Australian Government
Department of Health
Therapeutic Goods Administration

Medical devices post-market vigilance

Statistics for 2015

Version 1.0, November 2016

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, health 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>.

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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).

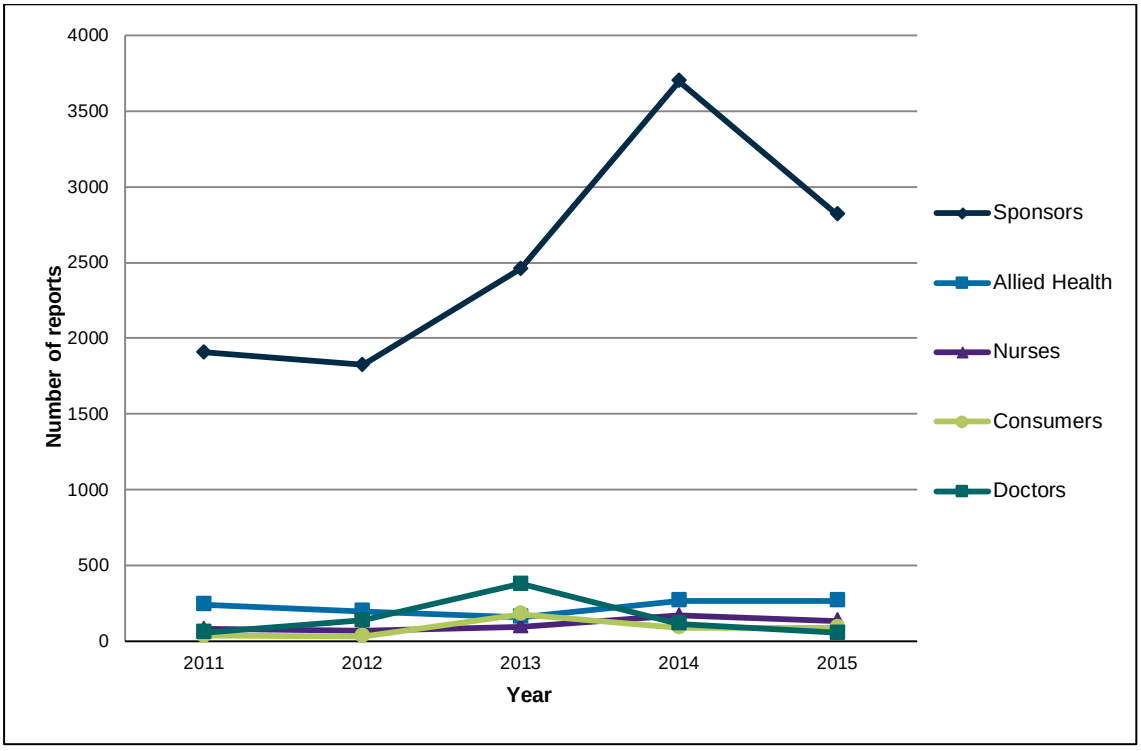
This report from the TGA's Medical Devices Branch includes an overview of the following aspects of post-market monitoring of medical devices in Australia:

- Medical devices adverse event reporting statistics for 2015
- The IRIS inSite project
- How to report an adverse event involving a medical device
- Database of Adverse Event Notifications
- Post-market reviews
- Expert advisory committees
- *Medical Devices Safety Update*
- Product vigilance.

Medical devices adverse event reporting statistics for 2015

The TGA's Incident Report and Investigation Scheme (IRIS) commenced in 1986. Since its inception, the TGA has received more than 36,600 adverse event reports involving medical devices.

Figure 1: Origin of medical device adverse event reports received by the TGA (2011–15)



In 2015, the TGA received 3359 adverse event reports relating to medical devices. As shown in Figure 1, the vast majority of reports made in 2015 were by sponsors of medical devices. The number of reports made by sponsors was 2817 (84% of all reports), compared with 3697 reports in 2014. There was a spike in reports from sponsors in 2014 and the number of reports returned to the longer-term growth trend in 2015. The number of reports made by doctors decreased from 115 in 2014 to 54 in 2015(1.6% of all reports). There was a spike in reports from doctors in 2012-13 due to issues with PIP breast implants. The number of reports from nurses and allied health professionals remains steady. Allied health professionals provided 266 reports (8% of all reports), the same as the previous year, and nurses provided 134 reports (4%), down from 167. The number of reports from consumers remained the same at 88 (2.6%)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 clinical technicians, pharmacists, biomedical engineers, ambulance officers, laboratory technicians and dentists.

