



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

President  
Endocrine Society of Australia  
145 Macquarie Street  
SYDNEY NSW 2000

Dear Madam/Sir

**Adverse event reporting – information for health care professionals**

I am writing to you to seek your assistance in raising awareness of the Therapeutic Goods Administration's (TGA) role in the collection of reports of adverse events associated with medicines and medical devices. Adverse event reporting allows the TGA to monitor, investigate and take action on medicines and medical device safety issues.

The TGA encourages health professionals to report all suspected adverse events associated with medicines and devices, particularly those associated with new products or serious outcomes such as admission to hospital or prolongation of hospitalisation. This information forms an important part of the TGA's post-market monitoring activities and it plays a key role in its work to identify potential relationships between a therapeutic good and a series of adverse events. Where a link can be established, the TGA takes action to ensure that medicines and devices available in Australia continue to meet appropriate standards of safety, efficacy and quality. Possible regulatory actions that the TGA may take vary from continued monitoring to withdrawing the product from the market.

I would be grateful if you could remind your members that they can assist the TGA in safeguarding public health by reporting suspected adverse events. I have enclosed a handout containing information on how to report an adverse event relating to a medicine or medical device. It would be appreciated if you could circulate this information through your networks.

Further information can be found on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) homepage under the Report a problem heading, or by contacting Dr Larry Kelly on 02 6232 8700.

Thank you for your cooperation and assistance.

Yours sincerely

A handwritten signature in black ink, appearing to read 'R Hammett'.

Dr Rohan Hammett  
National Manager  
2 December 2010



## 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 a patient has experienced or you suspect they may be experiencing an adverse event relating to a medicine or medical device, report the adverse event to the TGA.

Suspected adverse events should be reported the first time they occur, as well as any time they occur thereafter.

### ? What to report

Please report any suspected adverse event that your patient(s) may be experiencing, in particular:

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

### ? How to report

Report a suspected adverse event directly to the TGA using:

- the TGA website – <http://www.tga.gov.au/problem/index.htm>

In addition, for medicines you can report using the:

- 'Blue card' reply paid reporting form (download and further information are available on the TGA website – <http://www.tga.gov.au/adr/bluecard.pdf>)
- TGA's Adverse Medicine Events Line (1800 044 114).

### ? What to include in your report

In your report include (if applicable):

- basic details of the patient 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 patient experiencing the adverse event may be taking.

## Report a medicine or medical device adverse event to the TGA

### Medicines

Phone: 1800 044 114

Email: [adr.reports@tga.gov.au](mailto:adr.reports@tga.gov.au)

### Medical devices

Phone: 1800 809 361

Email: [iris@tga.gov.au](mailto:iris@tga.gov.au)

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