Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for medical devices

(ARGMD) Part 3–Post-market

Version 1.1, May 2011

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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, 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.

Version history

Version	Description of change	Effective date
V1.0	Initial publication	28/04/10
V1.1	· Updated references and contact details to reflect TGA's new organisational structure post TGA21 · Made multiple amendments and additions in Section 3. Essenti Principles, Principle 14—Clinical Evidence. · Made multiple amendments in Section 22. Post-market vigi ce and monitoring requirements. · Added a fourth part titled 'Navigation and Refer ce' t t includes: – a bibliography – consolidated contact details – an index – a glossary of terms · Made various punctuatio d grammar amendments · Reformatted for comp e w new TGA style manual	04/0 /1

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Section 21. Changes to ARTG Inclusions

This section to be drafted.

Section 22. Post-market vigilance and monitoring requirements

Overview

Once a medical device has been included in the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

The TGA, along with several international partners in the GHTF, have developed agreements and documents to promote a harmonised approach to medical device regulation around the world. The GHTF has produced a guidance document *Medical Devices Post-market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*, which is available from the GHTF website at <http://www.ghtf.org>.

The TGA has mandatory requirements for all manufacturers and sponsors of medical devices. These requirements are intended to monitor information about medical devices so that appropriate action can be taken. The requirements facilitate the systematic investigation of failures and/or deviations in the way a device performs, in an attempt to prevent an adverse event occurring again. For information about the corrective actions that may be taken, please see Section 23. Recalls, suspensions, cancellations, and tampering of medical devices.

There are four key stakeholders involved in improving outcomes for users of medical devices:

- sponsors—who are responsible for the legal supply of the device in Australia
- manufacturers as defined in section 41BG of the *Therapeutic Goods Act 1989* (the Act)
- the TGA—the Regulator
- users—consumers and health practitioners who by voluntarily reporting concerns with devices enable issues to be identified and corrective action to be taken

The TGA has a comprehensive strategy for ongoing monitoring and vigilance for medical devices, which includes four major components:

- sponsor's ongoing responsibilities
- manufacturer's ongoing obligations
- ongoing monitoring
- vigilance—adverse-event management

Sponsor's ongoing responsibilities

In accordance section 41FD of the Act, in applying to include a device in the ARTG, the sponsor has certified that:

- the products is a medical device
- its intended purpose as stated in the application form has been ascertained from the manufacturer's instructions from use, advertising material, technical documentation, and/or project label(s)
- the device is correctly classified
- the information included with the application is complete and correct

- the device complies with the Essential Principles and the manufacturer has available sufficient information to substantiate that compliance with the Essential Principles or have procedures in place, including a written agreement, to ensure that such information can be obtained from the manufacturer within 20 working days
- an appropriate conformity assessment procedure has been applied to the device
- the sponsor has available sufficient information to substantiate the application of those conformity assessment procedures or have procedures in place to ensure that such information can be obtained from the manufacturer within 20 working days
- any advertising material relating to the medical device complies with the TGA requirements—for more information see Advertising in Section 12. Information about a medical device.
- the device does not contain substances that are prohibited imports under the Customs Act
- the device is not an excluded device

The sponsor has ongoing responsibilities once a device has been included in the ARTG.

The Act requires that the sponsor will:

Requirement	Example(s)	Legislative reference
Allow entry and inspections of premises	· allowing a person authorised by the TGA to enter and inspect any premises, including outside Australia, where the devices are manufactured or located · while on the premises, to inspect the premises and medical devices on the premises · to take samples of medical devices from the premises	section 41FN(1) of the Act
Deliver samples upon request	· providing samples of the medical device to the TGA upon request	section 41FN(2) of the Act
Availability of information	· access to the technical documentation that demonstrates compliance with the Essential Principles · access to the evidence that appropriate conformity assessment procedures have been applied · on request, provide this information to the TGA within specified timeframes	section 41FN(3) of the Act
Advertising material	· ensuring any advertising material relating to the medical device complies with the TGA requirements	section 41FN(5) of the Act
Report details of certain incidents and performance issues to the TGA	· reports events in accordance with the requirements laid out in the *Therapeutic Goods Act 1989* and the *Medical Devices Regulations 2002* and this guidance document	section 41FN(3)(d) of the Act
Report any overseas regulatory actions to the TGA if the product involved is from the same batch or product run that was supplied Australia	an adverse event has occurred with a product in another country and the ensuing investigation by the manufacturer determines that a batch of the product should be recalled. If the batch is supplied in Australia the sponsor should notify the TGA of the overseas action to determine if the same action should occur in Australia	section 41FN of the Act
Report results of investigations undertaken the manufacturer to the TGA	· Relay the results to the TGA of an investigation into a returned sample associated with an adverse event report	section 41FN of the Act
Assist the TGA and the manufacturer in investigations if an incident occurs	· Pass information to the TGA and the manufacturer during an investigation of an adverse event · Assist in the gathering of information and samples from the user	section 41FN of the Act

Requirement	Example(s)	Legislative reference
Take corrective action when necessary	· recall medical devices · inform the public about medical devices that do not comply with requirements	section 41KA of the Act
Maintain distribution records for product supplied in or exported from Australia	· Regulation 8.1(b) · records of delivery to: – distribution warehouses – manufacturing sites – retails outlets	section 41FO of the Act
Conditions imposed when medical devices are included in the ARTG	· For Class III, Class AIMD, and Class IIb implantable devices to provide annual reports for first three years that the device is available in Australia	section 41FO(2) of the Act

Distribution records

Under section 41FO of the Act sponsors of medical devices supplied in and exported from Australia are required to keep distribution records of the medical devices to:

· expedite any recalls of batches of the medical devices

· identify the manufacturer of each batch of devices

Sponsors are not required to maintain records of the individual users of medical devices, however the sponsor should have records of distribution centres, hospitals and export countries the device has been supplied to.

Each sponsor is required to retain the distribution records for their medical devices for:

· 10 years for Class AIMD, Class III, and Class IIb implantable devices

· five years for all other devices

after the last product has been distributed. These records, or copies of the records, must be provided when requested by the TGA.

The Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use, available on the TGA website, sets out appropriate procedures for wholesalers and/or distributors to ensure that there is effective, efficient and safe handling, storage and distribution of products. It is in the sponsor's interest to encourage their wholesalers to follow this code.

Annual reports on problems—Class III, Class AIMD and implantable Class IIb medical devices

In addition to the penalties for failing to notify adverse events under sections 41MP, 41MPA,41MPB, 41MQ, 41MR of the Act the vigilance provisions, it is a condition of inclusion in the ARTG (section 41FN) that the sponsor of a medical device that is:

· an AIMD

· Class III

· implantable Class IIb

provides three consecutive annual reports to the TGA following inclusion of the device in the ARTG (as specified in 5.8 of the Regulations).

Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June.

The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. If the information is limited to the time the device has been on the Australian market because it hasn't been supplied elsewhere, this should be stated in the report. Subsequent reports are to be provided on 1 October for a further 2 years.

The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

Complaints received by the manufacturer relating to the use of the device, including its supply under a different name, in other countries where the device is available must also be included.

These reports are reviewed by the TGA and any issues arising will be discussed with the sponsor.

Note: Sponsors of products that have been transitioned to an inclusion, which were previously registered and were on the ARTG for three years prior to transitioning will have already submitted Annual Reports for these devices as it was a condition of registration. Annual Reports will not be required for products that meet this criterion. This should however be noted in Annual Reports to pre-empt enquiries from the TGA.

