Australian Government
Department of Health
Therapeutic Goods Administration

Medical device adverse event reports

Statistics for 2013

Version 1.0, June 2014

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Product Review	05/06/2014

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Foreword

The Therapeutic Goods Administration (TGA) is responsible for regulating medical devices in Australia, including monitoring the ongoing safety, performance and quality of devices once they have been included on the Australian Register of Therapeutic Goods (ARTG).

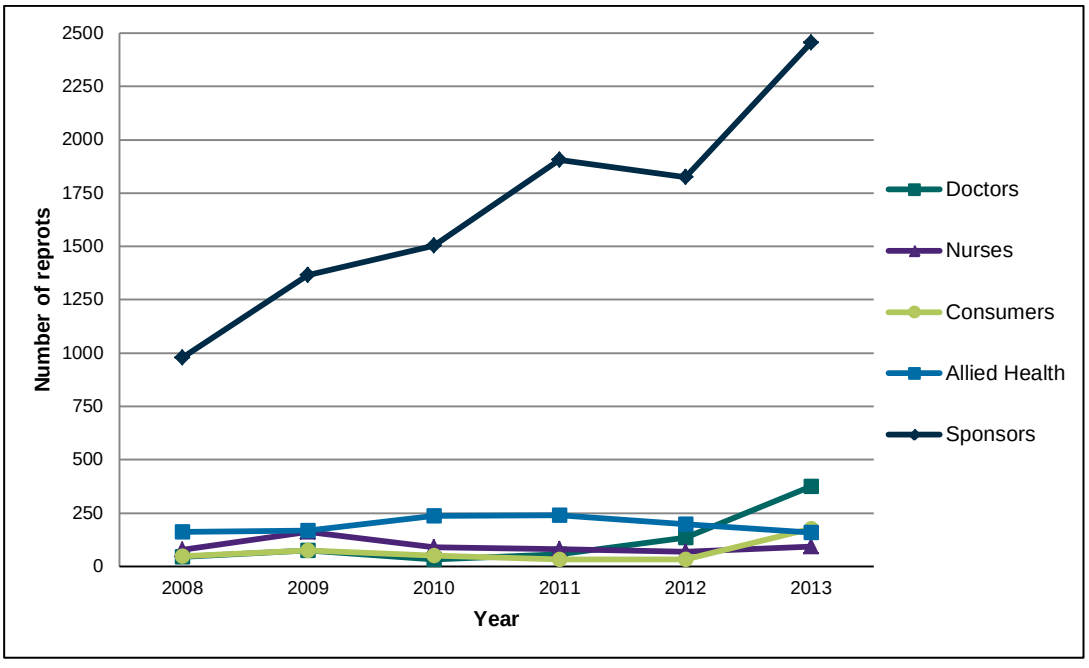
This report from the TGA's Office of Product Review (OPR) includes an overview of the following aspects of post-market monitoring of medical devices in Australia:

- Medical device adverse event reporting statistics for 2013
- How the Incident Report and Investigation Scheme works
- How to report an adverse event involving a medical device
- Post-market reviews
- Expert advisory committees
- Medical Devices Safety Update
- Product vigilance

Medical device adverse event reporting statistics for 2013

The TGA's Incident Report and Investigation Scheme (IRIS) commenced in 1986. Since its inception, the TGA has received more than 32,300 adverse event reports involving medical devices.

Figure 1: Origin of medical device adverse event reports received by the TGA (2008–13)



In 2013, the TGA received 3309 adverse event reports relating to medical devices. As shown in Figure 1, the vast majority of reports made in 2013 were by sponsors of medical devices. The number of reports made by sponsors resumed an upward trend to a record high of 2456 after a one-year dip from 2011-2012. The number of reports made by doctors increased from 136 in 2012 (6% of all reports) to 376 in 2013 (11%). The 2013 rate of reporting from nurses and allied health professionals remained relatively constant compared with 2012. Allied health

professionals provided 158 reports (5% of all reports) and nurses provided 93 reports (3%). There was a large increase in reports from consumers with 178 reports (5%) in 2013, up from 32 reports in 2012.

