AUSTRALIAN MEDICAL DEVICES GUIDELINES

Postmarket Activities

Guidance Document Number 11

Version 1.7

TGA THERAPEUTIC GOODS ADMINISTRATION

Commonwealth Department of Health and Ageing

DISCLAIMER

This document is provided for guidance only. It should not be relied upon to address every aspect of relevant legislation. Please refer to the *Therapeutic Goods Act*, and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144
Facsimile: (02) 6232 8299
Email: cab.medical.device.information@health.gov.au
Website: www.tga.gov.au/devices/devices.htm
Post: PO Box 100
WODEN ACT 2606

AMENDMENT SCHEDULE

Version Number	Date of Amendment	Summary of Amendments

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INTRODUCTION

This guidance document is one of a series that has been produced to help explain the new regulatory system for medical devices in Australia that commenced on 5 October 2002. The new system has been established by the *Therapeutic Goods Ac, 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002* and the *Therapeutic Goods (Medical Devices) Regulations 2002.*

Many other guidance documents are available in this series. The series was developed to assist a wide-ranging audience and additional documents can be included if there is enough demand. A separate guidance document is available describing the series.

Although each guidance document has been developed to provide information about particular aspects of the new medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

This guidance document describes the obligations and responsibilities of sponsors and manufacturers of medical devices after medical devices have been approved for supply in Australia.

MEDICAL DEVICE POSTMARKET ACTIVITIES

Once a medical device has been approved for supply it is necessary to make sure that the product continues to meet all the regulatory, safety and performance requirements and standards that were required for the approval. This is in addition to ensuring that any problems with the product are dealt with and reported through appropriate channels. This postmarket phase for a medical device is as important as all of the pre-approval activities.

Manufacturers must hold and make available on request by the TGA, the technical documentation that demonstrates the conformity of their products with the essential principles and evidence that an appropriate conformity assessment procedure has been applied. Sponsors must have access to this evidence and be able to provide it on request.

There are three major components of postmarket activities. The sponsor of the medical device has a role to play in each of them. The components are:

1. The manufacturer's post-market surveillance system,
2. Post-market monitoring of market compliance by the TGA, and
3. Vigilance programs.

1. The manufacturer's post-market surveillance system

The manufacturer's post-marketing surveillance system enables the manufacturer to gain and review experience about their medical devices supplied in Australia. The surveillance activities are part of the manufacturer's overall quality manufacturing system. They are also undertaken as one of the conditions of supplying the medical device in Australia, or simply as a result of ongoing research and development.

The post-market surveillance system requires manufacturers to:

- systematically review experiences gained after the device was supplied in Australia;
- implement corrective action, commensurate with the nature and risks involved with the medical device and;
- notify the sponsors of the medical device of adverse events and near events.

Information feeding into the surveillance system can come from many sources:

- 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 registers, and
- user reactions during training programs.

In most cases, the manufacturer's surveillance system already exists as part of the internal quality system. 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 a post-marketing system.

2. Post market monitoring of market compliance by the TGA

Market monitoring by the TGA is a series of activities carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market and to take action when this does not occur.

Monitoring activities may include:

- audits of technical and clinical information to show compliance to the essential principles;
- inspections of manufacturer's or sponsor's records and documentation;
- on-site tests or taking samples for off-site testing;
- testing or auditing to confirm compliance with the essential principles;
- audits of distribution records;

- audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts; and

- audits of compliance with Good Manufacturing Practice (GMP) requirements for selected therapeutic goods.

If problems are found the TGA may cancel or suspend entries in the ARTG under Part 4-6 of the Act. Other parts of the Act could then be invoked leading to:

- recalls (outlined in the section, Recalls of Therapeutic Goods, on page 20),
- safety alerts (outlined in the section, Non-Recall Actions for Therapeutic Goods, on page 21), and
- product improvements undertaken by the manufacturer.

3. Vigilance Programs

Vigilance programs are a range of activities undertaken by the TGA and the manufacturer or sponsor after any party becomes aware of:

- adverse events,
- malfunctions,
- results of testing, or
- other information,

about medical devices supplied in Australia.

Under the new regulatory system, notification and evaluation of adverse events is known as the Medical Devices Vigilance System. The vigilance system improves the health and safety of patients, users and others by reducing the likelihood of an adverse event being repeated. This is achieved by:

- evaluating reported adverse events;

- disseminating information, where appropriate, that could be used to prevent such repetitions, or to alleviate the consequences of such incidents; and

- modifying, where appropriate, the medical device or removing it from the market.

