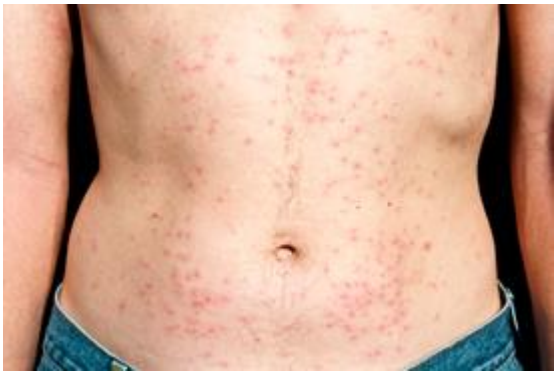
Pharmaceutical Society of Australia

Reporting medicine side effects

The Health Column

27 May
2015

What is an adverse event or side effect?



In health terms, an adverse event – sometimes called a 'side effect' – is an unusual or harmful effect that may be related to taking a medicine or vaccine. An adverse event can also be a problem associated with a medical device, including deficiencies in labelling, instructions or packaging, defective components, performance failures, and poor construction or design.

There were over 16,500 medicine and vaccine adverse events reported to the Therapeutic Goods Administration (TGA) in 2014, and over 4,000 medical device adverse events. It is also known that there are many adverse events that occur in Australia which are not reported at all.

The TGA is responsible for approving and monitoring therapeutic goods, such as medicines, vaccines, biologicals and medical devices, in Australia. The primary objective of the TGA is to ensure that therapeutic goods are made accessible to all Australians, and that the goods are of an acceptable standard for use; where the quality and benefits outweigh any potential risks to health. This involves monitoring the ongoing safety, quality and efficacy of medicines, vaccines, biologicals and medical devices.

Who is at greatest risk?

Patients who are taking a number of medicines, including prescription, over-the-counter (OTC) or complementary medicines, have an increased chance of experiencing drug interactions, and subsequent adverse events associated with their therapy. In addition, consumption of alcohol with medicines can increase the risk of an adverse event. Infants and young children have an underdeveloped drug metabolic capacity, meaning that they are at a high risk of adverse events. Older patients may be predisposed to accentuated effects of medicines and this increases the chance of adverse events.

The role of the Therapeutic Goods Administration

All therapeutic goods must undergo clinical trials and testing before be approved by TGA and being made available to Australian consumers. With new products, in particular, clinical trials may not detect all possible adverse events and therefore it is important that TGA be made aware of

these events as soon as possible after they occur. Timely reporting can result in early detection of adverse events and this can lead, in extreme cases, to saving the lives of others.

To facilitate monitoring of therapeutic goods the TGA relies upon consumers reporting adverse events. Reporting can be to pharmacists, doctors and other health professionals or directly to the TGA via their website at *www.tga.gov.au/report-side-effect-medicine* or by telephone on 1800 044 114.

Once adverse events are reported to the TGA, they are assessed and analysed and are entered into TGA databases. The TGA reviews all of the reports to identify possible safety issues. These issues are then investigated and appropriate actions undertaken. If they find a health risk associated with the therapeutic good, they may choose to:

- Request an update to the consumer medicines information (CMI), product information or instructions for use for medical devices
- Recall a product from the market
- Impose limits on a product's use through changes to the indications
- Request the company investigate the adverse event in more detail
- Suspend or cancel a product's registration
- Investigate the manufacturing facility.

The TGA will also alert the community (including health professionals) about any relevant safety information related to medicines, vaccines or medical devices via their website and through a number of different health bulletins which they circulate:

- Medicines Safety Update/Medical Devices Safety Update
- Safety alerts
- Monitoring communications.

Pharmacists are the most accessible health professionals in Australia and are among the most active voluntary reporters of adverse events and their professional expertise means their reports are generally of a high quality for analysis purposes. If you are concerned about any signs or symptoms that may be related to taking a medicine, an excellent first step is to speak to your pharmacist.

You can get more detailed information on adverse events from pharmacies providing the Pharmaceutical Society of Australia's Self Care health information.

For the nearest Self Care pharmacy location phone the Pharmaceutical Society of Australia on 1300 369 772, or go to *www.psa.org.au* 'Supporting practice' then 'Self Care', and then 'Find a Self Care pharmacy'.