If the device is included in the ARTG	then an annual report
before 1 April	is due in October of that year for information from 1 July of the preceding year to 30 June
after 1 April	will not be required until 1 October the following year

Examples—annual reports of problems with high-risk devices

A Class IIb implantable device is approved for inclusion in the ARTG on 10 March 2007. The first annual report will be due on 1 October 2007 and should cover the details for the device for the period 1 July 2006 to 30 June 2007. Even though the device has only been available in Australia since 10 March, if the device has been available in other countries prior to 10 March the report must include details of any problems reported to the manufacturer for the period 1 July 2006 to 30 June 2007. The second and third reports are due on 1 October 2008 and 2009 respectively.

A Class III medical device is approved for inclusion in the ARTG on 10 May 2008. The first annual report will be due on 1 October 2009 and should cover the details for the device for the period 10 May 2008 to 30 June 2009. The second and third reports are due on 1 October 2010 and 2011 respectively.

What the sponsor should include in the annual report

- ARTG no
- Product name
- Model no(s)
- Number supplied in Australia
- Number supplied world wide (Numbers should include devices that are the same but supplied under a different name in another jurisdiction)
- Number of complaints in Australia
- Number of complaints world wide
- Number of adverse events and incident rates in Australia (Rate= No. of events/ No. Supplied x 100 = Rate%)
- Number of adverse events and incident rates world wide
- A list of the more common complaints and all of the adverse events
- Device Incident Report (DIR) number of those adverse events reported to the TGA
- Regulatory/corrective action/notification by manufacturer

An example of how this might be presented is shown below:

ARTG #	Product name	Model #	# supplied in Aus	# supplied World Wide	# of complaints		# of Adverse Events	
					Aus	WW	Aus	WW
123456	Knee prosthesis—femoral component	ABC 123	200	8000	32		2	

Type of complaints	Number	Percentage in Australia	Percentage world Wide	TGA DIR #	Regulatory action
Adverse events					
loosening	2	0.025%		DIR 12234	Nil

Reports should be submitted to <iris@tga.gov.au> where possible. Otherwise, they may be sent to:

Annual Reports
The Coordinator
Medical Device Incident Report Investigation Scheme (IRIS)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Facsimile: 02 6203 1713
Telephone: 1800 809 361

Manufacturer's ongoing obligations

Manufacturers have ongoing legal obligations for medical devices that they manufacture that are supplied in Australia. These obligations are outlined in full in the therapeutic goods legislation.

As part of the approval process to market a medical device in Australia a manufacturer must sign an Australian Declaration of Conformity. The Australian Declaration of Conformity states which conformity assessment procedures the manufacturer has chosen to use to demonstrate that their medical device meets the Essential Principles. The ongoing obligations for a manufacturer vary depending on which conformity assessment procedures they have used. Full details of the ongoing obligations for each of the conformity assessment procedures are in Schedule 3 of the *Therapeutic Goods Regulations (Medical Devices) 2002* (the Regulations). These surveillance activities are a critical part of the manufacturer's overall quality manufacturing system.

Requirement	Example(s)	Legislative reference
Manufacturer must maintain appropriate records	· technical documentation that demonstrates the conformity of their devices with the Essential Principles · evidence that an appropriate conformity assessment procedure has been applied · the Australian Declaration of Conformity · details of any post-market activities undertaken after the device was supplied in Australia · details of any changes or variations to the device and/or quality management system—for more information, please see Section 21. Changes to ARTG inclusions. · any notice, report, certificate or other document in relation to the quality management system issued to the manufacturer by the TGA · for all devices that are not Class I non-sterile and non-measuring: · details of the manufacturer's quality management system · the design, production process and intended performance of the medical device These records must be kept for a minimum of 5 years after the manufacture of the last medical device. On request from the TGA, the manufacturer must make the records available to the TGA	Schedule 3 of the Regulations
implement appropriate measures to apply any necessary corrective action in relation to the design or production of a device	· unless covered by the exemption rules, notify the TGA or the sponsor, as soon as practicable after becoming aware of: - information relating to § any malfunction or deterioration in the characteristics or performance of the device § any inadequacy in the design, production, labelling or *Instructions for Use* of the device § any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device that might lead, or might have led, to the death of a patient	Schedule 3 of the Regulations

Requirement	Example(s)	Legislative reference
	or a user of the device in Australia, or to a serious deterioration or serious injury to his or her state of health. For more information, please refer to Vigilance in this section - information relating to any technical or medical reason for a malfunction or deterioration that has led the manufacturer to take steps to recover devices that have been distributed - systematically review information gained after the device was supplied in Australia. Information can come from many sources, for example: § Expert user groups § Customer surveys § Customer complaints and warranty claims § Service and repair information § Literature reviews § User feedback other than complaints § Device tracking and registration records § User reactions during training programs § Adverse event reports from users provided by the TGA	

Please note: Even though a certified quality system is not required for manufacturers of Class I medical devices (non-sterile or non-measuring), the manufacturer is still required to have an ongoing surveillance system established, in accordance with clause 6.5 of Schedule 3 of the Therapeutic Goods Regulations (Medical Devices) 2002.

Manufacturers must also notify the TGA of substantial changes to the design, intended performance or quality management system of the device. For more information on changes, please see Section 21. Changes to ARTG Inclusions.

Ongoing monitoring of compliance by the TGA

Ongoing monitoring by the TGA is a series of activities carried out to ensure that regulatory compliance and safety of the medical devices continues after supply to the Australian market.

Monitoring activities may include:

- reviews of technical and clinical information to ensure that compliance with the Essential Principles and conformity assessment procedures is demonstrated
- testing to confirm compliance with the Essential Principles
- inspections of manufacturer's or sponsor's records and documentation
- on-site testing of medical devices or taking samples for off-site testing
- audits of distribution records
- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts
- trend analysis and reporting to sponsors

The TGA may take corrective action in accordance with the legislation if problems are found, such as:

- sponsors and/or manufacturers not fulfilling their regulatory responsibilities
- safety concerns about a medical device
- certifications made in the device application are incorrect or no longer correct

For more information, please see Section 23. Recalls, suspensions, cancellations, and tampering of medical devices.

Post-market reviews for medical devices

Post-market reviews support the inclusion in the ARTG process for medical devices, which includes both random, flagged, and targeted reviews.

