions will ensure competitive neutrality, so as not to provide TGA's conformity assessment operations with actual or perceived access to 'insider' knowledge of the business processes and intellectual property of their competitor conformity assessment bodies.

Competitive neutrality requires that government business activities should not enjoy net competitive advantages over their private sector competitors simply by virtue of public sector ownership.[20]

TGA conformity assessments are currently delivered under cost recovery arrangements. Additional competitive neutrality requirements would additionally apply where TGA certifications are being offered in competition with private suppliers. These relate to taxation, debt and regulatory neutrality, rate of return and full cost pricing principles.

Cost recovery

- Should the costs of designation be recovered directly as fees from conformity assessment bodies, or is it appropriate that some or all costs be recovered through other mechanisms such as charge on all medical device sponsors?

Competitive neutrality

- Are there other competitive neutrality concerns for the Designating Authority function that you can identify?

[20] Commonwealth Competitive Neutrality Policy Statement, June 1996, p4 (http://archive.treasury.gov.au/contentitem.asp?ContentID=275&NavID=020)

Conformity assessment bodies

Roles and responsibilities

- **Issue conformity assessment certification:** Following appropriate audit and review of a manufacturer's conformity assessment procedures, for some or all conformity assessment streams under the Therapeutic Goods (Medical Devices) Regulations 2002 (Regulations), Schedule 3:
  - Full quality assurance procedures (Regulations, Schedule 3, Part 1)
  - Design examination for high risk medical devices (Regulations, Schedule 3, Part 1.6)
  - Type examination procedures (Regulations, Schedule 3, Part 2) – may be excluded as this conformity assessment route is rarely used in practice
  - Verification procedures (Regulations, Schedule 3, Part 3)
  - Production quality assurance procedures (Regulations, Schedule 3, Part 4)
  - Product quality assurance procedures (Regulations, Schedule 3, Part 5)
  - Declaration of conformity procedures (Regulations, Schedule 3, Part 6)
  - Clinical evaluation procedures (Regulations, Schedule 3, Part 8)

  Designation for individual conformity assessment bodies would be based on the scope of the application from the potential conformity assessment body, and assessed based on demonstrated competence and facilities of the organisation.[21] Designation may be limited based on the class or type of medical device being assessment (for example restricted to assessment of Class IIb and lower, medical devices not including IVDs, or restricted to only cardiac devices but including high risk devices within that scope).
- **Monitor and maintain conformity assessment certification:** Conformity assessment procedures must be maintained over time, and any substantial changes must be notified to the certification body. The certification body is responsible for ensuring ongoing compliance (such as through regular, including unannounced, site audits) and assessing substantial changes and amending, reissuing or revoking certificates.
- **Out of scope:**
  - ***In-house IVDs:*** Consideration will also be required on whether conformity assessment procedures applying to in-house IVD medical devices would also be in scope for certification bodies. Current regulatory arrangements (under Regulations, Schedule 3, Part 6A) require laboratories manufacturing Class 1-3 in-house IVD medical devices to be accredited as a testing laboratory by the National Association of Testing Authorities (NATA). Laboratories manufacturing Class 4 in-house IVDs have the choice of obtaining TGA conformity assessment certification prior to applying for inclusion in the ARTG or leveraging off their NATA accreditation or TGA Good Manufacturing Practice licence for

[21] For example, as outlined in NBOG's Best Practice Guide 2009-3, Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessments (available online at http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf) and NBOG's Best Practice Guide 2014-2, Guidance on the Information Required for Notified Body Medical Device Personnel Involved in Conformity Assessment Activities (available online at http://www.nbog.eu/resources/NBOG_BPG_2014_2.pdf)

the purpose of submitting an application for inclusion. However as the in-house IVD regulatory framework has not been fully implemented it is suggested that consideration of including these arrangements be deferred until after the transition period ends on30 June 2017.