It is important to note that it is mandatory under the *Therapeutic Goods Act 1989* for sponsors and manufacturers to report adverse events that have led to or could have led to a death, serious illness or injury to a patient, person using the device or others. There are some exemptions under the Australian regulatory guidelines for medical devices (ARGMD). All other adverse event reports are submitted on a voluntary basis. The majority of reports submitted from allied health professionals are from hospital supply and administration areas. The remainder of the reports are submitted by a range of allied health professionals, including biomedical engineers, clinical technicians, ambulance officers, laboratory technicians, pharmacists and dentists.

The TGA encourages both users and health professionals to report any adverse event they encounter involving a medical device.

How the Incident Report and Investigation Scheme works

The aim of the IRIS is to improve the standard of medical devices and to reduce the number and severity of adverse events involving devices in Australia through voluntary cooperation between medical device users, industry and government.

While suppliers and/or manufacturers are responsible for their products, the IRIS plays an important role in ensuring effective and efficient resolution or prevention of adverse events.

If you purchase, use or maintain medical devices, you are encouraged to report adverse events or difficulties associated with their use. An adverse event that has caused, or could have caused, an injury to the patient or the device user should be reported.

In Australia, reporting of such events by sponsors and manufacturers is mandatory. In addition to reporting safety issues, everyone is encouraged to report any issues associated with the quality and performance of medical devices, such as compromised sterility, packaging or labelling defects and poor construction or design.

All adverse events are risk assessed. A panel of scientific, engineering and clinical experts at the TGA assesses reports that require further investigation in cases where an adverse event may lead to, or have led to, serious injury or death. These types of events are given the highest priority.

Unusual adverse events, events that may have led to injury, or events that have unusually high levels of incidence, are routinely investigated. Isolated adverse events or events that are not likely to lead to an injury or have a detrimental effect on effectiveness are reviewed.

All reports are entered into the IRIS database for trending purposes and so that they may be easily referenced in the future. Once a report has been recommended for further investigation, it is assigned to the most appropriately qualified investigator.

The investigator will work with the company and the reporter to resolve the issue. Final outcomes may include, but are not limited to:

- publication of a safety alert or article in Medical Devices Safety Update and/or on the TGA website
- product improvement
- changes to the instructions for use (IFU)

- compliance testing
- user education
- recall
- cancellation.

Reports are treated confidentially, and both the reporter and the sponsor are informed of the outcome of the investigation.

The TGA may also exchange information relating to significant safety issues with other regulatory agencies. This is done via the National Competent Authority Reporting (NCAR) program. Information is exchanged on adverse events where corrective action, including recalls, is to be taken and there is a serious risk to the safety of patients and other users.

How to report an adverse event involving a medical device

While specific adverse event reporting is mandatory for sponsors and manufacturers of medical devices in Australia (see the Australian regulatory guidelines for medical devices Part 3 – Post-market, Section 22), the TGA encourages consumers and health professionals to report of any adverse events associated with the use of a medical device.

Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm. Some medical device issues that can lead to adverse events and initiate a report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors.

For further information about reporting suspected adverse events, visit the TGA website (click on 'Report a problem').

Post-market reviews

The TGA has the capability to undertake proactive post-market reviews on issues noted with medical devices included on the ARTG.

These issues are often derived from, but not limited to:

- adverse event reports
- unresolved/repeated recalls
- recurrent breaches of the Advertising Code
- findings of TGA laboratory testing (routine or as part of an investigation of an adverse event report).

Post-market reviews primarily focus on issues affecting a type of device, therefore all similar devices will be reviewed.

Other types of reviews may focus on an ingredient/formulation, material or manufacturing process, or a manufacturer who supplies several sponsors with devices.

These reviews are conducted to determine if the devices continue to meet the Essential Principles for safety and performance, and that the sponsor is complying with the conditions of inclusion on the ARTG following their supply in the Australian market.