There are three levels of post-market reviews for medical devices:

Level	Reason for the Review	Scope	Objectives of the Review
Flagged (Class I)	restricted word used in online eBS application	GMDN Intended Purpose of the device as specified by the manufacturer Classification	· check accuracy and consistency of ARTG information · check appropriate classification
Targeted (All Classes)	Targeted based on: · outcomes of Flagged review · recurrent breaches of advertising code · repeated device test failures · overseas regulatory activity/advice · trends from problem reports · random reviews · unresolved/repeated recalls · manufacturer audit reports · notice from manufacturer/sponsor · implant registers · particular words in the intended purpose · complaints	Flagged, Random + any or all: · Manufacturer audit reports · TGA laboratory testing · Manufacturer audit · clinical evidence · Manufacturer's Evidence · technical file · sterilisation validation evidence (where appropriate) · matters certified in the device application	· check accuracy and consistency of ARTG information · check appropriate classification · review available documentation for potential or real risks of safety and performance issues certifications in device application remain correct · sponsor is meeting the conditions of inclusion · manufacturer shows compliance with the Essential Principles
Random (Class I)	Random on ARTG inclusion	Flagged · labels · Instructions for Use · Australian Declaration of Conformity · manufacturer's advertising material	· check accuracy and consistency of ARTG information · check classification appropriate
Please note: it is important to be aware that any advertising material submitted is not assessed for compliance with the advertising requirements, but is only used to assist with clarifying the manufacturer's intended purpose for the device			

If an application is inconsistent with the definition of a Class I device:

- for Flagged reviews, sponsors will be sent a section 41JA letter requesting the Australian Declaration of Conformity, which will be reviewed and either accepted or
  - the sponsor will be issued with a proposal to cancel letter with 10 days to respond

Vigilance

The purpose of medical device vigilance is to improve the health and safety of patients, users, and others by reducing the likelihood of adverse events being repeated. This can be achieved by:

- evaluating reported adverse events
- disseminating information that could be used to prevent or minimise the consequences of adverse events, where appropriate
- modifying the medical device
- removing the medical device from the market

Action is undertaken by the TGA and the sponsor and/or manufacturer after a body becomes aware of information about a medical device supplied in Australia, such as:

- adverse event reports
- malfunctions
- results of testing
- any other information

The manufacturer and sponsor must inform the TGA of all reportable adverse events, within the appropriate timeframes. They must also ensure timely and appropriate action is taken.

To improve the monitoring of the performance of medical devices supplied in Australia, the TGA encourages the reporting of adverse events by users of devices.

Vigilance exchange

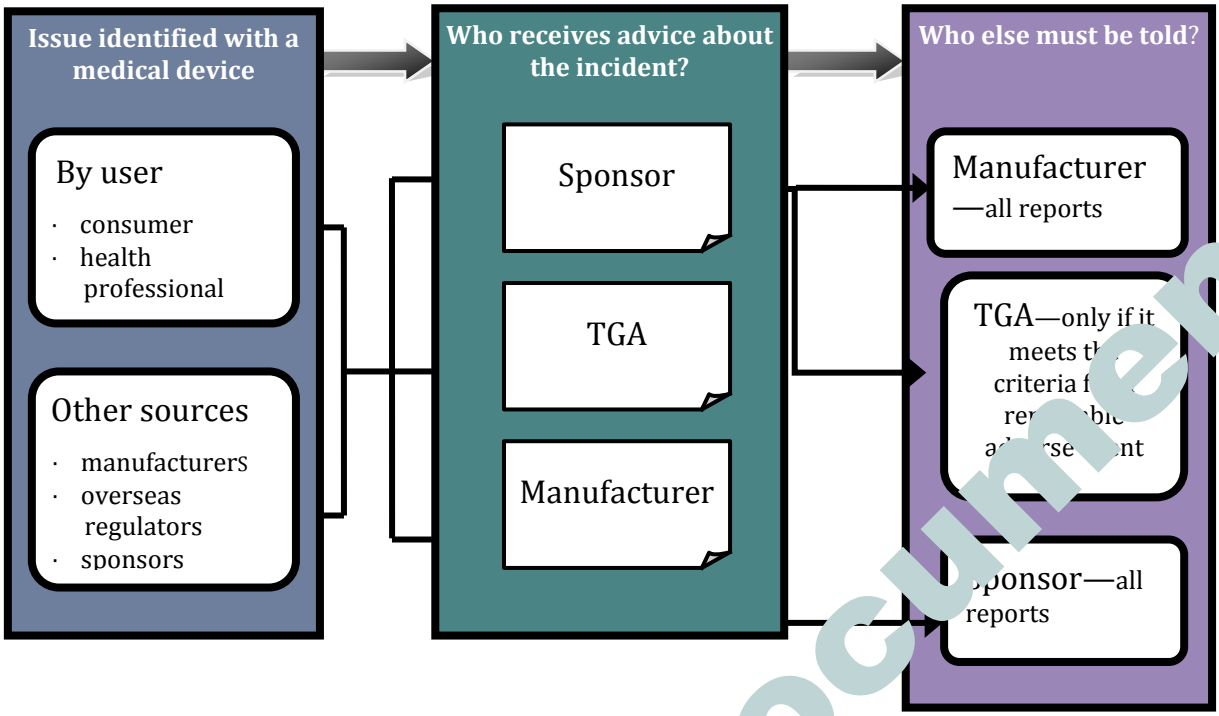
Through various Mutual Recognition Agreements for medical device regulation and its participation in the Global Harmonization Task Force (GHTF), the TGA has an obligation to exchange vigilance information with overseas regulatory agencies. Information will be exchanged on incidents and events where:

- corrective action, including a recall, is to be taken
- there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined.

The TGA will consult the sponsor when preparing a vigilance report to be sent to other regulatory agencies. It is the responsibility of the sponsor to ensure that the manufacturer is aware of the TGA vigilance report, and that any comments that are made by the manufacturer are passed on to the TGA for consideration. The TGA will only consider changes that address inaccuracies in the report.

Regulatory agencies generally use discretion where a manufacturer takes corrective action that is not considered to be essential to protect the safety of patients or others. Examples of this are minor improvements to current devices and updates of user information. In the case of doubt, however, a regulatory agency will generally disseminate information.

Who is notified when there is an issue with a medical device?



The sponsor is legally responsible for the supply of the dev in a, including the receipt and handling of complaints and adverse events. The sponsor may receive e eports from users, the TGA, the manufacturer or other sources, e.g., literature, consumer bodies, professio bo s. The sponsor must forward copies of all reports to the manufacturer and copies of all reportable adv event reports to the TGA.

The manufacturer must maintain records of any pr ems/incidents that occur involving a medical device that they manufacture that is supplied in Australia. e m ufacturer must inform the sponsor of any reports from users or other information that indicates the i ssible problem with a device supplied in Australia.

The TGA must be notified of any incide that ur in Australia and that are considered adverse events (please see below for an explanation of what con ered an adverse event). The TGA will forward details of incident and the device in the reports fro se e sponsor of the device.

Reportable adve se events

Any event that meets t ee sic reporting criteria, even if it does not involve a patient or user, should be reported to the T A

· an adverse eve occurred

· th ma f er's medical device is associated with the adverse event

· he nt ed to or might lead to (often referred to as a near adverse event) death or serious injury, or might d to eath or serious injury if it were to occur again

An adverse event is an event that led to:

- death
- a serious injury or serious deterioration to a patient, user or other person, including
  - a life-threatening illness or injury
  - permanent impairment of a body function
  - permanent damage to a body structure
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

A 'near adverse event' is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

- an event associated with the device happened
- if the event occurred again, it might lead to death or serious injury
- testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

Typical adverse events are as follows:

Event or cause of an adverse event	Description
Malfunction or deterioration in the characteristics or performance of a medical device	Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions *Please note: intended purpose means the intended use according to the data supplied by the manufacturer on the labelling, in the* Instructions for Use *and/or in advertising materials*
Inadequate design or manufacture of a device	Design or manufacturing of a device is found deficient
Inaccuracy in the labelling, *Instructions for Use* and/or promotional materials	Inaccuracies include omissions and deficiencies Omissions do not include the absence of information that should generally be known by the intended users
Significant public health concern	Can include an event that is of significant and unexpected nature that becomes a potential public health hazard, for example, human immunodeficiency virus (HIV) or Creutzfeldt–Jacob Disease (CJD) the TGA, the sponsor, or the manufacturer may identify these concerns
Other information becoming available	Can include: · information from the literature or other scientific documentation · the results of testing performed by the manufacturer on its products · reports from the user prior to the device being used on the patient

Reporting incidents with medical devices

The act of reporting a problem is not an admission of manufacturer, sponsor, user, or patient liability for the event or its consequences.

