Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Medicines Safety Update

Medicines Safety Update No.1; 2010

Introducing Medicines Safety Update

This is the site for the new Medicines Safety Update from the Therapeutic Goods Administration (TGA). Medicines Safety Update will appear in each edition of *Australian Prescriber.*

Medicines Safety Update is replacing the Australian Adverse Drug Reactions Bulletin and will continue to bring you practical information and advice on drug safety and inform you about emerging safety issues.

Look here over the coming editions to find out about:

- the Advisory Committee on the Safety of Medicines (ACSOM) – this is the TGA's new expert advisory committee on medicines safety and replaces the Adverse Drug Reactions Advisory Committee (ADRAC)
- Medicines Risk Management Plans – what are they and how are they used?
- development of a new medicines alert system to replace the ADRAC Drugs of Current Interest Scheme
- regular articles about emerging safety issues.

A new era of medicines safety monitoring and communication of benefit–risk information at the TGA

The TGA, Australia's national regulator of therapeutic products, is responsible for ensuring that medicines, medical devices, blood, tissues and cellular therapies meet appropriate standards of safety, quality and efficacy and are made available to the community in a timely manner.

In keeping with international initiatives, the TGA is implementing some important changes to the way in which it monitors and manages the safety of medicines and communicates important benefit-risk information about medicines to its stakeholders.

Enhanced postmarket risk management – Risk Management Plans

In April 2009 the TGA formally adopted the European Guideline on Risk Management Systems for Medicinal Products for Human Use (EMEA/CHMP/ 96268/2005).

Adoption of this guideline means that applications for the registration of certain higher risk prescription medicines (new chemical entities, applications for paediatric use, new dosage forms, new routes of administration and significant extensions of indication) are now required to include a Risk Management Plan as part of the application.

The Risk Management Plan is meant to document not only what is known about the safety of the medicine at that particular point in time (termed the Safety Specifications), but also potential risks that require further elucidation, and how the sponsor intends to investigate those risks. The sponsor is required to establish a plan for monitoring the medicine when it is approved (a so-called Pharmacovigilance Plan) and consider whether there is a need for additional risk minimisation activities (such as additional prescribing and educational material, restrictions on promotion of and access to the medicine) and outline these in a Risk Minimisation Plan.

ACSOM – a new expert advisory medicines safety committee

A new expert advisory committee on medicines safety, called the Advisory Committee on the Safety of Medicines (ACSOM), has replaced ADRAC. This new committee exists as a statutory committee in its own right and has broader and enhanced terms of reference compared to ADRAC. A key role of the ACSOM will be the provision of expert advice to the TGA about the appropriateness of risk management plans and risk minimisation strategies for new high-risk medicines.

Improved access to prescribing and consumer information

The TGA is also committed to enhancing its dissemination of important benefit–risk information for medicines.

Legislation amendments enacted in 2009 have expanded the range of regulatory information the TGA may release, while protecting commercially sensitive and personal information. This will allow the TGA to publish on its website recommendations from external advisory committees and summary decision statements on evaluations of prescription medicines.

Over the next 12 months, the TGA will be progressively publishing a variety of documents on its website:

- **Product information (PI)** – this document contains a concise scientific summary of what is known about a medicine, targeted at healthcare professionals
- **Consumer Medicines Information (CMI)** – this document presents information about the use and safety of a medicine in lay language
- **Australian Product Assessment Report (AUSPAR)** – this document contains detailed technical and scientific assessments of the efficacy, safety and benefit–risk of the medicine undertaken by the TGA and the considerations that led the TGA to approve or reject an application. An AUSPAR will be prepared for submissions that relate to new chemical entities, generic medicines, major variations, and extension of indications.

When this project is completed, the TGA website will provide a single point at which healthcare professionals, consumers and other interested parties can locate current, authoritative and reliable information about a medicine that is registered on the Australian Register of Therapeutic Goods (ARTG).

Hot news – experience with swine flu vaccine

Check out regular updates of suspected adverse reactions to the vaccine at:
www.tga.gov.au/alerts/medicines/h1n1vaccine1.htm

The Blue Card system is not changing

The cornerstone of medicines safety monitoring is spontaneous adverse event and incident reporting, so it's important that you continue to report adverse reactions to the TGA's Office of Medicines Safety Monitoring (OMSM).

The Blue Card system has been in operation for more than three decades and has resulted in more than 200 000 adverse drug reaction reports.

Anyone can report a suspected adverse drug reaction and the OMSM receives approximately 12 000 reports per year.

The Blue Card reporting form will continue to be distributed with the April, August and December issues of *Australian Prescriber.*

WHAT TO REPORT? (You do not need to be certain, just suspicious!)

The TGA encourages the reporting of all **suspected** adverse reactions to medicines, including vaccines, over-the-counter medicines, herbal, traditional or alternative remedies. The TGA particularly requests reports of:

- ALL suspected reactions to **new medicines**
- ALL suspected medicines interactions
- Suspected reactions causing
  - death
  - admission to hospital or prolongation of hospitalisation
  - increased investigations or treatment
  - birth defects

For blue cards

Reports of suspected adverse drug reactions are best made by using a prepaid reporting form ('blue card') which is available from the website: www.tga.gov.au/adr/bluecard.pdf or from the Office of Medicines Safety Monitoring, phone 02 6232 8744.

Reports can also be submitted:

online – go to the TGA website www.tga.gov.au and click on 'Report a problem' on the left
fax 02 6232 8392
email ADR.Reports@tga.gov.au

For further information from the Office of Medicines Safety Monitoring:
Phone: 1800 044 114 Fax: 02 6232 8392 Email: info@tga.gov.au