Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Adverse event reporting in Australia in 2011

Prepared for inclusion in Australian Statistics on Medicines 2011

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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 Ageing, 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 <www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
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Foreword

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

On an annual basis, the Office of Product Review (OPR) of the Therapeutic Goods Administration (TGA), prepare a report for incorporation into the Department of Health and Ageing 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 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 in Australia:

- Adverse event reporting statistics for 2011
- Processing and use of adverse event reports
- Reporting adverse events
- Expert advisory committee
- Medicines Safety Update
- Product vigilance

Adverse event reporting statistics for 2011

The TGA's reporting system for adverse events began in the late 1960's with the computerised database dating back to November 1972. At the end of 2011 there were approximately 247,000 reports of suspected adverse events in the database.

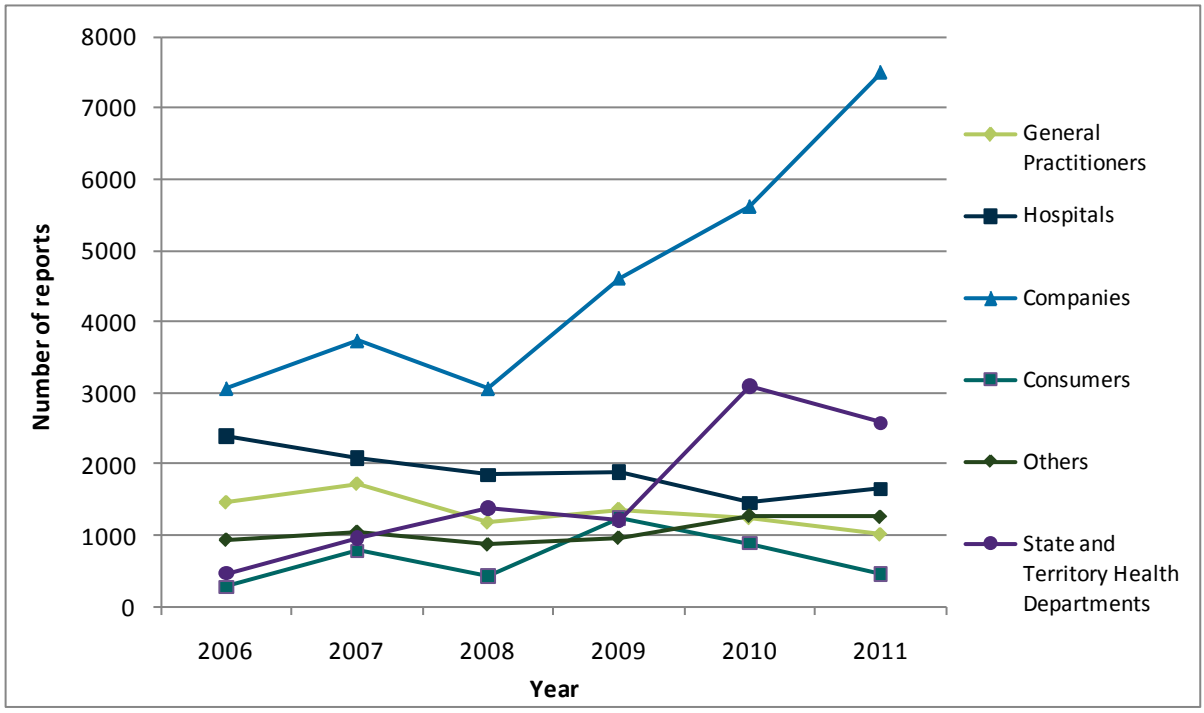

Figure 1: Origin of adverse event reports received by the TGA (2006–2011)

Note: A review of the quality control process had an impact on the searchable part of the Adverse Drug Reaction Database, causing a change in the number of events from data published in the *Adverse Drug Reaction Reporting in Australia in 2010*.

In 2011 the TGA received approximately 14,400 reports with 52% from pharmaceutical companies, 12% from hospitals, 7% from General Practitioners (GPs), 18% from State and Territory Health Departments and 3% from consumers. The sources for other reports (8%) include community pharmacists and specialists (Figure 1). On average, in 2011, the TGA received 1,200 reports per month. Health professionals are encouraged to report suspected adverse events directly to the TGA rather than through the sponsor or manufacturer to simplify communication.

The spike in the number of adverse events reported by companies in 2011 is attributed to a number of factors, including a greater number of drugs on the Australian Register of Therapeutic Goods (ARTG); and the possibility that GPs are reporting adverse events via sponsors, which would also account for the slight drop in the reporting rates for GPs. The increases observed in 2009 and 2010, particularly from State and Territory Health Departments and companies, is largely due to reports of adverse events following vaccination with the pandemic (H1N1) influenza vaccine in 2009 and the seasonal trivalent influenza vaccines in 2010.

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 applies a causality rating for the reaction(s) and in some cases requests further clinical or laboratory information from the reporter to allow causality to be assessed. 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 WHO 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 over 80 nations with over 5 million reports in the database.

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.

The TGA particularly requests reports of:

- all suspected reactions to new medicines
- all suspected medicines interactions
- unexpected reactions (i.e. those reactions that are not described in the Product Information)
- suspected reactions causing:
  - death
  - admission to hospital or prolongation of hospitalisation
  - increased investigations or treatment
  - birth defects

Reports of suspected adverse events can be made:

- online at <www.tga.gov.au> by following the link to 'Report a Problem'. Health professionals can also 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 <www.tga.gov.au/safety/problem-medicines-forms-bluecard.htm>.

Expert advisory committee

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.

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 2011:

- Clozapine and severe constipation
- Drug interaction between tamoxifen and antidepressants
- Methysergide and retroperitoneal fibrosis
- Thank you for your reports
- Suspected adverse reactions to vaccines: a reminder to report
- Drug-induced hyponatraemia
- Rotavirus vaccination and risk of intussusception: investigation of a possible safety signal
- Coversyl and Coumadin: new packaging to reduce potential for dispensing errors
- Risk of hypomagnaesaemia with proton pump inhibitors
- Use of 2011 seasonal influenza vaccines in children
- Investigation of Prevenar and deaths in children in Japan: what does it mean for Australia?
- Finding information about adverse reaction reporting on the new TGA website
- Medicine recalls in Australia
- Cramps, quinine and thrombocytopenia
- Venlafaxine and stress cardiomyopathy
- *In utero* antipsychotic exposure and neonatal extrapyramidal and withdrawal adverse effects
- Prescribing medicines in pregnancy – new TGA database
- Oral contraceptives containing drospirenone (Yaz and Yasmin) and venous thromboembolism
- Pioglitazone and risk of bladder cancer
- Modafinil (Modavigil) – safety update
- Subscribe to TGA email alerts

- Proton Pump Inhibitors (PPIs) and acute interstitial nephritis
- Dabigatran (Pradaxa) and the risk of bleeding
- Reducing the risk of myopathy and rhabdomyolysis with simvastatin – new dosage recommendations

Product vigilance

Transparency

Recent 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.

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.

Product vigilance

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 <www.tga.gov.au/safety/tga-therapeutic-product-vigilance.htm>.

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, Risk Management Plans 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.

Therapeutic Goods Administration

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