Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Adverse drug reactions

Australian Statistics on Medicines 2010

Version 1.0, September 2011

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Created document	Office of Product Review	27/09/11

Contents

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 drug reactions reporting statistics for 2010
- How adverse drug reaction reports are processed and used
- How to report adverse drug reactions
- Expert advisory committee
- Medicines Safety Update
- The Drugs of Current Interest Scheme

Adverse drug reactions reporting statistics for 2010

The TGA's reporting system for adverse drug reactions began in the late 1960's with the computerised database dating back to November 1972. At the end of 2010 there were approximately 233,300 reports of suspected adverse drug reactions in the database.

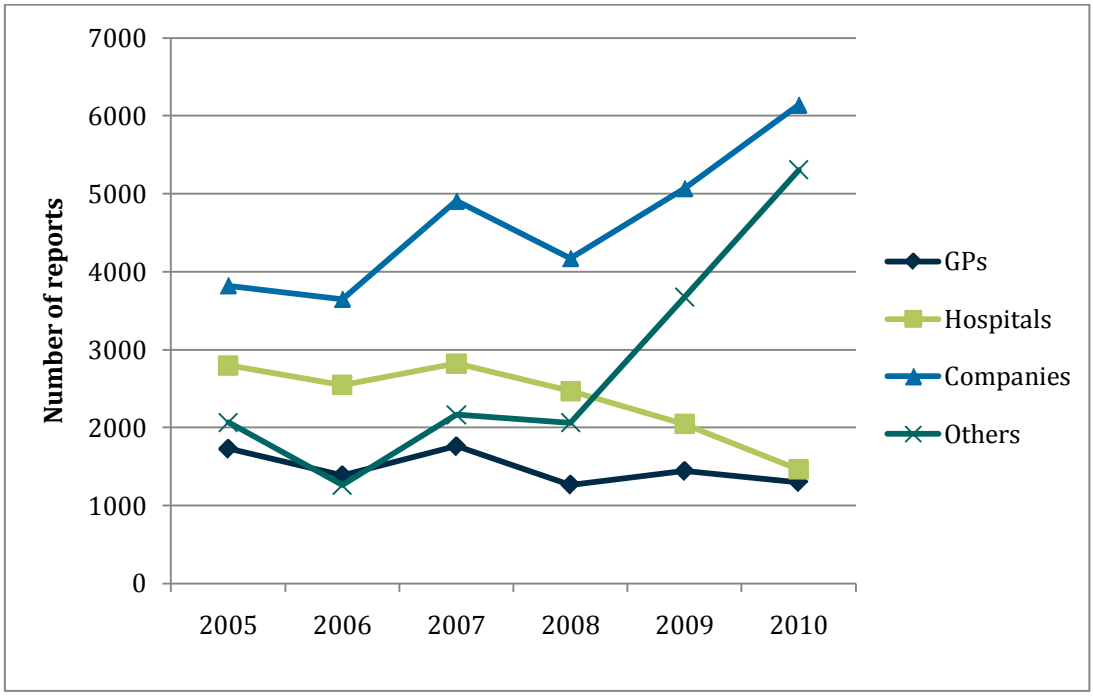

Figure 1: Origin of adverse drug reaction reports received by the TGA (2005-2010)

In 2010 the TGA received approximately 14,200 reports with 43% from pharmaceutical companies, 10% from hospitals, 9% from general practitioners and the remainder from other sources including State and Territory Health Departments, members of the public, community pharmacists and specialists (Figure 1). On average, in 2010, the TGA received 1,184 reports per month. The TGA encourages practitioners to report suspected adverse reactions directly rather than through the manufacturer to make communication simpler. The increase in report numbers in 2010, particularly from 'other' sources and companies, is largely due to reports of adverse events following vaccination with seasonal trivalent influenza vaccines. Similarly, the increase in 2009 was largely due to reports of adverse events following vaccination with pandemic (H1N1) influenza vaccine.

How adverse drug reaction reports are processed and used

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 reaction, 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.

