Prepared by the Adverse Drug Reactions Advisory Committee (ADRAC) and the Office of Medicines Safety Monitoring (OMSM) of the TGA. Members of ADRAC are: Professor Duncan Topliss (Chair), Dr Michael Gold, Dr Vicki Kotsirilos, Associate Professor Cecilie Lander, Professor John McNeil, Associate Professor Peter Pillans, Associate Professor Simone Strasser, Dr Dana Wainwright

AUSTRALIAN ADVERSE DRUG REACTIONS BULLETIN

Volume 28, Number 6, December 2009

☆ ADRAC comes to an end after 39 years
…..A new Advisory Committee on the Safety of Medicines from 2010

☆ The last Bulletin
A new medicines safety publication - look in Australian Prescriber from 2010

☆ Thank you to our readers

☆ A tribute to ADRAC from the TGA
ADRAC contribution to post market safety of medicines continues with the review of H1N1 influenza vaccine (Panvax) reports

☆ Consider applying to become an Expert Adviser to the TGA

Please report **all** suspected reactions to these **Drugs of Current Interest**

Duloxetine (Cymbalta)
Dabigatran (Pradaxa)
Paliperidone (Invega)
Pramipexole (Sifrol)
Ranibizumab (Lucentis)
Rivaroxaban (Xarelto)
Sitagliptin (Januvia)
Strontium ranelate (Protos)
Varenicline (Champix)

1. ADRAC comes to an end after 39 years

It is with mixed feelings that we announce that ADRAC will cease to exist at the end of this year after 39 years since its inception in May 1970 as a subcommittee of the Australian Drug Evaluation Committee, tasked with advising the TGA on the safety of medicines.

ADRAC has been in a privileged position of being able to bring together healthcare professionals and the TGA to help build one of the best pharmacovigilance systems in the world. We especially wish to acknowledge the key role healthcare professionals have played in this, since it is your reports that have predominately contributed to Australia's high quality pharmacovigilance system.

With your assistance, ADRAC has become fundamental for advising and reporting on all matters relating to the safety of medicines, to the extent that its functions, activities and strengths have long-since surpassed those usually mandated to a subcommittee answerable to its parent. These developments have prompted the changes described in this issue of the *Bulletin*.

A new Advisory Committee on the Safety of Medicines from 2010

In line with the world-wide trend of placing greater emphasis on monitoring and managing the safety of medicines after they have been registered, the TGA will from 2010 replace ADRAC with an expert advisory committee established in its own right under the *Therapeutic Goods Act*. This new statutory expert committee – the Advisory Committee on the Safety of Medicines (ACSOM) will encompass the activities and functions of ADRAC but will have broader terms of reference commensurate with the increasing prominence of pharmacovigilance in Australia and world-wide.

Risk management plans

A major role for ACSOM will be to advise the TGA on the quality and appropriateness of risk management plans (RMPs), which are designed to characterise and pro-actively manage risks relating to a medicine over its entire life cycle. RMPs are a valuable addition to current pharmacovigilance activities including the collection of spontaneous adverse drug reaction reports. However, they do not replace or diminish the importance of the spontaneous reporting system, which will continue to be the foundation of pharmacovigilance programs.

Your reports contribute to a world-class pharmacovigilance system

The Australian spontaneous reporting system is renowned as being one of the best in the world. This is due in large part to Australian healthcare professionals whose reports have allowed us to build a robust, functional and informative database on the adverse reactions profiles of medicines in the marketplace.

While the limitations of spontaneous reports are recognised, their importance should not be under-estimated as they cannot usually be matched for providing early identification of serious unanticipated safety issues that may not be apparent from the necessarily limited and restrictive clinical trials conducted before a drug can be registered.[1]

There are many examples of where spontaneous reports have resulted in the early identification and resolution of problems with medicines.[1] Some of the more recent examples highlight the contribution your reports have made towards improving the safety of medicines locally and world-wide:

- Lumiracoxib and liver failure
- Zolpidem and abnormal sleep-related behaviour
- Travacalm and anticholinergic syndrome
- Black cohosh and liver toxicity
- Cerivastatin and rhabdomyolysis
- The 'Triple Whammy' – acute renal failure due to the combination of ACE inhibitor, diuretic and NSAID
- Leflunomide and pancytopaenia and pulmonary toxicity
- Interactions with St John's Wort
- Flucloxacillin and hepatitis
- Amoxycillin with clavulanic acid and hepatitis
- Clozapine and myocarditis

These and countless others attest to the effectiveness and success of the ADRAC and our pharmacovigilance systems.

Please continue to report adverse reactions

We wish to reinforce the importance of continuing to report adverse reactions to the TGA, since these often provide the impetus for effecting changes to enhance the safety of medicines. Just as they have been critical for the work of ADRAC, your reports will continue to be heavily relied upon to inform and assist the work of ACSOM.

Reference:
1. Mackay K. Showing the blue card: reporting adverse reactions. *Aust Prescr* 2005; 28: 140-142.

2. The last Bulletin

The end of ADRAC inevitably means that our publication will also cease to exist, making way for a new-look and expanded report on medicine safety issues produced by the TGA.

Although modest in appearance and presentation, the Bulletin has stood along side other esteemed Australian publications, including *Australian Prescriber* and *NPS News*, to provide prescribers with practical information and advice on drug safety issues and to inform you about emerging safety issues. Much of the material has been sourced directly from your reports as they provide a real-life experience of clinical practice.

