Australian Government
Department of Health
Therapeutic Goods Administration

Pre-market regulatory

Processes for TGA approval and market access in Australia

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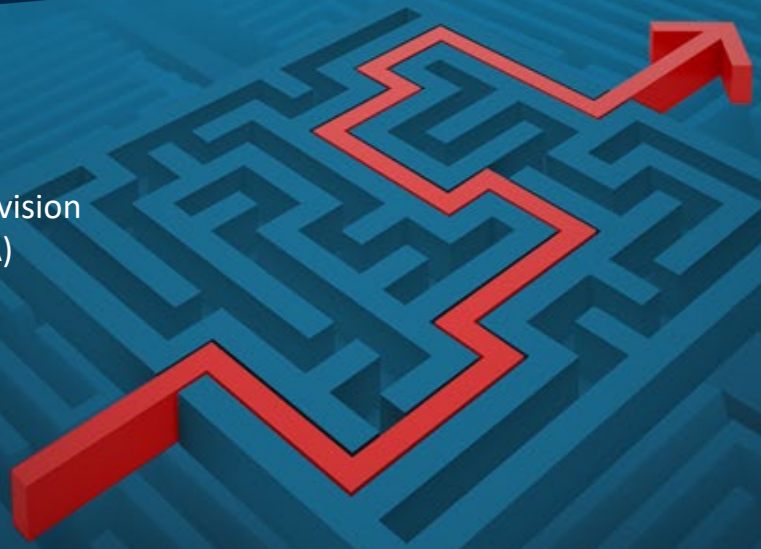


TGA Health Safety Regulation

Session 3

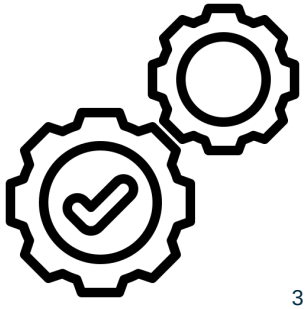
Manufacturer Evidence
and
Leveraging comparable overseas regulator approvals for TGA applications

Manufacturer Evidence (ME)

- *Manufacturer Evidence* refers to a manufacturer's *Conformity Assessment Document,* and is the pre-requisite to submitting an application for inclusion in the Australian Register of Therapeutic Goods (ARTG)

- The *Conformity Assessment Document* is a document that demonstrates an independent assessment of the manufacturer's quality management system (3rd party or regulator)

- Unless: Manufacturer's declaration of conformity made under Clause 7.5 (Systems or Procedure Packs)



Manufacturer Evidence

- *A Conformity Assessment Document* can be
  a) a conformity assessment certificate or
  b) an Australian conformity assessment body certificate or
  c) an overseas regulator conformity assessment document
  (Therapeutic Goods Act 1989, section 3)

- The Act sets out the conformity assessment procedures or comparable procedures and the requirements relating to the application of ***Quality Management Systems*** for medical devices and other requirements imposed on manufacturers, specifically in relation to the design and production of medical devices.

Manufacturer Evidence

- A Manufacturer Evidence application must be submitted in TBS and accepted by the TGA before you can commence an application for any medical device or IVD medical device other than:
  - Class I non-sterile / non-measuring
  - Class I IVD
  - Class I export only
  - Class I IVD export only
  - Class I (non-sterile, non-measuring) system or procedure pack
  - Class 1 IVD system or procedure pack

  - In these cases a declaration of conformity is required.
    - Guidance available on the TGA website

Acceptable conformity assessment documents (non-exhaustive list)

TGA conformity assessment certificate	Declarations of conformity made under Clause 7.5 of Schedule 3 (systems or procedure packs)
Certificates issued by Notified Bodies designated by the medical device regulators of European union member states, under the medical device regulatory frameworks of the European Union (Medical devices directives, IVD Directive, Medical Device Regulation, or IVD Regulation	
Approvals and licences issued by Health Canada	Decisions of the United States Food and Drug Administration (FDA)
Certificates and reports issued under the Medical Device Single Audit Program (MDSAP)*.	Pre-market approvals from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA) or Registered Certified Body
ISO 13485:2016 certificates issued by a certification body that is also a Notified Body designated under the IVDD 98/79/EC (for IVD inclusion applications only until 26 May 2022)	ISO 13485:2016 certificates issued by a body that is an accredited body that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA) (for IVD inclusion applications only until 26 May 2022).