How to report adverse drug reactions

The TGA encourages the reporting of all suspected adverse reactions to any medicine available in Australia, including prescription medicines, vaccines and over the counter and complementary medicines. The reporting of seemingly insignificant or common adverse reactions 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 (ie, 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 drug reactions can be made:

- online at http://www.tga.gov.au by following the link to 'Report a Problem'
- 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 http://www.tga.gov.au/safety/problem-medicines-forms-bluecard.htm

Expert advisory committee

In January 2010, a new statutory expert advisory committee called the Advisory Committee on the Safety of Medicines (ACSOM) was established.

The major roles for ACSOM are to provide expert advice to the TGA about safety issues under investigation and the quality and appropriateness of Risk Management Plans (RMPs). RMPs have been required with applications for registration of 'high risk' medicines such as new chemical entities from April 2009 and are designed to 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 effects.

Medicines Safety Update

In 2010 *Medicines Safety Update* replaced the *Australian Adverse Drug Reactions Bulletin*. The Medicines Safety Update is published 6 times a year in Australian Prescriber, and also on the TGA website.

Articles published in *Medicines Safety Update* in 2010 included:

- A new era of medicines safety monitoring and communication of benefit - risk information at the TGA
- Enhanced postmarket risk management - Risk Management Plans
- ACSOM - a new expert advisory medicines safety committee
- Improved access to prescribing and consumer information
- Safety of fish oil and omega-3 fatty acids
- AUST R and AUST L numbers - why are they important?
- Sibutramine
- Drug-induced pancreatitis and exenatide (Byetta)
- Varenicline (Champix): an update
- Australian experience with non-adjuvant H1N1 vaccine (Panvax and Panvax Junior)
- Cholinesterase inhibitors and syncope
- Statins, macrolides and rhabdomyolysis
- Uterine perforation with levonorgestrel-releasing intrauterine system (Mirena)
- Rivaroxaban (Xarelto) – an overview of adverse event reports
- Lamotrigine and serious skin reactions
- Serotonin syndrome: a reminder
- Drug-induced acute akathisia
- Unintended pregnancy due to interaction between etonogestrel implant (Implanon) and carbamazepine

The Drugs of Current Interest Scheme

The aim of the 'Drugs of Current Interest' (DOCI) scheme was to undertake enhanced and focused pharmacovigilance for new drugs that may have received widespread use and for which the TGA was interested in obtaining a comprehensive post-market safety profile.

'Drugs of Current Interest' used to be selected by the Adverse Drug Reactions Advisory Committee (ADRAC). The DOCI list was published on the front page of the *Australian Adverse Drug Reactions Bulletin* and served as an indicator to readers of the drugs for which the TGA particularly requested adverse drug reaction reports.

ADRAC ceased to exist at the end of 2009, and a new committee - the Advisory Committee on the Safety of Medicines - was established to provide expert advice to the TGA on drug safety matters. Also in 2009, the TGA began to require sponsors of new medicines to submit a 'Risk Management Plan' (RMP) outlining the activities that they would undertake to monitor and communicate with health professionals and the public about the risks of medicines. RMPs are evaluated by the Office of Product Review as part of the evaluation of applications for registration. In addition, sponsors are required to submit to the TGA 'Periodic Safety Update Reports' (PSURs) annually for at least the first 3 years after the drug is approved. PSURs include summaries of spontaneous reporting as well as other

sources of safety information for the drug. Late 2009 also saw the introduction of Australian Public Assessment Reports for Prescription Medicines (AusPARs). AusPARs provide information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. AusPARs incorporate the Product Information (PI) approved at the time of releasing the AusPAR. The TGA website also contains a PI/Consumer Medicines Information (CMI) search facility which provides up-to-date copies of the PI/CMI.

In the light of these changes, and the overlap between RMPs, PSURs and the DOCI scheme, the DOCI scheme is no longer maintained by the TGA; although the TGA is continuing to consider ways to focus reporting on new medicines or those with extensions of their indication into new populations. The TGA continues to monitor the safety of all medicines registered in Australia and encourage health professionals to report all suspected adverse drug reactions to the TGA.

Therapeutic Goods Administration

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