Requirements

There are a range of requirements which certification bodies will need to meet to support designation (explored further under the 'designation processes below). These are based on European requirements for notified bodies (as outlined in NBOG's Best Practice Guides) and/or MDSAP requirements. Requirements include:

- **Structure and legal status:** having an Australian legal presence and being a 'fit and proper' organisation.
- **Independence and impartiality:** demonstrated capacity to manage conflicts of interests and probity, such as where there is a commercial link between the Conformity Assessment body and manufacturer.
- **Competence and capacity:** personnel (in-house and sub-contracted) with skills and experience to perform the conformity assessment function and access to appropriate facilities to support the role.
- **Internal processes:** capability to manage confidentiality, having an appropriate quality system in place, and management of liability (insurance).

Market potential

Issues to be considered when assessing organisations as potential conformity assessment bodies under the Australian regulatory framework include:

- **Transfers from existing European certification:** Where conformity assessment bodies are also European notified bodies, they may secure certification work from manufacturers currently relying on European conformity assessment certification for Australian market authorisation. The scope of any shift is uncertain but may occur if conformity assessment bodies are also designated to provide conformity assessment certification in other larger markets and are able to leverage from that activity (e.g. European notified bodies issuing conformity assessment certification in both Europe and Australia, using shared work products). Transferring to using Australian conformity assessment bodies for certification would avoid the cost and delay of mandatory ARTG inclusion application audits.
- **No guaranteed market share:** Certification bodies would have no guarantee of market share. Where there are a variety of providers it is necessary that any decision about an appropriate conformity assessment body rest with the manufacturer, given the invasive nature of the conformity assessment certification process and the need for an ongoing, co-operative working relationship.

It is anticipated that the Australia conformity assessment certification market would be open to any suitable participants based on an application process, and no tender process would be conducted.

TGA conformity assessment function

- TGA would continue to offer a full suite of conformity assessment functions. Is this important to you or your organisation?

Possibly interested bodies

- Do you or your organisation have an interest in seeking designation as a conformity assessment body? What are the issues which would affect your decision to apply for designation?

Designation process

Designation framework

Given the alignment of existing Australian regulatory framework with the GHTF/IMDRF regulatory model two options are considered:

- **MDSAP:** Australia is one of five regulators developing MDSAP. The MDSAP designation process is in place for the pilot, with both assessment criteria and the assessment process in place. This also provides an avenue to implement MDSAP in Australia. There are a couple of limitations however in just using the MDSAP process for Australia:
  - ***Limited to QMS assessment:*** The existing MDSAP process covers only the assessment of manufacturers' quality management system and related regulatory requirements (e.g. recalls processes, etc. for each participating jurisdiction). MDSAP does not cover the assessment of medical device compliance with the essential principles and hence does not cover any of the following:
    - Design examination for high risk medical devices (Regulations, Schedule 3, Part 1.6)
    - Type examination procedures (Regulations, Schedule 3, Part 2)
    - Verification procedures (Regulations, Schedule 3, Part 3)
    - Clinical evaluation procedures (Regulations, Schedule 3, Part 8)
- As MDSAP only covers manufacturers' evidence for the QMS requirements of the Australian conformity assessment procedures a designation framework for the assessment of medical device compliance with the essential principles would need to be developed. IMDRF has established a working group for the competence required to undertake such assessment.[22] However this work is in its early stages and itself is only one aspect of a framework that would be required for a rigorous product assessment program that would require objective outcome criteria, processes, competence requirements and defined outputs.

  Adopting the MDSAP designation framework for third parties has a number of advantages – it has the scope to operate globally with at least partial (i.e. QMS level) recognition of third party certification bodies by Australia already built in, so promotes not only global harmonisation, but convergence (i.e. a single process, rather than simply an aligned process).

