

MEDICINES
AUSTRALIA

ANNUAL REPORT

2011-12



MEDICINES
Australia

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MEDICINES AUSTRALIA VISION + MISSION STATEMENT

VISION

A leader in positive health outcomes, productivity and economic growth through the availability of innovative prescription medicines.

MISSION

In partnership with stakeholders, drive the creation and development of an environment for the continued sustainable growth of the innovative research-based prescription medicines industry.

STRATEGIC DIRECTIONS

1. Achieve credibility with, and obtain the trust of key stakeholders.
2. Continuously improve access to innovative medicines.
3. Achieve an optimal environment for sustainable innovation.
4. Maintain a high standard of ethical industry conduct through effective self-regulation.
5. Demonstrate leadership as a model pharmaceutical industry association.





MR MARK MASTERSON • CHAIRMAN

CHAIRMAN'S REPORT

This is my first report since becoming chairman of Medicines Australia in May this year. I am personally very excited to have stepped into this role at what is a time of great opportunity and challenge for the medicines industry in Australia. As I embark on my first full year as chairman, I am greatly looking forward to working with the Board and with our member companies to ensure we capitalise on some of these opportunities.

I would like to acknowledge at the outset the significant achievements of my predecessor, Will Delaat, who retired as Medicines Australia chairman in February this year after 14 years on the Board, including six as chairman. There can have been no more fitting tribute to Will's contribution to this industry than his being recognised in the Queen's birthday honours list in June this year.

This is a genuinely exciting time for the industry in Australia. While there are undeniable challenges here and internationally, our annual exports exceed \$4 billion, we are investing more than \$1 billion a year in R&D and employ more than 13,000 Australians in high-wage, high-skill jobs.

Having worked for over 20 years in the medicines industry, including senior international roles, I have seen the industry change a lot. The challenges and opportunities facing our sector here and overseas are numerous and I am especially proud and delighted to have the opportunity to lead the industry here in Australia.

Around the world the industry is grappling with a rapidly evolving business environment initiated by changing business pressures, technology developments and government policy changes. The challenge for an industry association like Medicines Australia is to work constructively with our member companies to develop strategies for the industry to prosper through bringing new medicines and vaccines to the Australian community in the future.

Our industry continues to make the latest treatments available to Australian patients. We have a viable and well-managed Pharmaceutical Benefits Scheme and a Memorandum of Understanding with the Federal Government that is providing a more stable and predictable business environment than many other OECD countries.

Medicines Australia continues to enjoy trusting and constructive relationships in Canberra with all sides of politics, as well as with stakeholders across the healthcare sector. Coming into the role as chairman I have already met with many key stakeholders and decision-makers in politics, the bureaucracy, the health sector and broader industry. Even in my few months as chairman we have already covered a range of important policy and business issues including managing PBS expenditure, biologic medicines, clinical trials and a continuing public awareness campaign about the Australian medicines industry.

The membership of Medicines Australia remains strong, vibrant and united, and I welcome our two newest members, who have joined Medicines Australia this year: IQnovate, which joined in August 2011 and Vifor Pharma which joined in November.

There has been considerable turnover within the Medicines Australia Board this financial year, largely as a result of promotions and other redeployment of managing directors within the industry. These changes have allowed us to bring new talent on to the Board and I am very encouraged by the level of ability and depth of experience we have among our current directors. Indeed, I would like to thank the Board for their support and for their strong leadership of our industry and look forward to working with them in the future.

I would also like to acknowledge the tireless commitment of Medicines Australia's chief executive Brendan Shaw, and the secretariat staff who have been skilful and energetic advocates on behalf of our member companies. I would also like to thank those representatives from member companies who have participated so actively in various committees that are vital to informing our debate on relevant issues.

I look forward to continuing to represent the industry in Australia and to promoting the value that it contributes to the health and wealth of the nation.

A handwritten signature in black ink, appearing to read 'M. Masterson'.

Mark Masterson



DR BRENDAN SHAW • CHIEF EXECUTIVE

CHIEF EXECUTIVE'S REPORT

The past year has been a largely successful one for Medicines Australia, despite significant challenges on a number of fronts. It has been a year in which many of our member companies have had to adapt to a changing business environment characterised by patent expiries, global rationalisation and difficult economic conditions. They have done so with great resilience.