All adverse events, regardless of whether they have to be reported under the vigilance system, should be included in the manufacturer's post-market system.

AUSTRALIAN SPONSOR'S POST-MARKET RESPONSIBILITIES

The sponsor is responsible for ensuring that the manufacturer of the medical devices has procedures in-place for the introduction and maintenance of the post-marketing surveillance system. They should also have procedures to:

- collect information from users about incidents and the performance of devices and send this information to the manufacturer (section 41FN of the Act);
- report details of certain incidents and performance issues to the TGA (section 41FN of the Act);
- report any overseas regulatory actions to the TGA if the product involved from the same batch or production run was supplied in Australia (section 41FN of the Act);
- report results of investigations undertaken by the manufacturer to the TGA (section 41FN of the Act);
- assist the TGA and the manufacturer in the investigations (section 41FN of the Act);
- follow-up action taken under the Vigilance System (section 41KA of the Act); and
- maintain distribution records for product supplied in or exported from Australia (section 41FO of the Act).

- In addition, the sponsor is required to have access to:
- the technical documentation that demonstrates the conformity of the products to the essential principles (section 41FN of the Act), and
- evidence that appropriate conformity assessment procedures have been applied (section 41FN of the Act).

ADVERSE EVENTS

An "adverse event" is defined as an event that led to a death, or led to a serious injury to a patient, user or other person.

Serious injury (also known as serious deterioration in state of health) is:

- a life threatening illness or injury,
- a permanent impairment of a body function,
  (The term "permanent" means irreversible impairment or damage to a body structure or function. The term excludes minor impairment or damage.)
- permanent damage to a body structure, or
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
  (In this context, medical intervention is not in itself a serious injury. It is the reason that

motivated the medical intervention that should be used to assess whether an event should be reported.)

A "near adverse event" is defined as an event that might have led to a death or serious injury. 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 or;
- testing or examination of the device or the information supplied with the device, or scientific literature, indicated some factor which could lead to a death or serious injury.

REPORTING

To improve the monitoring of the performance of medical devices supplied in Australia, the TGA encourages the reporting of adverse events by the users. The TGA will, without delay, ensure that the sponsor of the medical device is informed about adverse event notifications it receives.

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

The sponsor is responsible for forwarding reports of all incidents to the manufacturer for assessment under the manufacturer's post-marketing system. It is possible that the sponsor will not have enough information to decide if the event should be reported to the TGA. In such a case, the sponsor should make reasonable efforts to obtain additional information to assist the manufacturer to make this decision. Where appropriate, the manufacturer should consult with the medical practitioners or other health-care professionals involved, and do their utmost to retrieve the particular device. If there is any doubt about whether an incident report should be submitted, the report should be submitted. 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 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 entry from the Register (Part 4-6 of the Act), as well as constituting an offence (section 41MN of the Act).

REPORTABLE EVENTS

The TGA, along with several international partners in the Global Harmonisation Task Force, have developed agreements and documents to promote a harmonised approach to medical device regulation around the world. One of the study groups within the Task Force, Study Group 2, has produced the document "Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (SG2-N21R8)". This document has established threshold criteria for adverse event reporting that will be implemented by the TGA. Consequently, any event that meets three basic reporting criteria, even if it does not involve a patient or user, should be reported to the TGA:

1. An adverse event has occurred.
2. The manufacturer's medical device is associated with the event.
3. The event led to death or serious injury, or might lead to death or serious injury if it were to occur again.

1. An adverse event has occurred

In this instance the manufacturer or sponsor becomes aware of information about an adverse event that is associated with the device they manufacture or supply. This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

Typical events are:

- A malfunction or deterioration in the characteristics or performance of a medical device. A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions. The intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in advertising materials.

- An inadequate design or manufacture of a medical device.
  This would include cases where the design or manufacturing of a device is found deficient.

- An inaccuracy in the labelling, instructions for use and/or promotional materials for a medical device.
  Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.

- A significant public health concern.
  This can include an event that is of significant and unexpected nature that becomes a potential public health hazard, eg. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). The TGA, the sponsor, or the manufacturer may identify these concerns.