Overseas evidence considerations

- The documentation should be issued by an overseas regulator or assessment body for the same medical device you are applying to have included in the ARTG. The device must:
  - have the same design and intended purpose
  - be intended for the same indications.

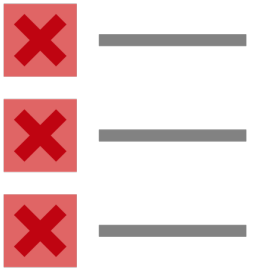
- Important that you Refer to Table 2 in the guidance document or the determination which outlines the evidence requirements for each classification.
  - *Therapeutic Goods (Overseas Regulators) Determination 2018*
  - *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

Example

- For example a **Class IIa** device can utilise CA evidence from (summarised)
  - TGA conformity assessment
  - Certificate issued under:
    - EU MDD 93/42/EEC
    - EU MDR
  - Japanese QMS certificate
  - MDSAP certificate (Japanese, Health Canada, USFDA)

Documents that are unacceptable as Manufacturer Evidence

- *Conformity assessment document* issued as the evidence of product assessment
  - EC MDD Annex II.4 Design Examination Certificate
  - EC Annex III Type Examination Certificate
  - MDR and IVDR: *Technical Documentation certificate*
  - Health Canada product licence
  - FDA: De Novo Decision Summary, 510(k) – Summary
  - Japan - Pre-market certificate



- Declaration of Conformity (except Declaration made under Clause 7.5 of Schedule 3) used for Procedure Packs

- **However, some of this information must be supplied as evidence of product assessment**

Overseas evidence considerations – evidence of product assessment

The comparable overseas regulator determination also defines the additional evidence of ‘Product assessment’ that is required for corresponding conformity assessment pathways.

- Using the previous slide example a **Class IIa** device has the following evidence of product assessment options available (summarised):
    - EU MDR – Assessment of Technical Documentation
    - Japanese Pre-market certificate
    - Health Canada Class II licence
    - US FDA De Novo Decision Summary or 510(k) Summary

Example from the Guidance

Class IIa (Regulation 3.8)

Regulators / Approvals	Manufacturer Evidence (QMS Certificate)	Documentation that must be provided with the application (Evidence of product assessment)
TGA CAC - MD Regulations Schedule 3[4]	• Part 1 - Full Quality Assurance (excluding clause 1.6 Design Examination), or • Part 3 - Verification (**for non-sterile devices**), or • Part 4 - Production Quality Assurance, or • Part 5 - Product Quality Assurance (**for non-sterile devices**)	N/A
EU EU MDD 93/42/EEC[5]	• Annex II.3, or • Annex IV (**for non-sterile devices** where specific batches are included on the certificate), or • Annex V, or • Annex VI (**for non-sterile devices**)	N/A
EU EU 90/385/EEC (AIMDD) for AIMD[6]	• Annex 2.3, or • Annex 4 (for non-sterile devices where specific batches are included on the certificate), or • Annex 5	N/A
EU EU MDR[7]	Annex IX, Chapter I (QMS) and III	Section 4, Annex IX (Assessment of Technical Documentation)
	Annexes II and III	Section 10 or Section 18 of Annex XI (one representative device per category)
Japan Ministry of Health, Labour and Welfare (MHLW)/PMDA	• QMS certificate, or • MDSAP Certificate	Pre-market certificate
Health Canada MDR SOR/98-282[8]	• MDSAP Certificate	Medical device licence Class II
FDA DeNovo	MDSAP Certificate	De Novo Decision Summary
FDA Premarket Notification - 510(k)	MDSAP Certificate	510(k) - Summary

Manufacturer Evidence - Steps

- Manufacturer Evidence Applications are submitted by the Sponsor through the eBS portal.
  - There is a step by step guidance on the TGA Website on How to Submit a new Manufacture's Evidence:

Manufacturer evidence for medical devices and IVD medical devices | Therapeutic Goods Administration (TGA)

Note: We aim to process Manufacturer Evidence applications within 15 working days.

Document Review

Information that must be included on the conformity assessment document:

- Manufacturers Name and Address
- Product Scope
- Conformity Assessment Procedure
- MDSAP certificates must be include reference to the Australian regulatory requirements
- Notified Body number/details
- Certificate number
- Certificate Issue date / Re-issue date / Expiry date

- If submitting a DOC (Declaration of conformity) all relevant fields must be answered and information provided.