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

The IRIS inSite project

The IRIS inSite program works closely with health facilities to improve awareness among health professionals about medical device adverse event reporting. Health professionals play an important role in reporting problems that have caused, or could cause, harm through quality issues, difficulty of use or malfunction.

The IRIS inSite project was introduced to hospitals in the northern suburbs of Sydney in 2015, following a successful pilot project trial in hospitals located in the ACT. The TGA provided education and training to several hospitals in northern Sydney, both public and private, and an increase in the number of adverse event reports submitted by hospitals in this region was noted. The project also began delivering education and training at a hospital in western Sydney.

How to report an adverse event involving a medical device

The TGA encourages consumers and health professionals to report 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').

Database of Adverse Event Notifications

Information in the publicly searchable Database of Adverse Event Notifications (DAEN) comes from reports made to the TGA by a wide range of sources, including device sponsors, doctors, nurses, allied health professionals and members of the public. Reports in this database start from July 2012 up to three months prior to the date of access. The TGA uses this three-month period to investigate each adverse event report.

The DAEN, which was launched in 2012, was created to support better health outcomes by providing access to the information that the TGA gathers while monitoring medical devices safety in Australia.

Post-market reviews

The TGA undertakes 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
- repeated recall actions
- 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 a 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 appropriate levels of 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 requiring improvements in design, changes to the Instructions for Use, or suspension/removal of the device from the ARTG.

During 2015, the TGA completed post-market reviews on:

- Hyperbaric chambers
- Infant positioners
- Infusion pumps
- INR diagnostic devices
- Urogynaecological meshes
- Left ventricular assist devices
- First-aid kits

More information regarding actions the TGA can take when post-market reviews identify safety concerns is contained within the 'Product vigilance' section later in this report.

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 2015. ACSMD meeting statements are published on the TGA website.

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 subcommittee met four times in 2015.

Medical Devices Safety Update

Medical Devices Safety Update provides health professionals with practical information and advice on medical device safety.

Six issues were published in 2015 and included articles on the following topics:

- Insights offered by joint registry data
- Reprocessing issues
- Cancellation of ‘mild' hyperbaric chambers
- Issues regarding 'synch' before undertaking cardioversion
- Recognising medical device incidents
- Grounding pad selection during electrosurgical and ablation procedures
- Practice points - HIV point-of-care testing
- TGA regulatory actions after analysis of registry data
- Environmental extremes and their effects of medical devices
- Button battery dangers
- Review of infant sleep positioners
- Retaining medical devices associated with adverse event reports
- Review of laparoscopic morcellators
- Practice points - pleural catheters
- Issues regarding intravenous catheters if power injection is required
- *Acanthamoeba keratitis* risks for contact lens users
- Medical device adverse event reports
- ‘Safety though adverse event reporting’ online continuing education modules
- Recommendations for avoiding or dealing with surgical implant tool breakages
- IRIS inSite pilot project
- Top 10 medical device hazards.

Product vigilance

The TGA applies a risk management approach to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance). 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 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. 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.

The TGA defines therapeutic product vigilance tools as tools designed to facilitate the collection and evaluation of information pertaining to the benefits and risks associated with the use of therapeutic products. The main product vigilance tools used by the Medical Devices Branch in relation to medical devices are analysis of adverse event reports, annual reports for high-risk devices, and 'environmental scanning' of scientific and medical literature, media and other sources.

Actions the TGA can take in response to an identified safety concern include:

- informing health professionals and consumers via safety alerts, Early Warning System monitoring communications and *Medical Devices Safety Update*,
- requiring the sponsor to undertake product improvement
- requiring changes to the Instructions for Use
- requiring compliance testing
- requiring user education
- recalling products from the market
- suspending or cancelling products.

When a product is cancelled, details are published on the TGA website. The TGA may also exchange information relating to significant safety issues with other regulatory agencies. This is done via the National Competent Authority Reporting 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch	2/11/2016

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R16/540779