- Other information becoming available.
  This can include information from the literature or other scientific documentation or the results of testing performed by the manufacturer on its products, or by the user prior to being used on the patient, or by other parties.

2. The manufacturer's medical device is associated with the event

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 care professional;
- information concerning previous, similar events;
- other information held by the sponsor.

This judgement may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event.

3. The event led to death or serious injury, or might lead to death or serious injury if it were to occur again.

These factors are:

- a death of a patient, user or other person.
- a serious injury of a patient, user or other person.
  (The interpretation of the term "serious" is not easy, and should be made in consultation with a medical practitioner when appropriate.)
- where no death or serious injury had occurred but the event might lead to the death or serious injury of a patient, user or other person if the event recurs. These types of events are also known as "near incidents".

Not all events lead to a death or serious injury or involve a patient or user. It may be that due to circumstances or to the timely intervention of health care personnel a death or serious injury did not occur. The event is considered "adverse", if in the case of re-occurrence, it could lead to death or serious injury. This applies also if:

- the examination of the device,
- a deficiency in the information supplied with the device,
- any information associated with the device, or
- results of testing

indicates some factor which could lead to an event involving death or serious injury.

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 significant blood loss.

Examples of reportable adverse events involving public health concerns

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

REPORTING EXEMPTION RULES

A report is not required if any one of the exemption rules apply. However, these rules do not apply to:

- a product, event or issue identified by the TGA;
- an adverse event, even if normally subject to a reporting exemption, where a change in trend (usually an increase in frequency) or pattern is identified; and
- adverse events associated with user error.

Whenever any one of the following eight exemption rules apply, the adverse event does not need to be reported to the TGA.

Rule Number	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. **Note:** *If the device is used the exemption does not apply - the event must be reported.*	**1.** 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. **2.** 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. **3.** 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 medical judgement would accept the same conclusion.	**1.** An orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision. **2.** The early revision of an orthopaedic implant due to loosening caused by the patient developing osteoporosis. **3.** A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.

Rule Number	Exemption Rule	Examples of adverse events exempt from reporting
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 mode is not unusual, the adverse event does not need to be 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.	**1.** 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. **2.** 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.
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 hazard (in accordance with relevant standards or documented design inputs), do not need to be reported.	**1.** An infusion pump stops, due to a malfunction, but gives an appropriate alarm (eg in compliance with relevant standards) and there was no injury to the patient. **2.** Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm, in compliance with relevant standards and there was no injury to the patient. **3.** 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.

Rule Number	Exemption Rule	Examples of adverse events exempt from reporting
5	**Remote likelihood of occurrence of death or serious injury** Adverse events which 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. **Note:** *A change in the trend(usually an increase in frequency)of these non-serious outcomes must be reported.*	**1.** 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. **2.** 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 instruction for use or labelling** Side effects which 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.	**1.** A patient receives a second-degree burn during the use of an external defibrillator in an emergency. The risk assessment 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. **2.** A patient has an undesirable tissue reaction that is previously known and documented in the device master record. **3.** A patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.

		4. 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.	**1.** 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.** Common and well-documented events may be exempted by the TGA from reporting or changed to periodic reporting upon request by the sponsor.	

TIMEFRAMES FOR SUBMITTING ADVERSE EVENT REPORTS

When a manufacturer becomes aware that an event associated with one of their devices has occurred, they, in conjunction with the sponsor, must determine whether it is a reportable adverse event.

If the event is a reportable "near adverse event", or the event did not result in death or serious injury, the sponsor must submit a manufacturer's report of the adverse event no later than 30 calendar days from the date of becoming aware of the event. (regulation 5.7(1)(c) of the *Therapeutic Goods (Medical Devices) Regulations 2002*)

If the event resulted in a serious injury or a death, the sponsor must submit a manufacturer's report of the adverse event no later than 10 calendar days from the date of becoming aware of the event. (regulation 5.7(1)(b) of the *Therapeutic Goods (Medical Devices) Regulations 2002*)

Reports of issues that represent a serious public health threat or concern, where there is imminent risk of death, serious injury, or serious illness and may require prompt remedial action, must be submitted within 48 hours. (regulation 5.7(1)(a) of the *Therapeutic Goods (Medical Devices) Regulations 2002*). The 48-hour timeframe is reserved for major issues where new evidence suggests that the risk profile of a device is not acceptable.