Only adverse events that occur in Australia are required to be reported to the TGA. Adverse events that occur overseas for devices supplied in Australia do not need to be reported to the TGA. However, records of these events should be available if requested. Also, any remedial action that arises overseas for devices supplied in Australia should be reported. For more information, please see Section 23. Recalls, suspensions, cancellations, and tampering of medical devices.

The reporting requirements for sponsors are conditions on the inclusion of medical devices in the ARTG. Breaching conditions of inclusion may lead to suspension or cancellation of the device from the ARTG (section 41G of the Act), as well as constituting a criminal and civil offence (section 41MN of the Act).

The sponsor is responsible for forwarding reports of all incidents to the manufacturer for assessment under manufacturer's surveillance system.

Please note: There are exceptions to the requirement to report, which are outlined over the following pages.

It is possible that the sponsor will not have enough information to decide if the problem should be reported to the TGA. This judgement may be difficult when there are multiple devices involved. The sponsor should make reasonable efforts to obtain additional information to assist in making this decision. In assessing the link between the device and the event, the sponsor should take into account:

- the opinion, based on available information, from a health professional
- information concerning previous, similar events
- other information held by the sponsor

In complex situations, it should be assumed that the device was associated with the event. If there is any doubt about whether a report should be submitted, the report should be submitted.

Where possible, the manufacturer should consult with the user and/or medical practitioners or other healthcare professionals involved, and do their utmost to retrieve the particular device.

Please note: Although it is the manufacturer who must assess an incident, the sponsor will be held accountable for forwarding information concerning events to the manufacturer and then for forwarding the results of any analysis to the TGA. The manufacturer must advise the sponsor but can also advise the TGA directly.

Reporting of events or near events by users is voluntary. The TGA promotes and encourages users to report but cannot enforce reporting by users. Device users are encouraged to report events associated with the use of a medical device to either the sponsor or the TGA.

Examples of reportable adverse events

- The premature revision of an orthopaedic implant due to loosening or fracture
- An infusion pump stops, due to a malfunction, but fails to give an alarm. The patient receives an under-infusion of needed fluids
- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to a malfunction
- An intravenous set separates and the comatose patient's blood leaks onto the floor, resulting in significa blood loss

Examples of reportable adverse events involving public health concerns

- Fatigue testing performed on a commercialised heart valve bioprosthesis demonstrates prem e fa re, which would indicate that a risk to public health could occur
- After delivery of an orthopaedic implant, errors were discovered in heat treatment rec raising questions about the effectiveness of the implant's materials that would create a risk to public h th
- A manufacturer provides insufficient details on cleaning methods for reusable su l instruments used in brain surgery, despite the obvious risk of transmission of CJD

Please note: A definition of what represents a serious threat to public hea can be found in Part 5, Division 5.2, Regulation 5.7 (2) of the Therapeutic Goods (Medical Devic) Re lations 2002.

Exemptions from reporting adverse events to the T

There are eight exemption rules that can apply (see table o xe ption rules overleaf). However, these rules do not apply when:

- a device, event or issue specifically identified by e TGA as an issue that requires close monitoring—sponsors of devices that are affected will b tifie by the TGA when this occurs
- an adverse event normally subject to a rep rting exemption, where a change in trend (usually an increase in frequency) or pattern is identified
- adverse events associated wi use or, as the TGA may use this data to identify trends with similar products that may lead to co endations for:
- corrective action for the de e
- revising the labelli or *structions for Use*
- identifying a d for increased user education.

If a manufa ur elieves an exemption rule applies to reporting an adverse event, the reasons for not reporting the e t sh d e documented.

Exemption Rules from reporting adverse events to the TGA

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
1	**Deficiency of a new device found by the user prior to its use** Regardless of the existence of provisions in the Instruction for Use provided by the manufacturer, deficiencies of devices that will be always detected by the user and where no serious injury has occurred, do not need to be reported. *Please note: If the device is used the exemption does not apply—the event must be reported.*	· A user performs an inflation test (standard procedure) prior to inserting the balloon catheter in the patient as required in the *instructions for use* accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured. · Sterile single-use device packaging is labelled with the caution 'do not use if package is opened or damaged'. Open package seals are discovered prior to use, device is not used. · An intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.
2	**Adverse event caused solely by patient conditions** When the manufacturer has information that the root cause of the adverse event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use. To justify not reporting, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to a death or serious injury. A person qualified to make a clinical judgement would accept the same conclusion.	· An orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision. · The early revision of an orthopaedic implant due to loosening caused by the patient developing osteoporosis. · A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.
3	**Service life of the medical device** The service life is defined as 'the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified'. The service life must be specified by the device manufacturer and included in the master record (technical file). When the only cause for the adverse event was that the device exceeded its service life and the failure is not unusual, the adverse event does not need to be	· Loss of sensing after a pacemaker has reached its end of life. The elective replacement indicator has shown up in due time according to the device specification. Surgical explanation of pacemaker is required. · A drill bit was used beyond the end of its specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
	reported. Assessment of whether an event is exempt from reporting under this rule must be based on the information in the master record, on the label or in *Instructions for Use* for the device.	
4	**Protection against a fault functioned correctly** Adverse events that did not lead to serious injury or death, because a design feature protected against a fault becoming a hazardous situation (in accordance with relevant standards or documented design inputs) do not need to be reported.	· An infusion pump stops, due to a malfunction, but gives an appropriate alarm (for example, in compliance with relevant standards) and there was no injury to the patient. Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm, in compliance with relevant standards and there was no injury to the patient. · During radiation treatment, the automatic exposure control is engaged and the treatment stops. Although the patient receives less than an optimal dose, the patient is not exposed to excess radiation.
5	**Remote likelihood of occurrence of death or serious injury** Adverse events that could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury and which have been established and documented as acceptable after risk assessment do not need to be reported. If an adverse event resulting in death or serious injury occurs, the adverse event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains remote, previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Please note: A change in the trend (usually an increase in frequency) of these non-serious outcomes must be reported.	The manufacturer of a pacemaker supplied to the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is remote. No patients experienced any adverse health effects. The manufacturer of blood donor sets obtains repeated complaints of minor leaks of blood from these sets. No patient injuries from blood loss or infections of staff have been reported. The chance of infection or blood loss has been re-evaluated by manufacturer and deemed remote.
6	**Expected and foreseeable side effects that are documented in manufacturer's Instructions for use labelling**	A patient receives a second-degree burn during the use of an external defibrillator in an emergency. The risk assessment

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
	Side effects that are clearly identified in the manufacturer's labelling or are clinically well known as being foreseeable and having a certain functional or numerical predicability when the device was used as intended need not be reported. Some of these events are well known in the medical, scientific, or technology fields. Others may have been clearly identified during clinical investigation and labelled by the manufacturer. Documentation, including the risk assessment, for the particular side effect should be available in the device master record prior to the occurrence of adverse events. The manufacturer cannot conclude in the face of events that they are foreseeable unless there is prior supporting information.	documents that such a burn has been accepted in view of the potential patient benefit and a warning is provided in the *Instructions for Use*. The frequency of burns is occurring within range specified in the device master record. A patient has an undesirable tissue reaction that is previously known and documented in the device master record. A patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Placement of central line catheter results in an anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.
7	**Adverse events described in an advisory notice** Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the TGA.	A manufacturer issued an advisory notice and undertook a recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarised in quarterly reports required for the recall action and individual adverse events did not have to be reported.
8	**Reporting exemptions granted by the TGA** Upon request by the sponsor, common and well documented events may be exempted by the TGA from reporting or changed to periodic reporting on a case by case basis.	