It seems that with every year the industry is confronted with more and more challenges either from the market, the community or the government sector. More than ever, the Australian medicines industry has been called upon to demonstrate its value to the community and to government. The best way to achieve this has been through a whole of industry approach as undertaken by Medicines Australia and this year has demonstrated how successful that approach can be.

Medicines Australia has again pursued a busy and focused policy agenda to secure a favourable operating environment and, through the 2010 Memorandum of Understanding, greater business predictability.

For member companies, the agreement has delivered greater certainty. In particular, it was pleasing that the Government demonstrated its commitment to the MoU by ensuring the 2012 Federal Budget contained no price-related savings measures. Indeed, the highest accolade for the MoU last year came from the Prime Minister Julia Gillard, who described it as "a template of effective and respectful engagement for those in industry who would seek to influence government".

A hallmark of that effective and respectful engagement with Government has been the constructive and collaborative approach we continue to take in tackling policy issues. In August 2011 more than 300 people attended the third Joint Medicines Policy Conference hosted by Medicines Australia and the Department of Health and Ageing. The conference achieved some key outcomes to advance health and medicines policy in areas ranging from health technology assessment to post-market surveillance and access for special patient groups.

Medicines Australia worked closely with the Government to achieve a solution – albeit a temporary one – to the issue of Cabinet's deferral of listing some medicines on the PBS. We will continue to advocate for a return to the well-established, independent, non-political process of bringing new medicines on to the PBS that has served Australian patients so well in the past. This is a position that we share with healthcare professionals, academics, multiple health consumer groups and the general public Australia-wide.

We have continued to strengthen our relationships with parliamentarians on all sides of politics, evidenced by the establishment and growth of the Parliamentary Friends of Medicines Group, which has been co-chaired by the Member for Bennelong John Alexander, and the Member for Blair, Shayne Neumann.

At the Medicines Australia Parliamentary dinner in March, the Prime Minister Julia Gillard gave an opening address in which she praised the industry's "magnificent contribution to the health of our people and the productivity of our nation", and hailed the industry as "a great success story". The Medicines Australia Parliamentary dinner was notable also for a keynote speech by Sir Andrew Witty, global chief executive of GlaxoSmithKline and President of the European Federation of Pharmaceutical Industries and Associations, who spoke about the tremendous impact on life expectancy that medicines have had over the past hundred years.

Medicines Australia has advocated strongly for improvements in industry policy both in the areas of R&D and manufacturing. In July 2011 the new R&D tax credit legislation came into effect. Medicines Australia had worked with the Federal Government for three years to develop this tax incentive, which will effectively reduce the cost of eligible research and development by up to 10 per cent.

We have contributed to various industry and economic debates through channels such as the Prime Minister's Manufacturing Taskforce, the Prime Minister's Economic Forum, the Australia in the Asian Century Taskforce, the Federal Opposition's Manufacturing Review, and the McKeon health and medical R&D review. In November I further underscored industry's enormous potential to contribute on all of these fronts in my address to the National Press Club, which was broadcast live to a national television audience.

Unfortunately, progress has been slower than expected in implementing the recommendations of the Clinical Trials Action Group, with the result that Australia continues to lose clinical trials to other countries. The delivery of the CTAG recommendations has been a case of two steps forward, one step back, and that has been extremely disappointing. Australia urgently needs to expedite the harmonisation of multi-centre ethical reviews of clinical trials, and improve patient recruitment and collaboration across trial networks. Most recently, the Federal and State Governments have re-committed to finalising the implementation of the CTAG recommendations by July 2013 at the latest and we look forward to this task being completed.

Through 2011-12 the industry also worked with the Government's regulator, the Therapeutic Goods Administration, on a range of important reforms. Most importantly for industry and patients, the reforms to the evaluation process for prescription medicines. These reforms are designed to improve the efficiency and effectiveness of the evaluation process without compromising its rigour. We continue to work with the TGA to ensure these reforms are implemented in full.