By virtue of its size and by intention, matters published in the *Bulletin* have necessarily been succinct. Therefore, we are pleased to announce that the TGA has decided from 2010 to expand its reporting capability on issues of medicines safety.

A new medicines safety publication – look in Australian Prescriber from 2010

The new TGA publication on medicines safety issues is expected to cover a broader range of issues with greater depth than has been possible given the space constraints of the *Bulletin*.

To maintain continuity, the TGA publication will be contained within the *Australian Prescriber* in 2010. Current subscribers to the *Bulletin* need do nothing to continue to receive this new publication. It will also continue to be available on-line at the TGA website as well as on the *Australian Prescriber* website; electronic subscription to the material will be possible *via* either website at <http://www.tga.gov.au> or <http://www.australianprescriber.com>.

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

ADRAC endorses this move by the TGA and we are pleased to commend to you this new publication.

What will happen to the ADRAC's Drugs of Current Interest scheme?

In line with changes described above, the TGA is developing a new medicines alert system to provide benefit-risk information on new and existing medicines to prescribers and the public. This new scheme will be considerably broader than the current DOCI scheme; further information on it will be published in the new TGA publication and on the TGA website.

3. Thank you to our readers

On behalf of past and current Members, ADRAC extends sincere thanks to our readers for your support and loyalty over the years. It has been our privilege to represent your interests in all matters concerned with medicine safety and we anticipate ACSOM will continue this role with equal enthusiasm. We hope you will welcome the changes described in this *Bulletin* and continue your relationship with the TGA and its new advisory committee on the safety of medicines.

4. A tribute to ADRAC from the TGA

ADRAC has been the cornerstone of post-market drug safety monitoring in this country for many years and has been one of the most important and effective resources available to assist the TGA monitor and manage the safety of medicines.

The effectiveness of this Committee in helping to identify medicine safety concerns and advising on appropriate remedial action has prompted the TGA to establish a new, statutory expert advisory committee on the safety of medicines which will continue and expand the work of the ADRAC into the future.

TGA has been fortunate to have as Members of ADRAC some of Australia's most esteemed and knowledgeable professionals assisting us in our efforts to safeguard the health of the public through the provision of safe medicines.*

We especially acknowledge and thank our current ADRAC Members, who continue to show unfailing willingness to contribute their time, expertise and knowledge in our efforts to build on the exemplary pharmacovigilance systems they have helped create: Professor DJ Topliss (Chair), A/Professor P Pillans, Dr M. Gold, A/Professor S. Strasser, Dr V. Kotsirilos, A/Professor C Lander, Dr D. Wainwright and Professor J. McNeil.

We hope these Members will continue their association with TGA, either as founding or future members of our new, broad-ranging Advisory Committee on the Safety of Medicines.

ADRAC contribution to post market safety of medicines continues with the review of H1N1 influenza vaccine (Panvax) reports

A willingness to assist the TGA in all matters of medicine safety, often at short notice and despite onerous demands on time, has been a consistent and valued trait of ADRAC Members. This is well demonstrated by Members agreeing to hold weekly teleconferences since September specifically to review reports of adverse reactions to Panvax, and to continue these reviews beyond the last official Meeting of ADRAC in December. We are grateful to all ADRAC Members, including co-opted Members Professors D. Isaacs and C Katelaris, for their continued assistance with this important public health issue.

To date, ADRAC is satisfied that the safety profile of Panvax is typical of influenza vaccines. Information on the safety profile of Panvax will be provided on the TGA website.

Once again, we sincerely thank past and present Members of ADRAC for their major contribution towards the provision of safe medicines in Australia.

*Past Members of ADRAC are: TI Robertson (Chair), ML. Mashford, ID Thomas and AM Walshe (founding Members); R. Zacest, B Ashley, J. Robilliard, D. Coventry, J. Raftos, J. Frew, P. Roeser (Chair), R. Hecker, J. Ingham, T Sorrell, D. Henry, M. Van der Weyden, R. Bradbury, S Pond, P. Desmond, L. Wing, G. Shenfield, D. Isaacs, R. Chow, T. Mathew (Chair).

5. Consider applying to become an Expert Adviser to the TGA

The TGA's work in regulating the quality, safety, efficacy and/or performance of medicines and medical devices available in Australia relies on advice from its Expert Advisory Committees and Panels, which comprise distinguished medical and scientific professionals. For information on the range and functions of some of our Committees, visit <http://www.tga.gov.au/committee/index.htm>.

If you are interested in being considered for one of our Expert Advisory Committees or Panels, please send an e-mail to info@tga.gov.au indicating your areas of interest and expertise.

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

ADRAC encourages the reporting of all **suspected** adverse reactions to medicines, including vaccines, OTC medicines, herbal, traditional or alternative remedies. ADRAC particularly requests reports of:

- *ALL suspected reactions to **new drugs** (see **drugs of current interest,** front page**)**
- *ALL suspected drug 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: <http://www.tga.gov.au/adr/bluecard.pdf> or from the Office of Medicines Safety Monitoring ☎ 02-6232-8744.

Reports can also be submitted electronically, by going to the TGA website <http://www.tga.gov.au> and clicking on "report problems" on the left, by fax: 02-6232-8392, or email: ADR.Reports@tga.gov.au

ISSN 0812-3837
The Bulletin is also available on the Internet at: **<http://www.tga.gov.au/adr/aadrb.htm>**
All correspondence to be addressed to: The Director, OMSM, PO Box 100, Woden, ACT, 2606