Timeframes for submitting adverse event reports to the TGA

The reporting requirements are conditions on the inclusion of medical devices in the ARTG. Breaching conditions of inclusion may lead to suspension or cancellation of the entry from the ARTG as well as constituting a criminal offence and/or resulting in a civil penalty.

From the *Therapeutic Goods Act 1989*...

5.7 Conditions applying automatically — period for giving information about adverse events etc (Act s 41FN)

For paragraph 41FN (3) (d) of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information of a kind mentioned in subsection 41MP (2) of the Act to the Secretary is:

a. if the information relates to an event or other occurrence that represents a serious threat to public health — 48 hours after the person becomes aware of the event or occurrence; and

b. if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 10 days after the person becomes aware of the event or occurrence; and

c. if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person — 30 days after the person becomes aware of the event or occurrence.

Details to be included in an adverse event report

There are two report forms available on the TGA website:

- Medical device adverse event reporting by medical device users—for use by medical device users (clinicians, patients or their relatives, etc) to report any suspected problems with a medical device that has or may present a health hazard. Typical problems include deficiencies in labelling, *Instructions for Use* or packaging, defective components, performance failures, poor construction or design

- Medical device adverse event reporting by medical device manufacturers and sponsors—to be used by medical device sponsors, manufacturers or their authorised representatives for mandatory reporting of adverse events associated with a medical device

The report should not be unduly delayed if the information is incomplete. It is important to get this process underway as additional information can always be provided later. It may also include a statement to the effect that the report is made by the manufacturer and sponsor without prejudice and does not imply any admission of liability for the incident or its consequences.

If a person is not able to access the forms on the TGA website, they should ensure that the report includes the following details:

- the sponsor's:
  - name
  - address
  - contact person
  - telephone number
  - fax number
- the date when the incident came to the knowledge of the:
  - manufacturer
  - sponsor
- information about the device including the:
  - kind of medical device
  - commercial name
  - catalogue number
  - ARTG number
  - model number
  - serial number
  - batch number
  - lot number
  - software version (if applicable)
- if implantable, date of implant and if applicable, date of explant
- any associated devices and/or accessories involved in the incident
- the known details of the event, including the date and patient or user outcome
- the current known location of the medical device involved in the event
- the contact point of the user where the event occurred. The patient's full identity should not be reported. The contact point need not necessarily be a person who actually witnessed the event. It is recommended that health care facilities have a contact person for all reported events
- any manufacturer and sponsor comments
- the action taken or proposed action and timeframe
- a statement of whether the manufacturer and sponsor are aware of the same type of events having an impact on the current report. This statement should include the:
  - names of any other regulatory authorities to which these events have been reported
  - date of the reports
  - number of similar events
  - number of devices supplied
  - rate of similar events, if available
  - any other countries in which the medical device is known to be on sale or supplied

Reports should be submitted to <iris@tga.gov.au> where possible. Otherwise, they may be sent to:

The Coordinator
Medical Device Incident Report Investigation Scheme (IRIS)
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: <iris@tga.gov.au>
Facsimile: 02 6203 1713
Telephone: 1800 809 361

Access to medical devices involved in adverse events

Where possible, a manufacturer, through a sponsor should consult with the medical device user ... the event before a report is submitted to the TGA. The manufacturer may also wish to have access to ... edical device involved in the event to help decide whether the event should be reported to the TGA. S... acce...s would be at the discretion of the user or healthcare facility concerned, but they are encouraged t... sist ... e manufacturer to determine the root cause of the incident.

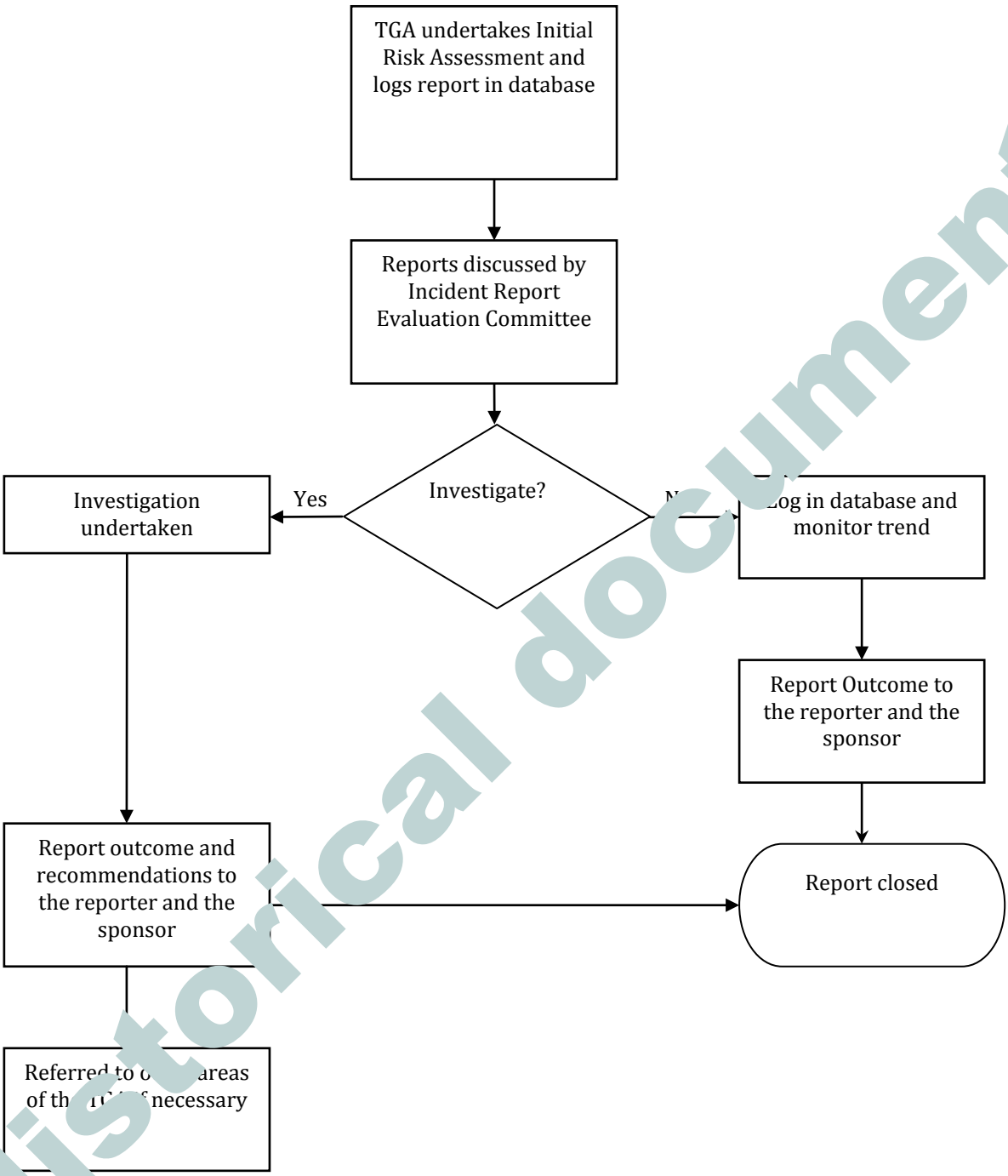
If the manufacturer has access to the medical device, and the initial assessmen... cl...ing or decontamination process will involve altering the device in a way that may affect subsequen... analy..., the manufacturer should, through the sponsor, inform the TGA before proceeding.