This type of review can have several outcomes, such as improvements in design, changes to the IFU, or suspension/removal of the device from the ARTG.

During 2013, the TGA completed post-market reviews involving 130 ARTG entries, including:

- automated external defibrillators (AED)
- ultrasound transmission gels
- oxygen concentrators
- breast tissue illuminators
- bed rails
- wound dressings
- hospital grade disinfectants
- UV light therapy unit
- orthopaedic bone cement
- ultrasonic periodontal scaler
- hyperbaric chamber
- x-ray system
- infant positioning aids
- spinal implant
- x-ray detectable gauze
- negative pressure vacuum wound devices
- patient lifters
- gel filled hot/cold pack
- synthetic knee ligament
- carotid stents.

Expert advisory committees

Advisory Committee on the Safety of Medical Devices

The Advisory Committee on the Safety of Medical Devices (ACSMD) advises and makes recommendations regarding the safety, risk assessment, risk management and performance of medical devices supplied in Australia.

The ACSMD met four times in 2013.

Orthopaedic Subcommittee

The Orthopaedic Subcommittee (OSC) of the ACSMD was established in 2013, superseding the Orthopaedic Expert Working Group.

The OSC is a group of independent orthopaedic surgeons who provide expert advice to the ACSMD and the TGA on the safety, quality and performance of orthopaedic devices. In particular, the OSC provides advice in relation to orthopaedic implants that have been identified through the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) as experiencing higher-than-expected revision rates.

The sub-committee met twice in 2013.

Medical Devices Safety Update

In 2013, TGA established a new bimonthly online publication, Medical Devices Safety Update (MDSU) to provide health professionals with practical information and advice on medical device safety.

The first issue of MDSU was published in November and covered issues involving:

- Riata and Riata ST silicone cardiac leads
- The correct use of blood collection packs – spiking
- Frova intubating catheter/introducer.

MDSU replaced the Medical Devices Vigilance and Monitoring (MDVM) email list.

Before the establishment of MDSU, articles published by MDVM in 2013 covered issues involving:

- the AMS 800 Control Pump – Artificial urinary control system
- the Adept Modular Head – used in hip replacements
- the joint TGA and Medsafe project for a trans-Tasman early warning system of safety concerns with therapeutic goods
- Isoline defibrillation leads.

The TGA continues to monitor the safety, performance and quality of all medical devices included on the ARTG and encourages all users and health professionals to report incidents involving medical devices.

Product vigilance

The TGA applies a risk management approach to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy. Once a therapeutic product is approved, the TGA continues to monitor the product in the market through therapeutic product vigilance activities.

The aim of therapeutic product vigilance is to continually monitor and evaluate the safety and efficacy (performance) profile of therapeutic goods and to manage any risks associated with

individual products over their life cycle. The TGA's therapeutic product vigilance framework is available on the TGA website at Therapeutic product vigilance.

The maintenance and improvement of health and safety is a shared responsibility. In addition to government and regulated industry, health professionals, consumers and their respective associations play an important role in reporting therapeutic product safety related issues.

Sponsors have the primary responsibility for the safety of any therapeutic products they import into, supply in or export from Australia. Sponsors must comply with legislative requirements for therapeutic product vigilance under the *Therapeutic Goods Act 1989* (the Act) and there are applicable offences and penalties under the Act for not complying. The legislative requirements for therapeutic product vigilance vary depending on the type of therapeutic good.

The TGA maintains up-to-date safety information on therapeutic products that is communicated through a variety of means to consumers and health professionals including via safety alerts, Early Warning System monitoring communications and Medical Devices Safety Update (MDSU), which provide information and recommendations about therapeutic goods.

The TGA is committed to advancing public health through market authorisation of beneficial, innovative therapeutic goods and by providing timely, evidence-based and authoritative information to allow consumers and health professionals to make informed decisions.

Therapeutic Goods Administration

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