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 Register (Part 4-6 of the Act), as well as constituting an offence. (section 41MN(1) of the Act).

DETAILS TO BE INCLUDED IN A REPORT

The report should include the following details as appropriate:

- the sponsor's name, address, contact point, telephone number, fax number;
- the date when the incident came to the knowledge of the manufacturer and sponsor;
- the kind of medical device, the commercial name, the catalogue number and/or the model, serial, batch and lot number, and the software version;
- 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 the person who actually witnessed the event. It is recommended that health care facilities have a contact person for all reported events;
- any manufacturer's and sponsor's comments;
- the action taken or proposed action and time-scale;
- a statement of whether the manufacturer and sponsor are aware of similar events having an impact on the current report. If a statement is provided, the names of any other regulatory authorities to which these events have been reported, and the reference date of the reports should be provided;
- the names of other countries in which the medical device is known to be on sale or supplied.

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.

An Adverse Event Report Form that should only be used by manufacturers or sponsors is included as Attachment 1. Medical device users and others are requested to use the Medical Device Incident Report Form included as Attachment 2. Copies of both forms can be downloaded from the TGA website.

ANNUAL REPORTS OF PROBLEMS – CLASS III & ACTIVE IMPLANTABLE MEDICAL DEVICES

In addition to the adverse event reports required under the vigilance provisions, annual summarised reports are required for all Class III devices and Active Implantable Medical Devices (AIMDs). The reports should include all the complaint, difficulty, malfunction and adverse event reports received by the sponsor over the year. The reports are reviewed in the medical devices program area and logged as section 28 reports. Any issues are raised with the company, either directly or through the Incident Report Investigation Scheme (IRIS) program area.

A summarised report of problems relating to the condition, use or application of the medical devices between 1 July and 1 October following the date of entry in the ARTG is required. Annual summarised reports between 1 July and 1 October for the following three years are then required.

ADDRESS FOR SUBMISSION OF ADVERSE EVENTS AND OTHER REPORTS

Reports can be submitted to:

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

Email: iris@health.gov.au
Facsimile: 02 6232 8555
Telephone: 1800 809 361

ACCESS TO A DEVICE SUSPECTED TO BE INVOLVED IN THE EVENT

A manufacturer, through a sponsor should, as necessary, consult with the medical device user about a particular event before a report is submitted to the TGA. The manufacturer may also wish to have access to the medical device involved in the event to help decide whether the event should be reported to the TGA. Such access would be at the discretion of the user or health-care facility concerned, but they should be encouraged to allow the manufacturer to apply their post-marketing system to determine the root cause of the incident.

If the manufacturer gains access to the medical device, and the initial assessment, or cleaning or decontamination process, will involve altering the device in a way which may affect subsequent analysis, the manufacturer should, through the sponsor, inform the TGA before proceeding.

Where the health-care facility sends the medical device directly to the TGA, the device will be inspected and its condition recorded and described. The TGA will not carry out any destructive testing without consulting both the manufacturer, through the sponsor, of the medical device and the healthcare-facility or reporter. On completion of the examination the medical device will generally be sent to the manufacturer, again through the sponsor, for their analysis provided the healthcare facility consents. The TGA encourages release of the medical device to the manufacturer so that they can complete their analysis.

VIGILANCE EXCHANGE

The exchange of vigilance information is known as the National Competentent Authority Reporting (NCAR) Program. Through its participation in the GHTF and various Mutual Recognition Agreements for medical device regulation, the TGA has an obligation to exchange this information with overseas regulatory agencies. This procedure is described in a document developed by Study Group 2 and is titled "Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria (SG2-N20R10)". Consequently, information will be exchanged on incidents and events where:

- corrective action, including recalls, is to be taken;
- there is a serious risk to the safety of patients or other users, but where no corrective action has yet been established although measures are under consideration, or where there is not yet a final report from the sponsor.

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. In the case of doubt, however, there is a predisposition on the part of regulatory agencies to disseminate the information.

The TGA will consult the sponsor when preparing a report. 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.

ENFORCEMENT

Additional elements of the efforts to provide for the "establishment and maintenance of a national system of controls relating to…..therapeutic goods", as listed in the Objects of the Act, to ensure that products supplied the Australian market place are safe, efficacious and are of suitable quality are focussed on:

- monitoring compliance with the Act,
- investigating alleged breaches of the Act, including illegal supply, and
- initiating criminal prosecutions where appropriate.