  The European Commission is also interested in MDSAP and has joined as an official observer.
- **European designation framework:** There is also the option to adopt the current European designation framework (as outlined in NBOG guides, etc.[23]), which is fully operational across the scope of medical devices[24] (although there is significant difference in relation to IVDs). The European system would be relatively straightforward to adopt in Australia, given the close parallels in European and Australian regulatory arrangements. There are some issues to consider:

[22] The Good Regulatory Review Practices - Competence and Training Requirements for Pre-market Reviewers working group has been tasked to take the MDSAP "Competence and Training Requirements for Auditing Organizations" document and mimic it in order to fill in the void of defined competence and training needs for personnel that perform premarket reviews/assessments of the technical documentation/design dossier.
[23] NBOG are the Notified Body Operations Group, consisting of the European Commission, and nominees from the Member States Designating/Competent Authorities. For further information see www.nbog.eu
[24] i.e. covers all of Medical Devices Regulations Schedule 3 – Conformity Assessment Procedures

- ***European reforms:*** The current European medical device directives are under review, and they are also implementing improved supervision of notified bodies. The reform process has been underway since 2012, but revised directives are still under negotiation in the European Parliament. They are expected to be passed in 2016, and may include further transitions periods before coming fully into operation.

- ***Global harmonisation versus convergence:*** While adopting the European designation framework would result in harmonisation, it should be noted that Australian issued conformity assessment certificates would still not be accepted for market authorisation in Europe. It is not clear whether Europe might recognise Australian designated certification bodies as notified bodies for European purposes under the MRA (e.g. able to issue CE certificates under European requirements). Advice is needed on whether this is possible under the MRA Sectoral Annex on Medical Devices.[25] MDSAP has the advantage that the Europeans are also considering how MDSAP might be incorporated into the European framework; however this work is in its early stages.

It should be noted that MDSAP and European designation processes, while not identical, are quite similar, and IMDRF work is ongoing to achieve greater harmonisation (and possibly convergence in the MDSAP context). Movement towards Australian designation of certification bodies at this time is likely to use a hybrid of these two systems, with refinement as the MDSAP matures (for QMS assessments).

Designation criteria

Irrespective of the framework decided upon, the designation criteria as outlined in both NBOG and MDSAP documents are similar. These criteria would be expected to cover:

- **Structure and legal status**:

  - ***Australian legal presence*:** The certification body will need to be subject to the Australian legislative and judicial framework. This would include Australian incorporation, indemnity insurance etc.

  - ***Corporate structures*:** It is possible a range of certification body functions may be undertaken by other corporate arms of global organisations for example, an Australian incorporated body may be the certification body but key functions may be undertaken by a UK- based parent company. Consideration is required on how the designating authority will have appropriate oversight of such 'critical locations', appropriate or preferred legal relationships, etc.

  - ***'Fit and proper' organisation*:** The certification body would be ineligible if it has been found guilty of an offence against related laws or regulations (or at least serious offences), or relating to fraudulent or dishonest practices.

- **Independence and impartiality:**

  - ***Conflicts:*** Need to ensure that the certification body, and the personnel it uses, have no conflict of interest with manufacturers (e.g. financial or based on consultancy) which could prevent, or be thought to prevent, the NB conducting a thorough, honest and impartial audit of the medical device manufacturer's activities.

[25] The MRA is available online at: http://www.austlii.edu.au/au/other/dfat/treaties/1999/2.html, and the amendments which came into effect from 1 January 2013 at: http://www.austlii.edu.au/au/other/dfat/treaties/ATS/2013/2.html

- ***Probity:*** There is also a need to ensure certification body audits and decisions are not affected by any improper pressure or inducements, particularly financial.

- **Competence and capacity:**

  - ***Personnel:*** The personnel employed by the certification body – especially those used as auditors – need to have appropriate skills, experience and training. They need not be based in Australia. This applies both at the individual and organisational level:

    - Individual employees will need to hold appropriate technical qualifications, substantial relevant experience, knowledge of various technical and regulatory issues, and skills on issues such as assessment processes and risk management.

