



Australian Government
Department of Health
Therapeutic Goods Administration

Australian statistics on medicines and vaccines 2012

Version 1.0, November 2013

TGA Health Safety
Regulation

A decorative graphic consisting of several overlapping, wavy lines in shades of blue and green, flowing from the left side of the page towards the right, positioned below the TGA logo.

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. The TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine, vaccine or medical device, please see the information on the TGA website <<http://www.tga.gov.au>>.

Copyright

© Commonwealth of Australia 2013

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Product Review	29/11/2013

Contents

Foreword	5
Adverse event reporting statistics for 2012	6
Processing and use of adverse event reports	7
Database of Adverse Event Notifications	7
Reporting adverse events	8
Expert advisory committees	9
Advisory Committee on the Safety of Medicines _____	9
Advisory Committee on the Safety of Vaccines _____	9
Medicines Safety Update	10
Product vigilance	11
Transparency _____	12

Foreword

The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods in Australia, including medicines, vaccines, medical devices, biological, blood and blood products. Once a therapeutic good has been included on the Australian Register of Therapeutic Goods (ARTG), the TGA continues to monitor it through product vigilance activities.

On an annual basis, the Office of Product Review (OPR) of the TGA prepares a report for incorporation into the Department of Health publication Australian Statistics on Medicines.

Australian Statistics on Medicines is produced by the Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) and is aimed at providing comprehensive and valid statistics on the Australian use of medicines and vaccines in the public domain to allow access by all interested parties.

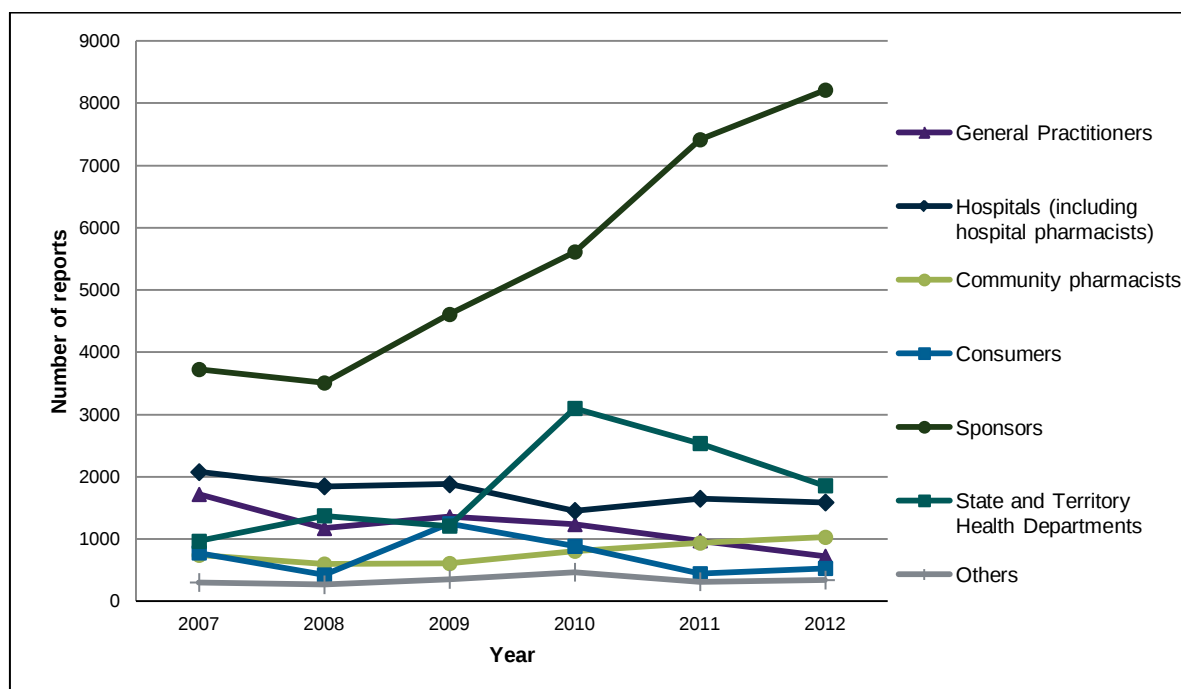
The report from the OPR includes a brief overview on the following aspects of post-market monitoring of medicines and vaccines in Australia:

- Adverse event reporting statistics for 2012
- Processing and use of adverse event reports
- Reporting adverse events
- Expert advisory committee
- Medicines Safety Update
- Product vigilance

Adverse event reporting statistics for 2012

The TGA's reporting system for adverse events began in the late 1960s with the computerised database dating back to the early 1970s. During 2012 the 250,000th report was received and by the end of the year there were approximately 261,000 reports of suspected adverse events in the database.