Application details (Manufacturer Evidence - ME)

- You are required to input information to the application, obtained directly from the Conformity Assessment Document. Once the relevant fields have been filled and the relevant document attached the evidence can then be submitted.

Manufacturer name:
Manufacturer address as on certification:
Type of product:
Certificate issued under:
Conformity assessment procedure:
Source of certification:
Certificate number:
Certificate issue date: (dd/mm/yyyy)
Certificate expiry date: (dd/mm/yyyy)

Not acceptable

- Two or more documents attached that are not related or referenced in the specific ME document.
- Incomplete conformity assessment document provided (product list/ Annex missing; product identification page missing)
- Notified Body not accredited for the type of medical device?
- Documents related to product assessment attached
- Declaration of Conformity (except declaration made under Clause 7.5) attached
- The document provided is not in English
- The conformity assessment document has been altered including highlighting, white-out or adding additional products
  - The document needs to be in its original state and all details need to be shown on the certificate. A watermark is acceptable.

Accepted Evidence

Once Accepted:

- You will receive an automated email in your inbox in TBS advising that your ME has been accepted.

- You can view your accepted ME by selecting '*Your TGA information*' from the menu on the left in your portal, and then selecting *'Medical Device Evidence'*.

- The ME Identifier number is unique to your evidence and is required to complete an application for inclusion.

Rejected Manufacturer Evidence

- You will receive written notification outlining the reasons for the rejection.
- Please review the reason for rejection and ensure that any deficiencies outlined are rectified before you submit a new Manufacturer Evidence application.
- You can recommence the process of submitting Manufacturer Evidence at any time.

Questions

Session 4

TGA Applications

Best practice for a good submission

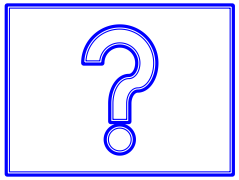
In this presentation

- Applications
- Procedure pack/kits
- Application audits
- Key documents
- Variation applications

Manufacturer Evidence

- ✓ACCEPTED
  - –What does it mean?

Go to the next step - lodging application for ARTG inclusion



Applications

- Forms
- Preliminary assessment
- Application review
  - Kind of device
  - Intended purpose
  - Unique Product Identifier
  - Variants
  - Functional description
- Global Medical Device Nomenclature (GMDN) codes

Application Form – Correct and Complete

- To ensure the application is processed efficiently it is the sponsors responsibility to ensure the information provided in the application aligns with the manufacturer's information (IFU; Label, DoC etc).

  For example for a Class III medical device application the intended purpose should be entered in the application as it is stated in the IFU.

- The correct evidence of Product assessment must be attached to the application.

- For a Class III application the Unique Product Identifier (UPI) must be able to identified in the document. If this is ambiguous the sponsor should attach a document outlining how the certificate supports the device in the application.

Application fees

- The medical device **application fee** must be paid prior to the commencement of TGA assessing the information provided in and with the application.

Preliminary assessment

- An application for ARTG inclusion must pass preliminary assessment to continue.
- To pass *preliminary assessment*, an application must meet the requirements in section 41FDB of the Therapeu*tic Goods Act 1989*
- The TGA will carry out an assessment of whether the requirements have been met for each application.
- Applications that do not pass preliminary assessment will be refused by the TGA.

Preliminary Assessment

- To pass *preliminary assessment*, an application must be:
  1. made in accordance with the form and manner approved for the **class of device** in the TGA application form
  2. accompanied by certain information of a kind (and in a form) prescribed for the class of device from comparable overseas regulatory bodies.
  3. The applicant has certified the matters in s41FD of the Act
  4. The prescribed fee for the class of medical device is paid

- An application that passes preliminary assessment will either proceed to the decision for the device to be included in the ARTG or for the application to be selected for audit.