These are the tasks of the Surveillance Unit of the TGA.

Options available to the TGA include criminal prosecutions under section 5A for offences included in the Act and fines detailed in many other parts. Illicit goods that have been seized during these investigations are forfeited to the Commonwealth and destroyed.

For further information or to provide information about the illegal supply of medical devices contact:

The Manager
Surveillance Unit
Business and Services Branch
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8640
Facsimile: 02 6232 8643

RECALLS OF THERAPEUTIC GOODS

When the need for a recall of a therapeutic good supplied in Australia has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods, or corrective action, while the Australian Recall Coordinator in the TGA assists by:

- advising the sponsor of the procedures,
- notifying agreed third parties, and
- monitoring the overall action.

The use of the "Uniform Recall Procedure for Therapeutic Goods" is obligatory for safety related recalls of therapeutic goods.

Most recalls are conducted on a voluntary basis. However, the *Therapeutic Goods Act 1989* and the *Trade Practices Act 1974* underpin the procedure. Recall provisions can be applied under the *Therapeutic Goods Act 1989* when:

- therapeutic goods are cancelled from the ARTG (section 30); or
- where therapeutic goods are unlawfully supplied in Australia (section 30A);
- where therapeutic goods fail to comply with an applicable standard (section 30B); or
- where therapeutic goods have been or could possibly be, subject to actual or potential tampering (section 42T)

The *Trade Practices Act 1974* contains provisions about the safety-related recall of consumer goods. The relevant parts of that Act, which are administered by the Consumer Affairs Division of the Department of Treasury, empower the Commonwealth Minister for Financial Services to take action when:

- notification is not made of safety related recalls, or
- where the recall has not been satisfactorily completed.

According to the Procedure, "…Failure to notify the Minister for Financial Services and Regulation of a safety related recall within two days of taking that action, or failure to provide the Minister for Financial Services and Regulation within ten days with a copy of notice sent to an overseas client advising of recall, have penalties of up to $15,000 for a corporation or a fine up to $3,000 for an individual.

Suppliers should also note that the Act empowers the Minister for Financial Services and Regulation to impose a mandatory recall if a supplier has not taken satisfactory action to remove the hazard created by the goods. Section 65L of the Act allows the Minister for Financial Services and Regulation to order an immediate recall of goods if the goods create an imminent risk of death, serious illness, or serious injury. This power has been used to order recall of therapeutic goods. A corporation convicted of a failure to comply with a mandatory recall may be fined up to $200,000 and an individual in a contravention up to $40,000."

Sponsors can use relevant parts of the Procedure to disseminate emergency information on the safe use of therapeutic goods. This will normally be restricted to situations involving a significant safety factor and where national distribution of the affected goods has occurred.

Detailed information about recalls can be found in the document "Uniform Recall Procedure for Therapeutic Goods" available from the TGA website at http://www.tga.gov.au/docs/pdf/urptg.pdf.

For further information contact:

Australian Recall Coordinator
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
MDP 122
PO Box 100
WODEN ACT 2606

Telephone: 02 6232 8637
Facsimile: 02 6232 8687

NON-RECALL ACTIONS FOR THERAPEUTIC GOODS

The Uniform Recall Procedure for Therapeutic Goods points out that:

- a safety alert (advice about a specific situation where a therapeutic good, while meeting all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions are not observed. Safety alerts are intended only to provide information on the safe use of therapeutic goods.),
- a product notification (precautionary information about a therapeutic good, when it is unlikely to involve significant adverse health consequences),
- withdrawal (therapeutic goods removed from supply or use for reasons not related to their quality, safety or efficacy), and
- recovery (therapeutic goods removed from sale or supply by the sponsor that have not left their direct control).

are four actions which are not recall actions, and are therefore not subject to the Procedure.

However, hazard alerts are considered to be recall actions which are subject to the Procedure. A hazard alert means issuing precautionary information about an implanted device where it has been proven that there is no stock to be recalled and all affected devices are already implanted. Hazard alerts only relate to implantable medical devices. The appropriate action to be taken, particularly where patient safety may be a consideration should be discussed with the Australian Recall Coordinator.