Where the healthcare facility sends the medical device directly to th... TGA, ...e device will be inspected and its condition recorded and described. The TGA will not carry out any ... est...ctive testing without consulting both the:

- manufacturer, through the sponsor, of the medical de... e
- healthcare facility or reporter.

On completion of the examination the medical devic... ill generally be sent to the manufacturer, again through the sponsor, for their analysis provided the h... ...re facility consents. The TGA encourages release of the medical device to the manufacturer so that the... ca... complete their analysis.

What the TGA does when it receives an adverse event report



The following is a summary of the key components of the TGA's strategy for investigating incident reports:

- Urgent, serious reports are reviewed and addressed as soon as possible by the TGA.
- A panel of scientific, engineering, and clinical experts assesses all reports. The panel determines what level of investigation will take place
- Isolated incidents or problems with a very low clinical risk and no impact on device performance are not usually investigated
- When a report is investigated the person who is investigating will contact the company responsible for t device and work with them to resolve issues
- Reporters' details are treated as confidential. Both the reporter and the supplier are informed of t outcome of the investigation
- All reports are entered into a database so that a trend analysis can be conducted and are eas ef enced in the future

The outcome of an investigation may include one or more:

- referral to other areas of TGA for regulatory actions, such as auditing of the manu ure
- recall of the devices to:
- remove the devices from supply in Australia
- allow correction at the user's site
- the issue of a Safety Alert where there is a need to reinf rce t ma ufacturer's *Instructions for Use* to those responsible for the use of the device or those affected b p m
- product improvement for problems that are not safet elat - carried out by the manufacturer
- report in the TGA News, on the TGA website /or appropriate journals

For more information on these actions, please Sec n 23. Recalls, suspensions, cancellations, and tampering of medical devices

TGA testing of devices

Medical devices involved in an vers ve may be sent to the TGA for testing. The TGA accepts devices that are contaminated. The TGA can t r v ally inspect all medical devices, although there are some devices for which the TGA cannot do a co plete amination as the equipment available for some of the tests is specific to the device manufacturer. The A will, however, test or examine the device as much as it is able, and, if granted permission by the repo e evice will be sent to the manufacturer for further testing. Analysis of the manufacturer's testing red red by the TGA as part of its investigation of the adverse-event report.

It is important th sers keep the device after submitting a report, until the TGA has contacted them to advise whether the d ice d d be sent to the TGA or the sponsor/manufacturer.

Pleas efe TGA website <http://www.tga.gov.au> for instructions on how to send a medical device to the TG A—S ples testing - *Protocol for sending medical devices to the TGA for testing*.

Section 23. Recalls, suspensions, cancellations, and tampering of medical devices

Overview

Once a medical device has been approved for supply in Australia the device must continue to meet all the regulatory, safety and performance requirements and any applicable standards.

If there is a problem with a medical device or the way in which it is being used, the sponsor and manufacturer will first conduct an analysis and make a decision on the appropriate action. One of these actions may require notifying or obtaining further advice from the TGA. Some actions that may need to be taken could include to:

- follow corrective actions / preventive actions procedures under the sponsor/manufacturer's quality management system or for Class 1 devices follow the post-market requirements under Part 6.5, Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- inform the users of the device
- make corrections to the device
- remove the device from the market

As a regulator, the TGA has established procedures for the ongoing monitoring and vigilance for medical devices supplied in Australia. This includes a range of penalties for the inappropriate supply of medical devices.

Recalls of medical devices

If the sponsor or manufacturer is considering any of the following:

- correcting product on the market
- removing product from the market, or
- advising users of a problem with a medical device

contact the Australian Recall Coordinator at the TGA via 02 6232 8636 or email <recalls@tga.gov.au> for advice.

When the need for a recall of a medical device supplied in or exported from Australia has been established, the sponsor of the affected device is responsible for the recovery of the devices. There are two key types of recalls:

- correction, which may involve temporary removal from the market or from use
- permanent removal of deficient medical devices from the market or from use

Most recalls are conducted on a voluntary basis. Where recall is refused, or is not carried out satisfactorily, the TGA may order a mandatory recall. Failure to comply with such an order may result in substantial fines.

The *Therapeutic Goods Act 1989* (the Act), in conjunction with the *Trade Practices Act 1974,* provides the legislative basis for recalls of therapeutic goods. Recall provisions can be applied under section 41KA of the Act when:

- the medical device does not meet the Essential Principles
- conformity assessment procedures have not been applied to the medical device

- the medical device has been illegally supplied
- the medical device has been cancelled or suspended from the ARTG.

In addition, in accordance with section 42V of the Act a recall may be conducted where therapeutic goods have been or could possibly be, subject to actual or potential tampering.

The Uniform Recall Procedure for Therapeutic Goods (URPTG), available on the TGA website, provides detailed information about the action to be taken by health authorities and sponsors when medical devices available in Australia are to be removed from supply or use, or are subject to corrective action

The sponsor has the prime responsibility for implementing recall action, and for ensuring compliance with the recall procedure at its various stages. However, no recall, regardless of level, should be undertaken without consultation with the Australian Recall Coordinator and without agreement on the recall strategy.

The role of the TGA is to assist the sponsor by:

