

# Medicines *Matter*

AN INFORMATION SERVICE FOR PATIENT GROUPS

July 2007

## *Your Key Contacts at Medicines Australia*

### **Ian Chalmers - Chief Executive**



In his role as Chief Executive of Medicines Australia, Ian represents the national interests of the research and innovation based prescription pharmaceuticals manufacturing industry.

Since his appointment the key issues that have been the major focus of Ian's attention have been around changes to the Pharmaceutical Benefits Scheme and the authorisation of Edition 15 of the Medicines Australia Code of Conduct.

Previous appointments over the past 16 years include leadership of national associations representing local government, private hospitals and life insurance intermediaries. Ian has also worked as a policy and research adviser within the Parliamentary Library and as a government relations consultant.

Earlier in his career, Ian spent 10 years as an officer in the Australian Army.

### **Diana Terry - Manager, Stakeholder Relations**



Diana's main area of focus has been around the value of medicines, specifically around a body of research commissioned by Medicines Australia, and on collaborative partnerships with a number of health consumer organisations.

As the Manager Stakeholder Relations, her role falls under the banner of Public Affairs and a major part of her work is establishing and maintaining effective working relationships with health consumer organisations based on openness, transparency and mutual benefit. In addition she is tasked with managing Medicines Australia's corporate social responsibility, philanthropy and sponsorship.

Diana has most recently emerged from the general practice arena where she worked on the national immunisation program and quality assurance. Her previous work experience was in public health, health promotion and education, community maternal and child health, aviation medicine and acute clinical settings. She worked in the UK and New Zealand for a number of years, and has ten years experience working in rural and remote areas across northern Australia, including the Pilbara, Kimberley, Cape York and Torres Strait Islands.

Special interest areas include indigenous health and access issues, quality assurance, and a commitment to social responsibility.

## Pharmaceutical Benefits Scheme Reform

The Australian Government has introduced major reform (changes) to the Pharmaceutical Benefits Scheme (PBS) to obtain better value from generics through changes to the PBS pricing system and, hence, ensure ongoing access to innovative medicines.

The reform distinguishes between single brand medicines with no alternatives for patients (most of which are patented medicines) and multiple brand and other medicines that are interchangeable at the patient level.

From August 2007, medicines on the PBS will be divided into two separate formularies or lists, one largely for single brand medicines, called (F1); and the other largely for multiple brand medicines (F2), where there is competition. Off-patent medicines which only have one brand so far will be in F1, while several single brand patented medicines (which the Government has deemed as interchangeable at the patient level) with multiple brand/generic medicines will be in F2.

There will be no reference pricing between F1 medicines and F2 medicines. Therefore, the price of F1 listed medicines will not be affected by the price of F2 listed medicines, but reference pricing may occur within each formulary. That is, the price of an F1 medicine may relate to the price of another F1 medicine.

### Why did PBS reform (changes to the way PBS-listed medicines are priced) happen?

In November 2006, the Australian Government said that its reforms to the PBS were designed to give Australians continued access to new and expensive medicines while ensuring the PBS remains economically sustainable in the future.

The Government recognised that the former system of reference pricing medicines across the PBS could not continue without: 1. foregoing significant potential savings to them in the off-patent/generic market; or 2. limiting treatment options for patients by not being able to list new (and usually more expensive) medicines on the PBS in the future.

The old system did not allow the Government to obtain savings from generic medicines without compromising patient access to newer medicines, nor did it encourage transparent competition in the generics market.

### Timing of PBS Reform

• **On 1st August 2007**, medicines on the PBS will be divided into two separate formularies, one largely for single brand medicines (F1) and the other largely for multiple brand medicines (F2).

• Medicines that the Australian Government has considered interchangeable at the patient level and will be included in F2, in addition to off-patent medicines, are: ACE Inhibitors,

calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and HMG A reductase inhibitors (pravastatin and simvastatin only).

• Until **1 January 2011**, F2 will be further separated into two parts: F2A (medicines where price competition between brands is low, defined as less than 25% discount) and F2T (medicines where price competition between brands is high, defined as greater than 25% discount).

• There will be a series of mandatory price reductions during the period of transition:

- from **1 August 2008**, an annual price reduction of 2% for three years for F2A medicines; and
- from **1 August 2008** a one-off price reduction of 25% for F2T medicines.

• **From 1st August 2007**, for medicines on F2A only and from 1 January 2011 for all medicines on F2, all new brands that list on the PBS will be subject to new **price disclosure** requirements. The **price disclosure** provisions ensure that the price that the Government pays for a multiple brand medicine more closely reflects the actual price at which the medicine is being supplied to pharmacies in the marketplace. The Government reimbursement price will be calculated using data disclosed by suppliers (e.g. pharmaceutical companies) to the PBS on the actual market price of their products, including monetary and non-monetary discounts.