Sponsors of therapeutic goods may use appropriate sections of the Procedure to assist disseminating safety alert information. Copies of safety alerts should be forwarded to the Australian Recall Coordinator for distribution to the relevant health authorities for their information.

OFFENCES, PENALTIES AND CANCELLATIONS

Offences and penalties

The offences in the Act include:

- illegal importation, exportation, manufacture or supply of medical devices not included in the register and not subject to an appropriate exemption (section 41MI with maximum penalties for individuals of imprisonment for 12 months or $110 000, or both, and $550 000 for corporations);
- non-compliance with the essential principles, unless the Secretary has consented (sections 41MA with maximum penalties for individuals of imprisonment for 12 months or $110 000, or both, and $550 000 for corporations);
- non-application of an appropriate conformity assessment procedure (sections 41ME and 41MF with maximum penalties for individuals of imprisonment for 12 months or $110 000, or both, and $550 000 for corporations);
- failure to comply with the conditions of entry in the ARTG (section 41MN with maximum penalties of $26 400 for individuals and $132 000 for corporations);
- failure to comply with the conditions of a conformity assessment certificate (section 41MN with maximum penalties of $26 400 for individuals and $132 000 for corporations);
- failure to notify adverse events (section 41MP with maximum penalties of $44 000 for individuals and $220 000 for corporations);
- failure to notify adverse events etc where an application is withdrawn or lapses (section 41MQ with maximum penalties of $44 000 for individuals and $220 000 for corporations);
- misuse of medical devices exempted for special or experimental uses (section 41MO with maximum penalties of $6 600 for individuals and $33 000 for corporations);
- claims about arranging supplies of medical devices not included in the ARTG (section 41MM with maximum penalties of $6 600 for individuals and $33 000 for corporations);
- making false declarations at the time of entry in the ARTG (section 41MH with maximum penalties for individuals of imprisonment for 12 months or $220 000, or both, and $1 100 000 for corporations) and;
- making misrepresentations about medical devices (section 41ML with maximum penalties of $6 600 for individuals and $33 000 for corporations).

Other penalties

In addition to financial penalties for offences under the Act, other penalties can be applied for a failure to comply with provisions of the Act. These include:

- suspension or cancellation of the medical device from the ARTG (Part 4-6);
- suspension or revocation of conformity assessment certification (Part 4-4 Division 3 and Division 4); and the
- recall of medical devices supplied, either to batch level or all medical devices (section 41MI(1)).

Cancellations

The TGA will cancel products from the register under Part 4-6 of the Act only in those cases where there has been a severe breach of the law or, more often, where there is a safety concern associated with the use of the product. If a sponsor cannot satisfactorily establish the quality, safety or efficacy of their product and a decision to cancel the entries in the ARTG is confirmed, the sponsor will also be required to recall any affected products.

The principles of natural justice are followed by the TGA whenever a proposal to cancel a product in the ARTG is considered. The cancellation proposal will be submitted to a sponsor and they will be allowed a certain period of time to show cause why the cancellation should not take occur. The sponsor may also be given the opportunity to submit any data to support their case. A decision will be made when this time has elapsed and any submitted information has been assessed. If it is decided to cancel the registration, listing or inclusion, sponsors normally have an opportunity to lodge an appeal. The sponsor's rights in the cancellation process are explained in the cancellation letter.

DISTRIBUTION RECORDS AND OTHER KINDS OF INFORMATION

Under section 41FO of the Act sponsors of medical devices supplied in 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 the medical devices.

Each sponsor is required to retain the distribution records for their medical devices for five years after the last product has been made and to provide the records, or copies of the records, when requested by the TGA (Regulation 8.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*).

There are other kinds of information that must be kept available about compliance with the essential principles and the application of appropriate conformity assessment procedures under section 41FN of the Act. Among these are:

- the product's full technical documentation,
- risk assessment, and
- quality records.

For more information please refer to the guidance documents dealing with the essential principles, conformity assessment procedures and the conditions of entry in the ARTG.