Matters certified must be correct – s41FD

- medical device
- intended purpose
- correctly classified
- essential principles and availability of information to substantiate compliance
- application of conformity assessment procedure and availability of information
- requirements (if any) relating to advertising
- prohibited imports
- excluded purposes (for IVD only)
- information in or with the application is complete and correct

Therapeutic Goods Act 1989, section 41FD

Application review - Common questions

- Kind of device
- Intended purpose
- Classification
- Conformity assessment procedure
- GMDN code

Kind of device

a medical device is taken to be **of the same kind** as another medical device **if they have the same**:

- Sponsor
- Manufacturer
- Device nomenclature system code (GMDN)
- Classification
- Unique product identifier (UPI) (for Class III devices)

Therapeutic Goods Act 1989, section 41BE and *Therapeutic Goods (Medical Devices) Regulations 2002,* regulations 1.6 and 1.7

Unique Product Identifiers (UPIs)

- The Unique Product Identifier (UPI) is assigned by the manufacturer to uniquely identify the device and any of its variants.

Note - Ensure the UPI is consistent on QMS certificates, Labelling, IFU, advertising and other documents

Variants

- Variant means a medical device, the design of which has been varied to accommodate different patient anatomical requirements, for example, relating to the shape, size, length, volume, diameter or gauge of the device.

- Class III devices can have one or more variants associated with a single Australian Register of Therapeutic Goods (ARTG) entry.

Note - Demonstrate the variants are acceptable by provision of product assessment, technical documents or brochure

Intended purpose of a kind of device

- Means the purpose for which **the manufacturer** of the device **intends it to be used**, as stated in the information provided with the device (labelling, instructions for use, advertising material and technical documentation)
- **Intended purpose stated in the application** must be consistent with the purpose for which the manufacturer intends the devices of the kind to be used
  - 500 characters only (in the application)

Functional Descriptions

- A functional description is only required for **Class III medical devices**.
- The functional description should:
  - describe the operation of the medical device.
  - explain the technical function of the device with the specifications.
  - if applicable, it should include how the device interacts with other devices within a system and any special features which enable the device to serve its primary intended purpose.

Example - Cardiac radio-frequency ablation system catheter

Intended Purpose

Indicated for interruption of accessory atrioventricular conduction pathways associated with tachycardia for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia.

Functional Description

The device is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities. Its electrode segment is comprised of a radiopaque 4mm tip electrode and 3 ring electrodes. The electrodes record EGM signals for mapping electrical pathway behaviour, deliver radiofrequency energy for ablation, and deliver electrical stimulus for pacing. The tip electrode has an embedded temperature and a position sensor for magnetic tracking and navigation.

Choosing the right GMDN Term

- Find a suitable active GMDN Term to match the characteristics and intended purpose of your device. Obsolete terms cannot be used.

- If there are multiple GMDN Terms that could apply to a kind of device, choose the most appropriate GMDN Term for your device based on what type of device it is, and how it is intended to be used.

GMDN Agency

- Contact the GMDN Agency for assistance (https://www.gmdnagency.org/) if you cannot find a suitable GMDN Term to match the characteristics and intended purpose of your device.
- In some cases, a new GMDN Term may need to be developed.
- If you have sourced your GMDN Term from the GMDN Agency and it is significantly different from what is in TGA database you should:
  - use the applicable GMDN Term from the GMDN Agency list; and
  - send an email to devices@health.gov.au advising of the issue

Information provided in the application

- Do not provide information that is not relevant in the application, for example:
  - Declaration of conformity made under EU Medical Device Directive
  - Test reports

- Ensure ‘Device Product Characteristics’ section in the application is correctly filled in

Device Product Characteristics
Is the device, or any form of the device, supplied sterile:
Sterilisation Method:
Is the device intended to be invasive:
s the device, or any form of the device, intended for single use:
Is the device an active device:

Procedure packs

- Types of procedure packs
- ARTG entry
- Conformity assessment

Procedure pack/kits

- Two or more goods (including at least one medical device) are a system or procedure pack (SOPP) if all of the goods are

  (a) to be interconnected or combined for use in a medical or surgical procedure; or

  (b) packaged together for use in a medical or surgical procedure.

- SOPPs are medical devices in their own right and must be included in the ARTG.