Figure 1: Origin of adverse event reports received by the TGA (2007-2012)



In 2012 the TGA received approximately 14,300 reports of adverse events. Approximately 57% of these were from pharmaceutical companies, 11% from hospitals (including hospital pharmacists), 5% from general practitioners (GPs), 13% from State and Territory health departments, 7% from community pharmacists and 4% from consumers (Figure 1).

Adverse event reports from pharmaceutical companies continued to rise in 2012, continuing a four-year trend. Reports from State and Territory health departments continued to fall after a spike in 2009-10 due to safety issues with influenza vaccines but have continued to remain above the number reported prior to 2009. Health professionals are encouraged to report suspected adverse events directly to the TGA rather than through the sponsor or manufacturer to simplify communication.

In 2012 MIMs, in association with the TGA, introduced a new mechanism for health professionals [to submit adverse event reports via MIMS online](#).

Processing and use of adverse event reports

Reports are assessed by the Office of Product Review (OPR) within the TGA. This involves checking the report for the presence of 'minimum' details, i.e. an individual patient, an adverse event, at least one (suspected) drug, and, preferably, an identifiable reporting health professional. The specific reaction terms are identified along with the suspected, interacting or 'other' drugs and these are entered into the database.

The TGA assesses causality of adverse event(s) and in some cases requests further clinical or laboratory information from the reporter. Medical officers review serious reports and staff in OPR regularly analyse reporting data to identify potential safety signals.

Reports are forwarded to the Uppsala Monitoring Centre in Sweden which administers the World Health Organization Collaborating Centre for International Drug Monitoring. This global database began in 1968 as a pilot program involving 10 nations, including Australia, and now receives reports from more than 80 nations with more than 7 million reports in the database.

Database of Adverse Event Notifications

The TGA introduced the publicly searchable [Database of Adverse Event Notifications](#) (DAEN) in 2012.

Information in the DAEN comes from reports made to the TGA by a wide range of sources, including members of the public, general practitioners, nurses, other health professionals and the therapeutic goods industry. Reports in this database start from 1 January 1971 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 was created to support better health outcomes by providing access to the information that the TGA gathers while monitoring medicine and vaccine safety in Australia.

Reporting adverse events

The TGA encourages the reporting of all suspected adverse events to medicines available in Australia, including prescription medicines, vaccines, over the counter and complementary medicines. The reporting of seemingly insignificant or common adverse events can contribute to the TGA's investigation of a potential safety signal.

Sponsors of all medicines on the Australian Register of Therapeutic Goods (ARTG) have [mandatory reporting requirements](#) regarding adverse events.

The TGA particularly requests reports of:

- Suspected adverse events involving new medicines and vaccines
- Suspected drug interactions
- Unexplained adverse events (i.e. reactions that are not described in the Product Information)
- Serious adverse events, such as those suspected of causing:
 - Inability to work
 - Admission to hospital
 - Prolongation of hospitalisation
 - Increased investigation or treatment costs
 - Danger to life
 - Birth defects
 - Death.

[Reports of suspected adverse events can be made:](#)

- online by following the link to 'Report a Problem'
- health professionals can submit a report directly from MIMS online
- using a 'Blue Card' available from the TGA's Office of Product Review (1800 044 114 or adr.reports@tga.gov.au) or downloaded from the TGA website at 'Blue card' adverse reaction reporting form.

Expert advisory committees

Advisory Committee on the Safety of Medicines

The [Advisory Committee on the Safety of Medicines](#) (ACSOM) was established in January 2010 to provide expert advice to the TGA about safety issues under investigation and the appropriateness of [Risk Management Plans](#) (RMPs). RMPs outline sponsors' plans to monitor and communicate risks, and are evaluated as part of the registration process for new medicines. RMPs accompany applications for registration of high risk medicines, such as new chemical entities. RMPs characterise and pro-actively manage risks relating to a medicine over its entire life cycle. ACSOM also provides advice to the TGA on other matters related to pharmacovigilance, including the detection, assessment, understanding and prevention of adverse events.

Advisory Committee on the Safety of Vaccines

The government's [Review of the management of adverse effects associated with Panvax and Fluvax](#) (the Horvath Review), amongst other things, included a recommendation to establish a working party to review governance of the vaccine safety system. Following a recommendation from the Horvath Review Implementation Steering Committee in 2012 "to consider the current governance arrangements for monitoring and responding to vaccine safety issues in Australia and make recommendations for an improved system of governance for vaccine safety monitoring" the Advisory Committee on the Safety of Vaccines (ACSOV) was established in the Therapeutic Goods Regulations. The functions of ACSOV are to provide advice and make recommendations to the Minister for Health, the TGA and the Office of Health Protection on the safety, risk assessment and risk management of vaccines.