ATTACHMENT 1 – ADVERSE EVENT REPORT FORM

(For use by medical device manufacturers, sponsors or authorised representatives for mandatory reporting)

Last revised: October 2002

TGA THERAPEUTIC GOODS ADMINISTRATION

Form # MDIR01, for use by medical device manufacturers, or authorised representatives for mandatory reporting. For voluntary user reporting please use Form # UDIR01

-Mfr report #	
-TGA DIR #	

IRIS: Medical Device Incident Report Investigation Scheme

I- Administrative Information

Report Type (select one)

Initial ☐ Follow-Up ☐ Final ☐ Trend ☐

Report Category

S Pblc Hlth Threat ☐ Death/Serious Injury ☐ Other ☐

Date of this report (dd-mmm-yyyy)	
Date of adverse event (dd-mmm-yyyy)	
Date mfr aware (dd-mmm-yyyy)	
Date of next report (dd-mmm-yyyy or n/a)	

Person (authorised representative), submitting this report

Name			
Company			
Address			
Tel.		Fax	
E-mail			

Identity of other Regulatory Authorities, Notified Bodies, etc., that this report was *also* sent.

II- Clinical Event Information

Description of event or problem

III- Healthcare Facility Information

Name			
Address			
Tel		Fax	
E-mail			
Contact name at site of event			

IV- Device Information

Generic Device Information

Device ARTG #	
GMDN Code	

GMDN Code Text (eg catheters, central venous, peripherally inserted)

Specific Device Information

Brand Name			
Model #			
Catalogue #			
Ser. or Lot #'s			
Mfr. Name			
Contact Name			
Address			
Tel.		Fax	
E-mail			
ARTG Mfr. #			

Operator of Device at Time of Event (select one)

HC Prof'nal ☐ Other Caregiver ☐ Patient ☐ N/A ☐

Usage of Device

Single Use ☐ Reuse of Single Use ☐

Reuse of Reusable ☐ Re-serviced/Refurbished ☐

Device Disposition/Current Location

V- Results of Mfr's Investigation

Manufacturers Device Analysis Results

(Specify, for this event, details of investigation methods, results, and conclusions)

Remedial Action/Corrective Action/Preventive Action

(Specify if/what action was taken for the reported specific event or for all similar type of events or products. Include what action was taken to prevent recurrence. Clarify the timeframes for completion of various action plans.)

VI- Patient Information (rpt. if required)

Age (yrs, mnths)		M/F		Wt. (kg)	

Patient-focused resolution of events and Outcomes

Corrective action taken relevant to the care of the patient:

Patient outcome:

List of other devices involved in the event

VII- Other Reporting Information

Mfr/Sponsor aware of other similar events? (#, rate or N/A)

Countries where these similar adverse events occurred:

Additional Comments

Submitting this report:

By mail: Reply Paid 32
IRIS : Medical Device Incident Report Investigation Scheme
PO Box 100, Woden, ACT 2606

By fax: +61 (0) 2 6232 8555

By e-mail: iris@health.gov.au

Submission of this report does not constitute an admission that medical personnel, healthcare facility, sponsor, distributor, manufacturer or product caused or contributed to the event.

Guidance on how to fill this form

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time)

If some of the applicable information required in this form is not available by the time the deadline (2, 10, or 30 days) for the particular category of report has expired, a report should be submitted containing all the available information. Such a report should be marked "initial" in Section I.

The form may be filled long-hand or electronically using Word® - simply <tab> to the appropriate field and type the required information. The form can then be submitted by fax or mail or saved and attached to an email and sent to the email address provided. This page should not be included in the submission (This section is not protected and may be deleted).

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Section I – Administrative Information

Report Type, Initial: The first report that the reporter (reporter, manufacturer) is submitting about an event. The reporter expects to have to submit further information about the event at a later date.

Report Type, Follow-up: Additional information to a previous (initial, follow-up or final) report.

Report Type, Final: The last report that the reporter expects to submit about an event. It is possible for the final report to be the first report about an event.

Report Type, Trend: Under Quality Management System requirements, the manufacturer is expected to monitor trends of significant adverse events. Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called "trend" reports.

Report Category, S Pblc Hlth Threat: (Serious Public Health Threat or concern) these reports must be submitted within 48 hours of the manuafcaturer becoming aware of the event, please refer to the Medical Devices Regulations and Guidance for interpretation on the meaninng of this description.

Report Category, Death/Serious Injury: Choose this category where the event subject of the report resulted in the death or serious injury of a patient, user or other person.

Report Category, Other: Choose this category where the event subject of the report was a "near miss" or is the result of testing or other analysis and an event or further occurence could lead to the death or serious injury of a patient, user or other person.

Section IV - Device Information

Device ARTG #: The number assigned to the device in the ARTG.