In June 2012 Medicines Australia members unanimously voted to adopt Edition 17 of the Code of Conduct, which was subsequently submitted to the Australian Competition and Consumer Commission for authorisation. This resolution marked the culmination of a 10-month review process that was ably led by Bristol-Myers Squibb managing director and Medicines Australia board member James Cain. Subject to authorisation by the ACCC, Edition 17 of the Code will come into effect on 1 January 2013.

In July 2011 Medicines Australia launched a major campaign to raise awareness of the value of the Australian medicines industry and to promote the contribution we make to the health and wealth of the nation. This important initiative included digital and print advertising in the national media, the establishment of a new website – www.ausmedindustry.com.au – and enhanced public relations activity with a sharpened focus on the value of the industry. Tracking research indicates that the campaign is having a positive impact on public awareness of the industry.

This year Medicines Australia also successfully completed a number of major sponsorship projects to improve Aboriginal health. We completed our two year partnership with the Jimmy Little Foundation. This partnership sponsored the development of educational material, classroom visits and workshops in remote Australia to educate Aboriginal children about healthy eating and living. Unfortunately Jimmy Little passed away earlier this year. It was an honour and pleasure to have worked with him and to be part of growing the Foundation in his name. Medicines Australia also sponsored the building of a mobile dialysis truck for the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation which was launched in December 2011 and has started providing dialysis services to people in remote communities.

Last year also marked Will Delaat's retirement as chairman of Medicines Australia after 14 years on the Board. Will made an enormous contribution to the association as chairman between 2008 and 2011, and during his previous time in that position between 2003 and 2005. I wish to thank Will personally not only for the support he has shown me, but also for the unremitting passion and energy and astute leadership he brought to the position of chairman. He has been a great industry leader, an inspiring mentor and a fine friend and I wish him well in his future endeavours.

The Board could not have appointed a better replacement than Mark Masterson, and I have greatly enjoyed working with Mark during the latter part of the year. His earnest passion and support for Medicines Australia and the industry, combined with his counsel derived from more than 20 years of working in the industry has been invaluable. Mark has already led Medicines Australia's engagement on several key issues and his appointment will serve the industry well.

I would like to thank all those people in the companies that make up the membership of Medicines Australia who assisted the industry through 2011-12, be they members of the Board, representatives on strategic committees and working groups, industry employees who participated in Medicines Australia events, or people who supported the industry in various other ways. They contribute a lot to this is great industry and we have much to be proud of.

Finally, I want to acknowledge the outstanding and dedicated secretariat staff who have again worked tirelessly to ensure the interests of the membership are represented effectively. The staff of Medicines Australia are critical to its success. Every day I am impressed and inspired by their knowledge, professionalism and good grace. It is a pleasure to work alongside them.



Brendan Shaw

MEDICINES AUSTRALIA BOARD MEMBERS 2011-12

Directors 2011-12

Mr Mark Masterson	Appointed Chairman
Dr Dominic Barnes	Vice President & General Manager, Shire Australia Pty Ltd
Dr Graeme Blackman	Chairman, Institute of Drug Technology Australia Ltd
Mr James Cain	Managing Director, Bristol-Myers Squibb Australia Pty Ltd
Dr Susanne Fiedler	Vice President & Managing Director Australia & New Zealand, MSD Pty Ltd
Mr Mark Fladrich	Managing Director, AstraZeneca Pty Ltd
Mr Bruce Goodwin	Managing Director, Janssen Pty Ltd
Mr Rene Klemm	General Manager, Bayer Australia Limited
Mr John Latham	Regional Director (Australia & New Zealand), Pfizer Australia Pty Ltd
Mr Geoff McDonald	Vice President/General Manager, GlaxoSmithKline Australia Pty Ltd
Mr Chris Miskel	General Manager Australia & New Zealand, Eli Lilly Australia Pty Ltd
Ms Kirsten O'Doherty	General Manager, Abbott Australasia Pty Ltd
Mr Ian Thompson	Managing Director, Amgen Australia Pty Ltd