    - At an organisational level the certification body will need access to a diversity of employees to ensure access to the diverse range of skills, experience, training and technical competence which may be needed for any assessment in scope for their organisation (e.g. if designated to assess IVD medical devices, specialist IVD experience and knowledge would be required). This will include the capacity for appropriate technical supervision of employees.

    - These requirements must be specific to the scope of the designation – without appropriate technical expertise the capacity to certify should not be granted (e.g. medical specialities such as orthopaedics, cardiac, IVDs, etc., or process specialities such as sterilisation, software, etc.).[26]

  - ***Facilities:*** In addition to competent employees, appropriate facilities will also be required for the certification body to carry out the relevant tasks for which it is designated. Again these need not be based in Australia, but would need to be accessible to the designating authority for verification.

  - ***Subcontracting:*** It may not always be possible to have personnel with the full range of required competencies in house. However where specific functions are outsourced governance arrangements will need to be determined (documented contracts or agreements, audit trails, management of potential conflicts, etc.). It may be inappropriate to outsource some functions.

- **Internal processes:**

  - ***Confidentiality:*** The certification body and its staff will be required to respect the confidentiality of any information obtained as a result of carrying out their tasks. In additional to being important to the individual organisation, this is also critical to providing assurance in the certification system, particularly given that certification bodies will have access to commercial-in-confidence intellectual property.

  - ***Quality system:*** It is appropriate to require the certification body to have an appropriate internal quality system to cover their operations. The requirements identify the areas that the system has to cover including document control and ensuring that it is being effectively implemented.

  - ***Liability:*** Consideration needs to be given on whether certification bodies should have mandatory liability insurance. Given it is anticipated that many Australian conformity assessment bodies may be the Australian arm of international organisations (such as European notified bodies and MDSAP auditing organisations) this may be particularly

[26] For example, as outlined in NBOD's Best Practice Guide, *Guidance on the Information Required for Notified Body Medical Device Personnel Involved in Conformity Assessment Activities,* available online at http://www.nbog.eu/resources/NBOG_BPG_2014_2.pdf

important to ensure the Australian legal entity is practically as well as legally responsible for its Australian operations.

Designation framework

- Should the designation framework be aligned to MDSAP requirements, European requirements or a hybrid?
- Should particular aspects of each system be adopted for a hybrid approach?
- How might alignment to the MDSAP and/or European framework be managed as international regulatory convergence develops?

Designation criteria

- Are the listed criteria appropriate and comprehensive?
- Are there particular issues which should be considered in developing these criteria for the regulatory framework?

Implementation

Legislative amendments

Legislative amendment to the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Charges) Act 1989* are expected to be necessary to implement these changes. The changes will establish the framework for TGA designation of certifying bodies (including establishment of the powers of the designating authority), the use of certification to support market authorisation in Australia and charging of designation fees.

It is expected that legislative change would be minimal, primarily providing for the Minister to make regulations for designating conformity assessment bodies.

A Cost Recovery Impact Statement (CRIS) will be required to support fees and charges arising from these changes. Regulatory amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 will be required. Amendment to the Therapeutic Goods (Charges) Regulations 1990 is also likely to be necessary.

Based on the outcome of this consultation and the passage of legislation, the regulatory amendments will be developed during 2017, for a scheduled 1 January 2018 commencement.

Following implementation consultation, a timetable for regulatory amendments will be published on the TGA website.

Operational arrangements

Policy, procedures, guidance and operational supports (information technology, etc.) to support the operation of the new designation function will be prepared.

Based on the outcomes of this consultation, these would be developed throughout 2017, to be in place in anticipation of the scheduled 1 January 2018 commencement.

Overall

- In addition to any feedback on specific aspects of the proposed approach to designation of Australian conformity assessment bodies, we are also interested in broader comments on the proposal.
- Comments might take into consideration the context for change and issues to consider outlined in the introduction, and consider the risks and benefits of this proposal and how these might be managed.

Version history

Version	Description of change	Author	Effective date
V1.0	DRAFT	Business Improvement and Support Section, Medical Devices Branch	November 2016

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Reference/Publication #