Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

HOW TO REPORT A PROBLEM WITH A MEDICINE OR MEDICAL DEVICE TO THE THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing and is responsible for regulating medicines and medical devices. The work of the TGA is based on applying scientific and clinical expertise 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 so that the TGA can identify and respond to safety matters.

When to report

If you have experienced or suspect you may be experiencing an adverse event relating to a medicine or medical device, *seek medical advice from your doctor as soon as possible*. The adverse event should then be reported to the TGA.

What to report

You may report adverse events experienced by yourself, or someone you care for. Please report any suspected adverse event, in particular:

- serious reactions (e.g. resulting in hospitalisation)
- unexpected reactions (reactions not consistent with consumer medication information or labelling)
- all suspected adverse events that may be caused by combinations of medicines
- faults with medical devices resulting in an adverse event (keep the faulty equipment until you have contacted the TGA).

How to report

You can report a suspected adverse event:

- to your doctor or pharmacist (who will then report to the TGA), or
- directly to the TGA – http://www.tga.gov.au/problem/index.htm

In addition, for medicines you can report using the:

- Consumer Adverse Medicine Events Line (1300 134 237), or
- 'Blue card' reply paid reporting form (download and further information are available on the TGA website – http://www.tga.gov.au/adr/bluecard.pdf).

What to include in your report

In your report include (if applicable):

- basic details of the person experiencing the adverse event – initials, date of birth, gender
- details of the adverse event or reaction – date it occurred, symptoms experienced (including duration), description of device fault resulting in adverse event, treatment required and outcome (if known)
- details of the medicine or device involved – name, description, dose, for a complementary medicine include AUST L number
- details of any other medicine(s) the person experiencing the adverse event may be taking.

Report a medicine or medical device adverse event to the TGA

Medicines
Phone: 1300 134 237, or
1800 044 114
Email: adr.reports@tga.gov.au

Medical devices
Phone: 1800 809 361
Email: iris@tga.gov.au

or visit the TGA website – http://www.tga.gov.au/problem/index.htm