Medicines Safety Update

The [Medicines Safety Update](#) is published six times a year in Australian Prescriber, and also on the TGA website. The Medicines Safety Update replaced the Australian Adverse Drug Reactions Bulletin in 2010.

The following articles were published in Medicines Safety Update [in 2012](#):

- Ondansetron and QTc interval prolongation – dosing change
- Domperidone (Motilium) – serious ventricular arrhythmias and sudden cardiac death
- Cardiovascular safety risk with fingolimod (Gilenya) – updates to the Product Information
- Disposal of unwanted medicines
- Changes to over-the-counter cough and cold medicines for children
- Post-market vigilance and introduction of the Database of Adverse Event Notifications
- Lenalidomide (Revlimid) and second primary malignancy
- Kogenate: home use Factor VIII and filtration
- Accidental paracetamol poisoning
- Strontium ranelate and venous thromboembolism and serious skin reactions
- Better information on medicine labels – have your say.
- Candesartan, fetal malformations and use in pregnancy
- Zolpidem: continued reporting of abnormal sleep-related events and amnesia
- Renal function assessment in prescribing
- Anaphylaxis with chlorhexidine-impregnated central venous catheters
- Change in the pregnancy category for topiramate
- Use of 2012 seasonal influenza vaccines in children
- Dasatinib (Sprycel) and pulmonary arterial hypertension
- Pulmonary oedema associated with topical phenylephrine
- Pneumovax 23 – updated revaccination recommendations
- Caveat emptor 'buyer beware' – the risks of purchasing unregistered medicines online
- Citalopram and QT prolongation – important changes to the dosing recommendations
- Atomoxetine (Strattera) – risk of increased blood pressure and/or heart rate

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 continually to monitor and evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products over the life cycle of a product. 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* 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 health professionals and consumers. The TGA is committed to advancing public health through the market authorisation of beneficial, innovative therapeutic products 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 OPR are adverse event reports, RMPs and Periodic Safety Update Reports (PSURs).

Adverse event reports are reports of any untoward occurrence in a patient administered a medicine and which does not necessarily have a causal relationship with the medicine. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicine, whether or not considered related to this medicine.

RMPs provide a summary of the known important safety information about the therapeutic product, plans to identify and characterise known or potential safety concerns and plans to minimise any identified or potential safety risk. A full outline of the scope of RMPs is above (see Expert advisory committee). PSURs give an annual overview of the safety of the drug, including adverse events, a summary of the registration status of the drug world-wide, actions taken for safety reasons, the world-wide usage of the drug and an analysis of safety requirements. Sponsors must submit PSURs for at least three years after registration of a drug.

An important aspect of product vigilance is ensuring there are mechanisms to communicate safety information to both health professionals and consumers. To achieve this, the TGA publishes [Australian Public Assessment Reports](#) (AusPARs) about recently registered prescription medicines on the TGA website. The AusPAR outlines the findings of the TGA's evaluation of a product including important effectiveness and safety

information. The TGA also publishes the [Product Information](#) (PI) and [Consumer Medicine Information](#) (CMI) for prescription and some non-prescription medicines, Medicines Safety Update and alerts, which provide important information and recommendations about therapeutic goods.

Transparency

Reviews of the functions and activities of the TGA have identified a need to ensure the public is aware of the activities undertaken by the TGA to monitor the safety of therapeutic products available to the community. In December 2011 the Government released [TGA reforms: a blueprint for TGA's future](#) (the Blueprint) which included plans to improve the Australian community's understanding of the TGA's regulatory processes and decisions and enhance public trust in the safety and quality of therapeutic goods.

The Blueprint consists of a range of interconnected projects the TGA will undertake to achieve more effective and transparent regulation of medicines, meet emerging challenges in the regulation of therapeutic goods and provide more timely information about the goods it regulates.

As at 31 December 2012, implementation [of eleven recommendations had been completed](#) and, of these, the following related to product vigilance:

- Publication of the TGA External Communication and Education Framework: Priorities and projects 2013-15
- Publication of a clear explanation of the TGA's risk based framework on the TGA website
- Publication of further information on the role of TGA statutory advisory committees and clarification of their reporting arrangements.

In addition, by 31 December 2012 work had been completed to address aspects of other recommendations. This work included:

- Conduct of a pilot project to investigate how the TGA might more effectively respond to phone and email enquiries
- Release of an online system for reporting problems with medical devices
- Provision of access by consumers, health professionals and industry to online information on adverse events which have been reported to the TGA relating to medicines
- Provision of public access to Australian and New Zealand adverse event data for medicines, hosted on ANZTPA.org
- Work towards the establishment of an Advisory Committee on the Safety of Vaccines (ACSOV), under the Therapeutic Goods Regulations 1990.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605

<http://www.tga.gov.au>

Reference/Publication #