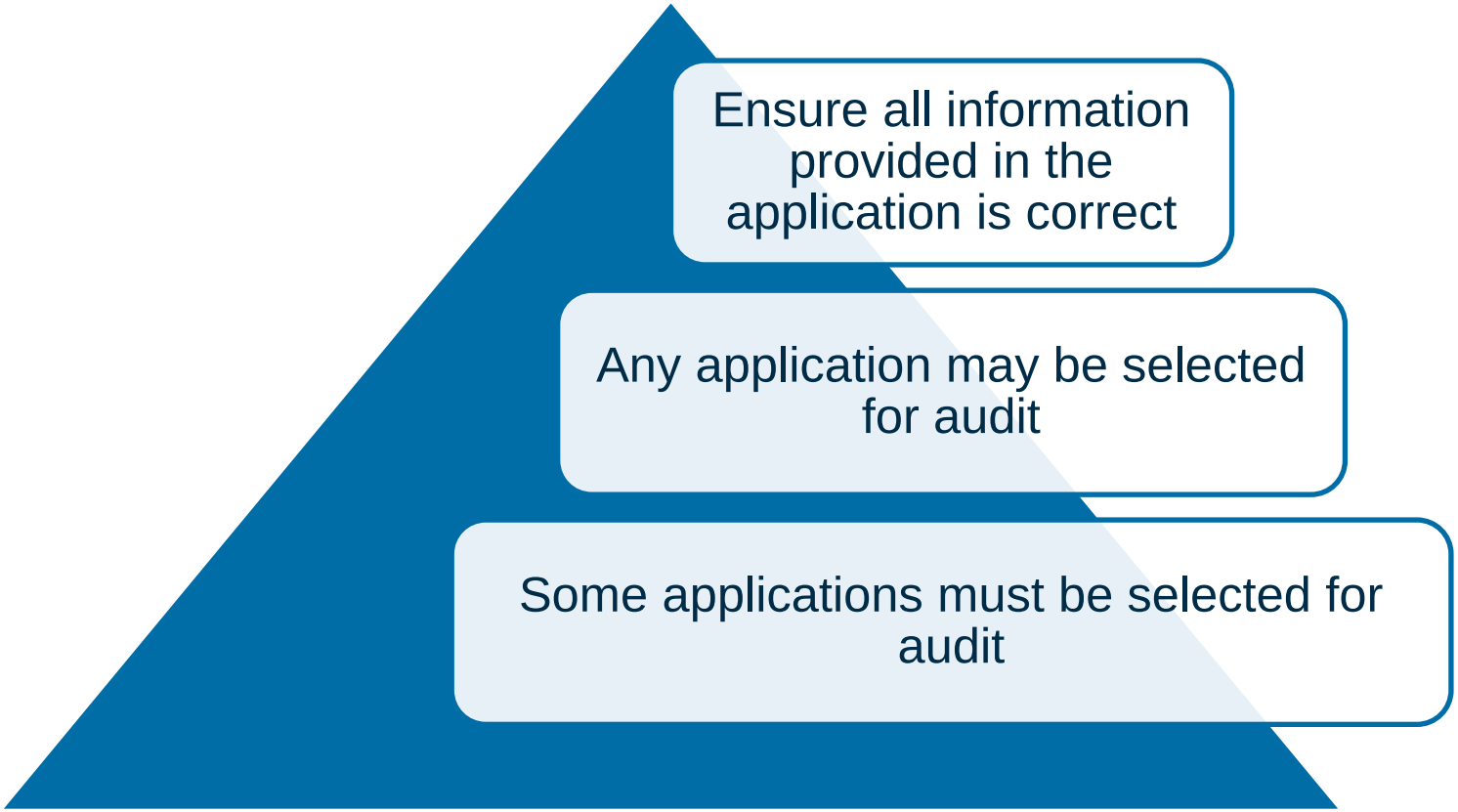
- If individual medical devices in the SOPP are also supplied separately from the SOPP, these devices must be included in the ARTG separately from the SOPP.

- The overall classification of the SOPP is based on the intended purpose and is determined by the medical device with the highest classification of those included in the SOPP.