GMDN Code & Text: Global Medical Device Nomenclature (GMDN) Code and explanatory text, (eg 40589 – clamp, surgical tubing, single use).

ARTG Mfr #: The number assigned to the device manufacturer in the ARTG.

Device Disposition/Current Location: Where and in what state the device is at the time of the report – eg destroyed/lost or with manufacturer undergoing testing, or with original reporter, etc.

Section VI – Patient Information

(Note: in some cases, the patient's age gender and/or weight will be irrelevant. In others this information will be essential - eg weight of patient in regards to orthopedic implants – The reporter should exercise judgement when filling these fields.)

List of other devices involved in the event…. Some events are caused by the combined action of two or more medical or other devices. A brief list any other device(s) involved should be provided.

Section VII - Other Reporting Information

Mfr/Sponsor aware of other similar events? (# or N/A): If there have been other similar events reported to either the sponssor or the manufacturer enter the number. The number should preferably be provided in the form of an incidence rate, for example: 12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over 5 years worldwide. If none write "0".

ATTACHMENT 2 – MEDICAL DEVICE INCIDENT REPORT FORM

Commonwealth Department of Health and Ageing

TGA THERAPEUTIC GOODS ADMINISTRATION

MEDSAFE NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY

A BUSINESS UNIT OF THE MINISTRY OF HEALTH

The Australian and New Zealand Medical Device Incident Report Investigation Scheme

What is it? A medical device is any material instrument, apparatus, machine implement, contrivance, implant etc including any component, part or accessory which is used in health care and includes in-vitro diagnostics. The Scheme is a joint venture between the Australian Therapeutic Goods Administration and Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, intended to help maintain the standard of devices used in health care through voluntary co-operation between users, government and industry. It should be used in conjunction with local reporting channels. It provides an additional means by which unsafe products or procedures can be identified quickly so that appropriate action is taken.

Medical device users (clinicians, patients or their relatives, etc.) should use this form to report any suspected problems with a medical device which has or may present a health hazard. Reports originating in Australia should be sent to the Therapeutic Goods Administration and reports originating in New Zealand should be sent to the Ministry of Health.

What should be reported? Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. If appropriate both Agencies will assess the issue and it may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following: 1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, efficiency or quality. 2. Safety Alert - urgent information to inform those responsible for the device, or affected by the problem. 3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical Device Incident Report

Form # UDIR01: For use by medical device users to report any suspected problem with a medical device that may create a health hazard. Medical device manufacturers or their authorised representative should use form # MDIR01.

A. Product Identification *(Provide all available details. Where * appears, delete whichever is not applicable)*

1. Product Type/Application (eg Urinary Catheter)

2. Brand/Trade * Name and Model Number

3. Serial/Batch/Lot * Number

4. Date of manufacture | Date of purchase | Date of expiry | * AUSTL or AUSTR No.

5. Manufacturer's name address and telephone

6. Supplier's name address and telephone

7. Has the manufacturer been informed of the problem? Yes ☐ No ☐

   If Yes, please supply the date and contact name

8. Is the product/packaging * available for inspection? Yes ☐ No ☐ ***(please do not discard these items)***

Important: Please fill in Sections B and C overleaf

B. Problem Description:

1. Consequences and history of problem:
(please Include history, circumstances, consequences and where relevant sketches or explanatory information)

C. Reporter Identification Do you want your identity to remain confidential? Yes ☐ No ☐

1.	Name			
2.	Position/ occupation			
3.	Dept **AND** Institution			
4.	Address			
5.	Telephone		Facsimile	
6.	E-mail		Date	
7.	Initial Reporter			
8.	Occ'n. and Dept **at** Instn.			
9.	Telephone		Facsimile	

D. Submitting the Form

In Australia:

Reply Paid 32
IRIS: Medical Device Incident Report Investigation Scheme
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
AUSTRALIA

Fax Number: (02) 6232 8555,
E-mail : **iris@health.gov.au**
Urgent problems may be reported by telephone to our **HOTLINE : 1800 809 361**

In New Zealand:

Compliance Team
Medsafe
Ministry of Health
PO Box 5013, Wellington
NEW ZEALAND

Fax Number: (04) 496 2599,
E-mail : **trevor_nisbet@moh.govt.nz**
Urgent problems may be reported by telephone on **(04) 496 2364**