• Some barriers to prescribing will be removed with the introduction of a new **streamlined authority** provision, which will negate the need for doctors to gain prior approval on around 200 medicines.

### More information on the Australian Government's reforms to Australia's Pharmaceutical Benefits Scheme

**PBS reform website:** <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbsreform-index>

### Australian Department of Health and Ageing:

**Minister for Health and Ageing announcement of PBS reform policy:** <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2006-ta-abb152.htm?OpenDocument&yr=2006&mth=11>

**Submission to Senate inquiry on PBS reform legislation:** [http://www.aph.gov.au/Senate/committee/clac\\_ctte/nat\\_hth\\_pbs\\_07/submissions/sub04.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/submissions/sub04.pdf)

**Australian Prime Minister, the Hon John Howard, MP Radio address 20 November 2006 on PBS reform:** <http://pm.gov.au/media/Speech/2006/speech2258.cfm>

### Medicines Australia's comments on PBS reform:

**Media release: Medicines Australia welcomes focus on patients in PBS reform package** <http://www.medicinesaustralia.com.au/pages/page74.asp>

**Submission to Senate inquiry on PBS reform:** <http://www.medicinesaustralia.com.au/pages/images/Submission%20to%20PBS%20Senate%20inquiry%20final.pdf>

**Opening statement to Senate inquiry hearing:** <http://www.medicinesaustralia.com.au/pages/page97.asp>

**Senate Community Affairs Committee inquiry into PBS reform legislation:**

**Submissions made by various stakeholders, including Medicines Australia:** [http://www.aph.gov.au/Senate/committee/clac\\_ctte/nat\\_hth\\_pbs\\_07/submissions/sublist.htm](http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/submissions/sublist.htm)

**Transcript of the Committee public hearing held Friday, 15 June:** [http://www.aph.gov.au/Senate/committee/clac\\_ctte/nat\\_hth\\_pbs\\_07/hearings/index.htm](http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/hearings/index.htm)

**Committee's final report:** [http://www.aph.gov.au/Senate/committee/clac\\_ctte/nat\\_hth\\_pbs\\_07/report/index.htm](http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pbs_07/report/index.htm)

## Medicines Australia Code of Conduct

Medicines Australia's Code of Conduct sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislative requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act. Code provisions include standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals.

Established in 1960, the pharmaceutical industry Code of Conduct has been reviewed on a regular basis to ensure that the Code continues to reflect current community and professional standards and current government legislation. Only Medicines Australia member companies are bound by this Code. The Edition 15 of the Code took effect from 6 December 2006.

Consultations with, and feedback from, consumer groups, peak medical associations (eg AMA, RACGP, ADGP), Pharmacy Guild and Society, member companies, government and other independent groups have provided the Code Review Committee with valuable insights, recommendations and views on the amendments to the Code.

The Code of Conduct has two arms, firstly the adjudication of complaints undertaken by the Code of Conduct Committee and secondly the proactive monitoring of promotional activities undertaken by the Monitoring Committee.

The Australian Competition Tribunal (the **Tribunal**) granted authorization of Edition 15 of the Code for a period of 5

years subject to compliance with a condition in relation to the reporting of events sponsored by member companies. This condition requires companies to submit records to Medicines Australia every six months, and reports on the details of these events will be made publicly available on the Medicines Australia web site. Details to include the following information:

- Company name
- Number of events held
- Venue
- Description of function including the duration of educational content delivered
- Professional status of attendees
- Hospitality provided
- Total cost of hospitality
- Number of attendees
- Total cost of function

For detailed information on the Code of Conduct please refer to the Code document on the Medicines Australia website - <http://www.medicinesaustralia.com.au/pages/page5.asp> - or contact Medicines Australia on 02 6282 6888.

### Contact Details for Questions or Complaints

If you have any concerns in relation to the activities of a prescription medicine company or wish to lodge a complaint please contact the Secretary, Code of Conduct Committee at Medicines Australia on 02 6282 6888 (9.00am – 5.00pm Monday – Friday) or send an email to [secretarycodecommittee@medicinesaustralia.com.au](mailto:secretarycodecommittee@medicinesaustralia.com.au).

## Upcoming Events

### Jeans for Genes Day

3 August 2007  
[www.jeans4genes.com.au](http://www.jeans4genes.com.au)

### Continence Awareness Week

5 - 11 August 2007  
[www.continence.org.au](http://www.continence.org.au)

### National Healthy Bones Week

5 - 11 August 2007  
[www.osteoporosis.org.au](http://www.osteoporosis.org.au)

### The Heart Foundation Annual Doorknock Appeal

1 - 30 September 2007  
To register to become a Doorknock volunteer please call 1800 55 22 55 or register online at [www.heartfoundation.org.au/doorknock](http://www.heartfoundation.org.au/doorknock)

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