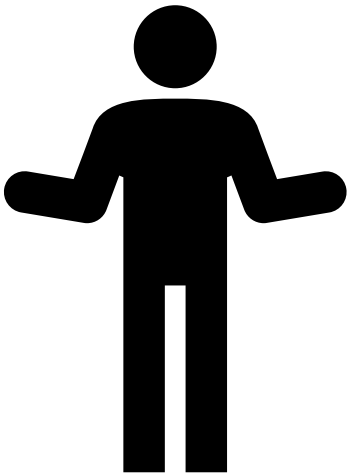
Conformity assessment of SOPPs

- For inclusion in the ARTG, manufacturers have two options to apply conformity assessment procedures to system or procedure packs.
- Option 1: The manufacturer of a system or procedure pack may obtain market authorisation evidence, issued by an independent assessment body or regulator for the system or procedure pack; or
- Option 2: use the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the 'Regulations') if they meet the eligibility criteria defined in Regulation 3.10.
- If the eligibility criteria described in Regulation 3.10 are met, the SOPP manufacturer can use the special conformity assessment procedure and make a declaration that complies with clause 7.5 of Schedule 3 of the Regulations. The declaration must cover certain information about the individual items placed in the SOPP, related documentation and the manufacturing process

Where do we go from here?



Questions so far?



Application Audits

- Mandatory Vs Non-mandatory
- Fees
- Audit Notice

Application Audits – Mandatory / Non-Mandatory

- Application audits are conducted to verify that devices submitted for inclusion in the ARTG meet the relevant legislative requirements.

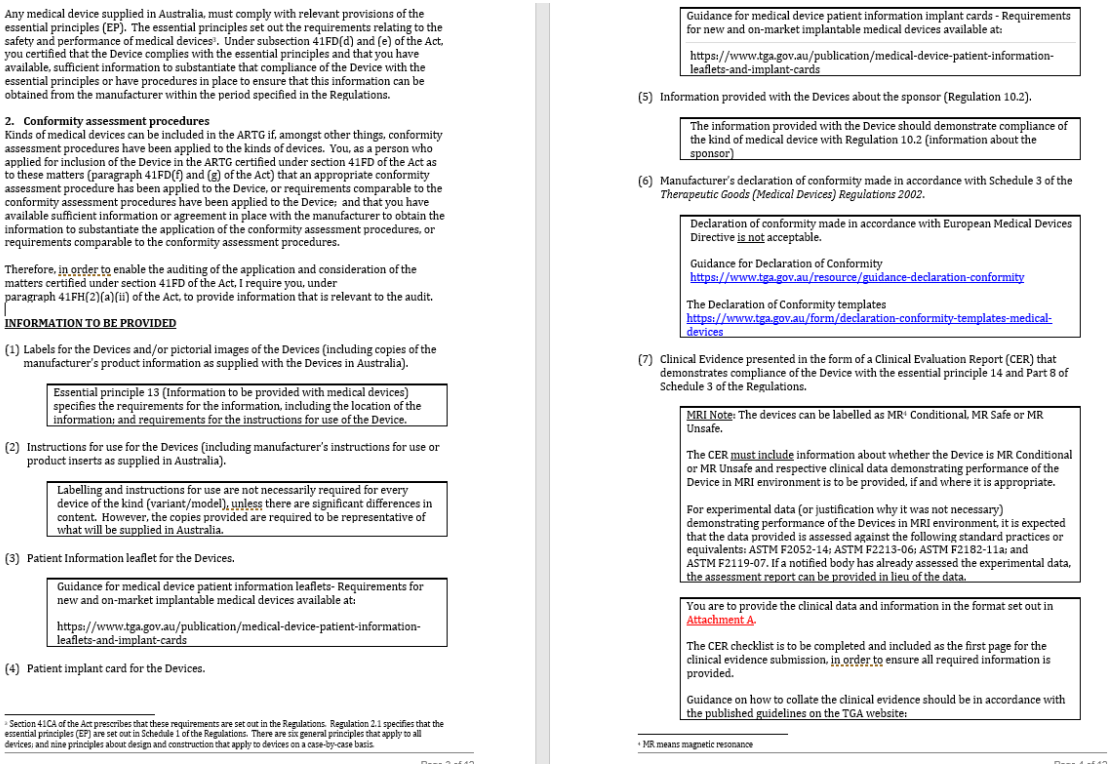
- For some applications, an audit is mandatory under the legislation. Others may be selected for auditing at the discretion of the delegate.

Application Audits - Fees

- Applications subject to mandatory audit under the legislation incur an audit assessment fee, which is additional to the application fee.
- Applications selected for audit at the discretion of the delegate, do not incur an audit assessment fee.
- If the application is selected for audit (Section 41FH), you will be notified within 20 days of paying the application fee and an invoice will be issued by the TGA.
- The audit fee is dependent on the level of audit assessment: Level 1 or Level 2.