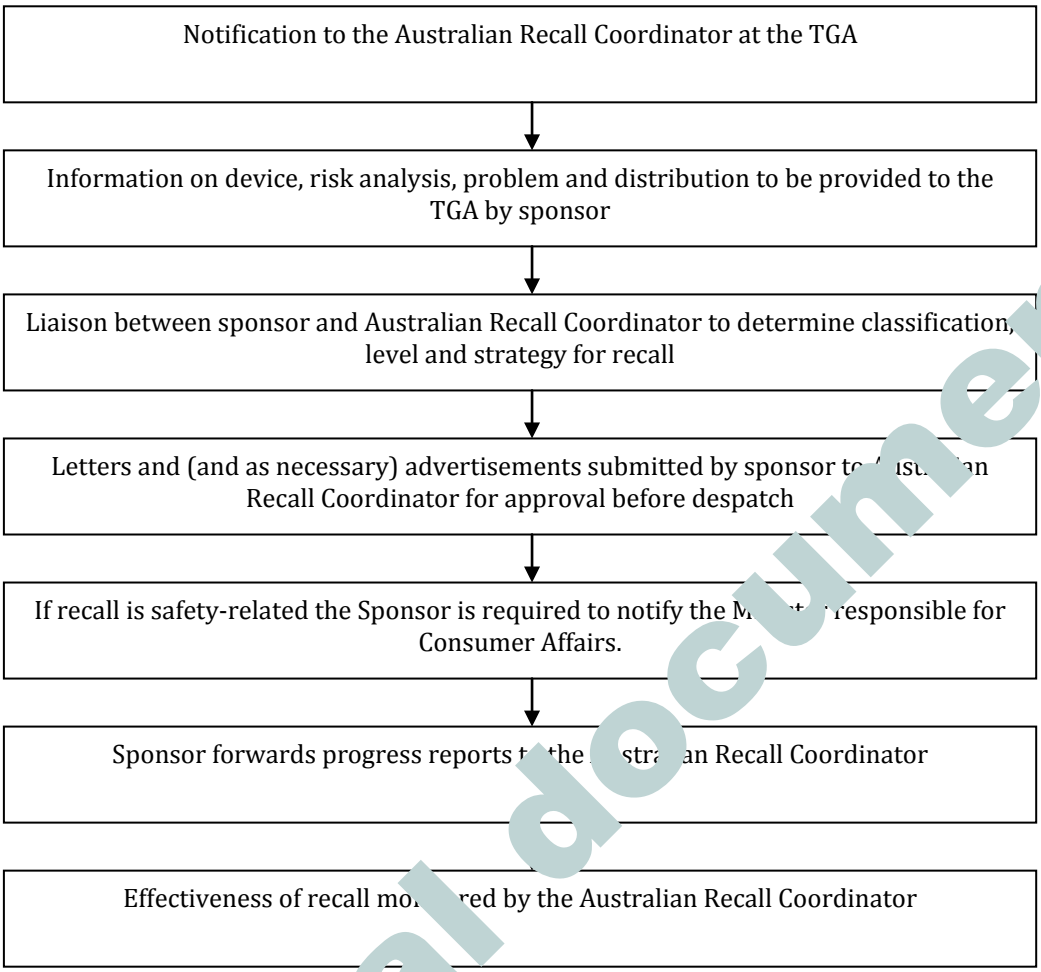
- advising the sponsor immediately of problem reports with medical devices that may necessitate recall
- where there may be a hazard to the user, providing expert advice on the classification and level of recalls. More information on classifications and levels of recalls in Australia is provided later in this section
- providing advice and assistance in relation to letters, advertisements and recall strategies
- notifying agreed third parties, such as state/territory health departments, as well as regulatory agencies, the Australian Competition and Consumer Commission
- monitoring the overall action
- considering and reaching agreement with the sponsors recall procedures or in serious situations to mandate a recall. Appeal provisions will apply with a mandated recall and should be provided

Please note: A Hazard Alert may be issued by the sponsor for implantable medical devices where it has been proven that there is no stock to be recalled and all affected devices are already implanted. The appropriate action to be taken for a device that has been implanted in a patient should be discussed with the Australian Recall Coordinator, as the risk of surgery to replace the implantable device must be balanced against the risk of a problem occurring with the device

Please note: A Hazard Alert as defined in URPTG is issued by the sponsor for implanted medical devices as part of a recall action

A Safety Alert as defined in URPTG is not related to a recall and is intended only to provide information on the safe use of a medical device where the issue was related to the inappropriate use of the device. A Safety Alert is issued by the sponsor or manufacturer not the TGA

Stages of a recall



Recall classifications

Recalls are classified as follows:

Classification	Description	Examples
Class I (Safety related)	Product defects are potentially life-threatening or could cause permanent debilitating health issues	· Hot/cold gel packs that contain a toxic substance that could be ingested accidentally by a young child · A software error in a CT scanner that could cause the g… to rotate in an unintended direction and cause an injury … or the death of a patient · Implantable pacemakers with a defect that results … loss of pacing output, which for pacemaker-dep… patients may result in death or serious injury · A false result on an IVD test for a me… …ith a narrow therapeutic index that could lead … overdose, causing permanent injury
Class II (Safety related)	Product defects could cause illness or mistreatment and the recovery of the patient is likely	· Microbial contamination … …gical lubricant · A software error in … radi…tion treatment planning tool that could lead to thera… …g miscalculated and incorrectly administered · The *In…ct… …r Use* for a catheter omits a precaution for certa… …edures that could cause complications in its remo… The incorrect combination of metal femoral heads and …ers has been supplied to surgeons. If implanted then t…ere is a high risk of accelerated wear and tear An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment
Class III (Non-Safety related)	Product …ect… …may not po… …sign…icant haz…rd t… …alth…out withdrawal … …e initiated for …her reasons	· A disinfectant has been mislabelled with an expiry date that predates the actual expiry date · The outer packaging of a consumable medical device indicates a different size to that which is actually in the supplied in the box. It would be obvious to the clinician that the consumable was the incorrect size · An IVD reagent is causing calibration failures towards the end of its shelf life. There is no effect on patient results

…s I or Class II recalls are considered to be urgent safety-related recalls. Class III recalls are considered to be ro…ne non safety-related recalls

Recall levels

The sponsor determines the applicable outlets in accordance with the URPTG.

There are four levels of recall in Australia:

Level	Outlets
Wholesale	· medicine and medical device wholesalers · State purchasing authorities
Hospital	Outlets at the wholesale level and where applicable any of the following: · nursing homes, hostels and other institutions · clinical investigators and the institutions in which clinical investigations are performed · hospital pharmacists, blood banks, pathology laboratories, operating theatres · fractionators, human tissue banks and personnel in other hospital departments · Ambulance Services, Flying Doctor Services
Retail	Outlets at the wholesale and hospital levels and where applicable any of the following: · retail pharmacists · medical, dental and other health care practitioners · other retail outlets, e.g., supermarkets and health food stores
Consumer	Outlets at the wholesale, hospital and retail levels and where applicable patients and other consumers

More information about recalls

For further information on recalls of medical devices, please refer to the Uniform Recall Procedure for Therapeutic Goods available on the TGA website or contact the:

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Non-recall actions for medical devices

Where the sponsor is unsure of the appropriate action to be taken, and particularly in cases where patient safety may be a consideration, the issues involved should be discussed with the Australian Recall Coordinator.

Other action may be taken by a sponsor voluntarily that is not considered to be a recall:

Action	Description
Safety Alert	· intended to provide information on safe use of devices, as distinct from recall action, which addresses product deficiencies · are issued to provide additional advice to health professionals in situations where the device, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of substantial harm if certain specified precautions or advice are not observed. For example, specific precautions about the longevity of an implanted medical device
Product Notification	· issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences
Product Withdrawal	· sponsor's removal from supply or use of devices for reasons not related to their quality, safety or performance
Product Recovery	· the sponsor recovers devices that have been manufactured or imported but not yet supplied to the market. For example, recovery of devices in a warehouse
User information	· generally conducted by the sponsor in response to issues with the use of a medical device · includes in-house sessions, seminars and improved educational materials such as posters

Please note: Terms such as upgrade notice, market correction, field safety correction that are commonly used by overseas manufacturers and/or regulators may be considered a recall in Australia.

If a sponsor is uncertain of the interpretation of these terms please contact the Australian Recalls Co-coordinator for advice.