Application Audit Notice

- TGA will send you a notice under s41FH of the Act notifying you of the audit. The letter will list the information requested.



Any medical device supplied in Australia, must comply with relevant provisions of the essential principles (EP). The essential principles set out the requirements relating to the safety and performance of medical devices[3]. Under subsection 41FD(d) and (e) of the Act, you certified that the Device complies with the essential principles and that you have available, sufficient information to substantiate that compliance of the Device with the essential principles or have procedures in place to ensure that this information can be obtained from the manufacturer within the period specified in the Regulations.

2. Conformity assessment procedures

Kinds of medical devices can be included in the ARTG if, amongst other things, conformity assessment procedures have been applied to the kinds of devices. You, as a person who applied for inclusion of the Device in the ARTG certified under section 41FD of the Act as to these matters (paragraph 41FD(f) and (g) of the Act) that an appropriate conformity assessment procedure has been applied to the Device, or requirements comparable to the conformity assessment procedures have been applied to the Device; and that you have available sufficient information or agreement in place with the manufacturer to obtain the information to substantiate the application of the conformity assessment procedures, or requirements comparable to the conformity assessment procedures.

Therefore, in order to enable the auditing of the application and consideration of the matters certified under section 41FD of the Act, I require you, under paragraph 41FH(2)(a)(ii) of the Act, to provide information that is relevant to the audit.

INFORMATION TO BE PROVIDED

(1) Labels for the Devices and/or pictorial images of the Devices (including copies of the manufacturer's product information as supplied with the Devices in Australia).

> Essential principle 13 (Information to be provided with medical devices) specifies the requirements for the information, including the location of the information; and requirements for the instructions for use of the Device.

(2) Instructions for use for the Devices (including manufacturer's instructions for use or product inserts as supplied in Australia).

> Labelling and instructions for use are not necessarily required for every device of the kind (variant/model), unless there are significant differences in content. However, the copies provided are required to be representative of what will be supplied in Australia.

(3) Patient Information leaflet for the Devices.

> Guidance for medical device patient information leaflets- Requirements for new and on-market implantable medical devices available at:
>
> https://www.tga.gov.au/publication/medical-device-patient-information-leaflets-and-implant-cards

(4) Patient implant card for the Devices.

> Guidance for medical device patient information implant cards - Requirements for new and on-market implantable medical devices available at:
>
> https://www.tga.gov.au/publication/medical-device-patient-information-leaflets-and-implant-cards

(5) Information provided with the Devices about the sponsor (Regulation 10.2).

> The information provided with the Device should demonstrate compliance of the kind of medical device with Regulation 10.2 (information about the sponsor)

(6) Manufacturer's declaration of conformity made in accordance with Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

> Declaration of conformity made in accordance with European Medical Devices Directive is not acceptable.
>
> Guidance for Declaration of Conformity
> https://www.tga.gov.au/resource/guidance-declaration-conformity
>
> The Declaration of Conformity templates
> https://www.tga.gov.au/form/declaration-conformity-templates-medical-devices

(7) Clinical Evidence presented in the form of a Clinical Evaluation Report (CER) that demonstrates compliance of the Device with the essential principle 14 and Part 8 of Schedule 3 of the Regulations.

> MRI Note: The devices can be labelled as MR[4] Conditional, MR Safe or MR Unsafe.
>
> The CER must include information about whether the Device is MR Conditional or MR Unsafe and respective clinical data demonstrating performance of the Device in MRI environment is to be provided, if and where it is appropriate.
>
> For experimental data (or justification why it was not necessary) demonstrating performance of the Devices in MRI environment, it is expected that the data provided is assessed against the following standard practices or equivalents: ASTM F2052-14; ASTM F2213-06; ASTM F2182-11a; and ASTM F2119-07. If a notified body has already assessed the experimental data, the assessment report can be provided in lieu of the data.

> You are to provide the clinical data and information in the format set out in Attachment A.
>
> The CER checklist is to be completed and included as the first page for the clinical evidence submission, in order to ensure all required information is provided.
>
> Guidance on how to collate the clinical evidence should be in accordance with the published guidelines on the TGA website:

[3] Section 41CA of the Act prescribes that these requirements are set out in the Regulations. Regulation 2.1 specifies that the essential principles (EP) are set out in Schedule 1 of the Regulations. There are six general principles that apply to all devices, and nine principles about design and construction that apply to devices on a case-by-case basis.

[4] MR means magnetic resonance

Level 2 Mandatory Application Audit Documents to be provided

- Manufacturers Australian Declaration of Conformity (DoC)
- Confirmation of products to be supplied
- Labelling
- Pictorial images of the device
- Packaging - inner and outer packaging for the device
- Instructions for use
- Product manual
- Advertising material for the medical device including brochures
- Clinical evidence report (relevant to the subject device)
- Risk management report (relevant to the subject device)
- Efficacy and performance data (for medical devices that are intended to be used for disinfecting other medical devices)
- +/- Patient Implant Card and Patient Information leaflet

Key Documents

- Clinical Evaluation Report
- Risk Assessment Document
- Cover Letter

Clinical Evaluation Report

The clinical evaluation report (CER) is a standalone document that includes:

- ❑ a comprehensive evaluation of the clinical data
- ❑ data appraisal and analysis
- ❑ conclusion reached about safety and performance of the medical device and a risk-benefit determination by a demonstrated clinical expert.

- NOTE – Clinical evidence guidelines are available

Review the CER

- Ideally the CER should be specific for the subject device(s) or system. If not, mark up the relevant sections in the CER before submission and prepare a separate table of contents.
- For devices already in the market, post-market data including complaints/ adverse events, CAPA and recalls action displayed by region and year should be provided in detail. Complaints / adverse events data need to be tabulated by type and severity.
- To demonstrate substantial equivalence, the technical, biological and clinical comparison table should incorporate the similarities as well as differences.
- If the device is a new device without a predicate, then detailed pre-market assessment is necessary to establish the safety and efficacy along with explanation on the unmet clinical need that the device would fulfill.

Risk Assessment Document

- Up-to-date risk management with Failure Mode Effects Analysis (FMEA) risk assessment tables.
- Focus/highlight the design and uses of the product.
- If the device has been upgraded to a new version, the risk assessment should be updated to capture the new risks that were identified to implement a version upgrade.

Cover Letter

- A well prepared cover letter significantly helps in progressing the audit review.

- It should include:
  - A table of contents and pagination

-When responding to TGA requests it is also a good practice to include the questions and provide the corresponding response along with relevant attachments to each question rather than providing consolidated response for multiple questions.

Cover letters for types of applications

- For **reclassification** applications:
  - highlight the regulatory changes that constitute the device application and include the previous ARTG number and any recent technological changes in the up-classified device.

- For **novel devices**:
  - provide a description of the new technology and how it is superior to the existing technology.

- For **an established technology**:
  - provide predicate or substantial equivalence device's name and their ARTG number
  - provide approval Regulatory History in other countries and date of approval.

Additional Requests for Information (s41JA)

Common issues that lead to additional requests for information:

- Insufficient evidence to demonstrate substantial equivalence (detailed comparisons are required
- not including risk matrices & FMEA tables as part of risk management documentation
- issues with registry and post market data ie only sales data is presented – detailed information is required on complaints, CAPAs and recalls.
- Inconsistencies between application and provided documents
- Issues with Patient Information Materials (PIC's/PIL's)

Changes to ARTG Inclusions

- Varying entries to the ARTG
- Variations to Class III/AIMD

Varying entries in the ARTG

- If a sponsor has multiple ARTG entries where the request is **exactly the same** the TGA will vary up to **10 ARTG** entries on one application form. Examples of this could be a change of the manufacturer's name and/or address; relink to a different Manufacturer Evidence ID.

- The TGA does not charge any evaluation fee for varying ARTG entries.

- A **Device Change Request** (DCR) application form has a free text field where the sponsor can identify the ARTG number(s) and briefly describe the required information in the ARTG to be varied.

Variations to Class III/AIMD

- Class III devices can have one or more variants associated with a single Australian Register of Therapeutic Goods (ARTG) entry.

- The sponsor should attach the following documents to the variation application:
  - Sponsor letter outlining the requested changes
  - Design Examination Certificate or equivalent document
  - Manufacturer's Declaration of Conformity (DoC) that outlines all the models of the devices been supplied under the ARTG
  - Product information to validate the device and its variants (if applicable)
  - Manufacturer's Instructions for Use (IFU) for the device

Questions

Australian Government

Department of Health

Therapeutic Goods Administration