Suspending medical devices from the ARTG

The *Therapeutic Goods Act 1989* provides the TGA with the power to suspend a medical device from the ARTG, as follows:

Legislative reference	Description
Section 41GA—Suspension of kinds of medical devices from the register Section 41GB—Notice of proposed suspension must be given in certain cases Section 41GC—Duration of suspension Section 41GD—Revocation of suspension Section 41GE—Treating applications for revocation as having been refused	· the TGA Delegate may by written notice suspend a device from the ARTG if: – there is a potential risk of death, serious illness or serious injury if the device continues to be included in the ARTG and – it is likely that the sponsor and/or the manufacturer will within period of the suspension, be able to take the action necessary to ensure that the kind of device would not cause a potential risk of death, serious illness or serious injury if it were to continue to be included in the ARTG; or – that it is likely that there are grounds for cancelling the entry under division 2 – the suspension may be limited to one or more medical devices of that kind covered by the ARTG inclusion · the TGA will: – inform the sponsor by written notice of the proposed suspension and set out the reasons for it – give the sponsor an opportunity to make submissions to the TGA in relation to the proposed suspension – consider any submissions the sponsor makes before making a decision relating to the proposed suspension · the period of the initial suspension will not exceed 6 months, but may be extended by up to another 6 months · the suspension may be revoked if the grounds for the suspension no longer apply, for example, if the corrective action is implemented within the timeframe. The suspension can be revoked on the written request of the sponsor or on the TGA's own initiative. · if the suspension is not revoked by the TGA Delegate before the end of the suspension period (for example, the corrective action has not been implemented in the timeframe), the device is automatically cancelled from the ARTG · does not affect the powers to cancel an entry
Section 41GF Suspensions of kinds of medical devices from the register	· the TGA may by written notice suspend a device from the ARTG if a conformity assessment certificate (either issued in Australia or by an overseas regulatory agency) is suspended · the suspension in place until revoked by TGA Delegate

The TGA must publish in the Gazette, as soon as practicable, a notice setting out the suspension, any extensions to the suspension, and the revocation of the suspension.

Cancellation of medical devices from the ARTG

The TGA will cancel devices from the ARTG under Part 4-6 of the Act in cases where there has been a breach of the legislation or safety or performance issues associated with the use of the device that has or could lead to risk of death, serious illness or injury. If the devices are cancelled from the ARTG, the sponsor may be required to recall any affected devices. There are four legislative provisions for cancelling medical devices from the ARTG:

Legislative reference	Description
Section 41GK—Automatic cancellation of medical devices from the ARTG	The TGA must cancel a device from the ARTG if: · the device has been suspended from the ARTG under section 41GA of the Act and the period applying to the suspension expires before the suspension is revoked under section 41GD; or · a TGA Conformity Assessment Certificate applying to that device is revoked under Part 4-4 of the Act. The TGA will provide written notice of the cancellation to the sponsor of the device.
Section 41GL—Immediate cancellation of devices from the ARTG	The TGA may, by written notice given to the sponsor, cancel the entry of a device from the ARTG if: · the TGA Delegate is satisfied that there would be an imminent risk of death, serious illness or serious injury if the device continues to be included in the ARTG; or · devices of that kind are no longer therapeutic goods; or · devices of that kind are no longer medical devices; or · the sponsor requests in writing the cancellation of the entry of the kind of device from the ARTG; or · the TGA Delegate is satisfied that a statement made in or in connection with the: – application for including the device in the ARTG – the certification or purported certification under section 41FD of the Act relating to the application; was false or misleading; or · the annual charge is not paid within 20 working days after it becomes payable; or the sponsor does not comply with the direction or requirement to ensure that advertising complies with the Therapeutic Goods Advertising Code; or there is a serious breach involving the device, of the requirements relating to advertising applicable under Part 5-1 or under the Regulations, and the TGA Delegate is satisfied that the breach is significant and the presentation of the devices is misleading to a significant extent.
Section 41GM—Cancellation of devices from the ARTG after section 41JA notice	The TGA may, by written notice given to the sponsor cancel the entry of a device from the ARTG if: · the TGA gives the sponsor a notice under section 41JA requiring them to give the TGA information or documents relating to the device and – the notice is given for the purposes of ascertaining whether the device should have been included in the ARTG – the sponsor fails to comply with the notice within a further 10 working days from the day specified in that notice

Legislative reference	Description
	· the TGA gives the sponsor a notice under section 41JA requiring them to give the TGA information or documents relating to whether medical devices are being: – supplied in Australia – imported into Australia – exported from Australia and either the: – information or documents given are to the effect that medical devices of that kind are not being supplied in Australia, imported into Australia or exported from Australia; or – sponsor fails to comply with the notice within a further 10 working days from the day specified in that notice.
Section 41GN—Cancellation of entries of devices from the ARTG after notice of proposed cancellation	Before cancelling the device from the ARTG under this section, the TGA must: · inform the sponsor in writing of the proposed cancellation and set out the reasons for it; and · give the sponsor a reasonable opportunity to make submissions to the TGA in relation to the proposed cancellation. The TGA will not make a decision relating to the proposed cancellation until any submissions from the sponsor have been considered. Examples of when the TGA may, by written notice to the sponsor, cancel a device from the ARTG are if: · a medical device has changed since inclusion on the ARTG so that device is no longer a device of the same kind · the sponsor refuses or fails to comply with a condition to which that inclusion is subject · the sponsor does not comply with a request for information under section 41JA of the Act · the sponsor does not notify the TGA of adverse events within the required timeframes · the TGA is satisfied that the safety or performance of the device is unacceptable · the TGA is satisfied that certification in relation to the application for inclusion of the device in the ARTG is incorrect, or is no longer correct. This includes: – compliance with the Essential Principles – application of conformity assessment procedures – compliance with advertising requirements.

The TGA must arrange for a notice to be published in the Gazette setting out particulars of the cancellation, as soon as practicable, after cancelling an entry from the ARTG.

Date of effect of cancellation of medical devices from the ARTG

If the TGA cancels a medical device from the ARTG the cancellation has effect:

- if the cancellation is under section 41GK or 41GL—on the day on which the notice of cancellation is given to the sponsor
- in any other case, on the date specified in the notice but not earlier than 20 working days after the notice is given to the sponsor

Product tampering

Any and all reports of actual or potential tampering with a medical device will be taken seriously and investigated, and should be immediately reported to the Australian Recall Coordinator. There is also a legal obligation for the sponsor under Section 42T of the Act to report such matters to the TGA within 2 days of becoming aware.

The Australian Recall Coordinator will convene a Crisis Reference Group (CRG) that will coordinate the activities required to resolve the crisis. For any tampering crisis, the CRG will comprise:

- Australian Recall Coordinator
- State or Territory Health Department Recall Co-ordinator
- appropriate State Police officers nominated for this purpose by the Police Ministerial Council
- senior personnel of the company concerned

The following documents have been developed as joint industry-government initiatives with the aim of assisting managers in responding to a product contamination and/or extortion event directed at the therapeutic goods industry:

- *Product Contamination & Extortion - A Protocol for the Therapeutic Goods Industry*
- *Crisis Management Guidelines - For the management of actual, potential or threatened tampering of medicines, complementary healthcare products and medical devices*

In order to maintain the usefulness of these documents, their availability is being limited to legitimate therapeutic goods industry stakeholders. These documents are available to sponsors from therapeutic goods industry associations or the TGA. Where a sponsor is a member of an industry association, access should be sought through that association in the first instance.

Where a sponsor of therapeutic goods is not a member of an industry association, a written request for a copy of the documents can be forwarded to the TGA. Such a request should be signed by a duly authorised person occupying a senior position within the sponsor's company.

Written requests should be forwarded to the:

Australian Recall Coordinator
Office of Product Review
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8636

Any requests for a copy of the documents by persons who are not sponsors of therapeutic goods will be considered on a case-by-case basis and may be referred to an expert committee for advice on whether release would be in the best interests of the therapeutic goods industry.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 02 6232 8444 Fax: 02 6232 8605
www.tga.gov.au

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