Appointed to Board

1 May 2012
1 January 2012
June 1995
7 September 2010
26 June 2012
1 January 2012
12 May 2009
24 May 2012
6 March 2007
15 June 2012
1 January 2012
24 May 2012
1 May 2009

		Appointed	Resigned
Mr Will Delaat	Chairman (joined Board August 1998)	4 April 2008	29 February 2012
Mr Mark Glover	Allergan Australia Pty Ltd	30 May 2011	14 October 2011
Mr Frederic Guerard	Managing Director, Novartis Pharmaceuticals Australia Pty Ltd	23 June 2009	30 June 2012
Mr Jean Monin	General Manager, Sanofi Australia Pty Ltd	1 July 2011	15 June 2012
Ms Jane Orr	Managing Director, MSD Pty Ltd	18 December 2010	28 April 2012
Mr Dean Phizacklea	Managing Director, Abbott Australasia Pty Ltd	7 September 2010	16 Dec 2011
Mr José Antonio Toledo Vieira	Managing Director, AstraZeneca Pty Ltd	1 January 2008	31 August 2011
Ms Deborah Waterhouse	General Manager, GlaxoSmithKline Australia Pty Ltd	9 December 2008	30 April 2012

MEDICINES AUSTRALIA BOARD MEMBERS 2011-12



1 Mark Masterson
2 Dominic Barnes
3 Graeme Blackman
4 James Cain
5 Susanne Fiedler
6 Mark Fladrich
7 Bruce Goodwin

8 Rene Klemm
9 John Latham
10 Geoff McDonald
11 Chris Miskel
12 Kirsten O'Doherty
13 Ian Thompson
14 Will Delaat

15 Mark Glover
16 Jean Monin
17 Frederic Guerard
18 Jane Orr
19 Dean Phizacklea
20 José Antonio Toledo Vieira
21 Deborah Waterhouse

MEDICINES AUSTRALIA SECRETARIAT 2011-12

LEADERSHIP



- | | | |
|---|-----------------|---|
| 1 | Brendan Shaw | Chief Executive |
| 2 | Louise Collett | Executive Assistant to the Chief Executive |
| 3 | Katie Whitehead | Director Corporate Services & Company Secretary |
| 4 | Di Phillips | Finance Manager |
| 5 | David Newman | IT Manager |
| 6 | Rochelle Pelaez | Executive Officer |
| 7 | Amna Khanzada | Office Administrator |
| 8 | Prya Sonah | Finance Assistant |

ACCESS



- | | | |
|---|--------------------|-------------------------------------|
| 1 | Andrew Bruce | Director Health Policy and Research |
| 2 | Jim Crompton | Reimbursement Strategies Manager |
| 3 | Elizabeth de Somer | Regulatory Affairs Manager |
| 4 | Kristin Trace | Policy Manager |
| 5 | Amish Chaturvedi | Research Manager |
| 6 | James Turnley | Access to Medicines Policy Officer |

INNOVATION AND ETHICAL CONDUCT



- | | | |
|---|----------------|---|
| 1 | Deborah Monk | Director Innovation and Industry Policy |
| 2 | Sophie Hibburd | Code of Conduct Manager |
| 3 | Omar Ali Khan | Innovation and Industry Senior Policy Officer |
| 4 | Zoe Morton | Code of Conduct Administration Officer |

IMAGE



- | | | |
|---|-----------------|-----------------------------------|
| 1 | Donna Edman | Executive Director Public Affairs |
| 2 | Jamie Nicholson | Media Communications Manager |
| 3 | Andrew Simpson | Government Relations Manager |
| 4 | Diana Terry | Stakeholder Relations Manager |
| 5 | Julie Johnson | Public Affairs Officer |

**Staff who departed in 2011-12**

- | | | |
|---|-----------------|--|
| 1 | Romina Bognolo | Code of Conduct Administration Officer |
| 2 | Larissa Karpish | Policy Manager |
| 3 | Juanita Wall | Personal Assistant to the Innovation and Industry
Policy and Public Affairs Directors |

MEDICINES AUSTRALIA MEMBERS 2011-12

CLASS ONE

Abbott Australasia Pty Ltd
 Actelion Pharmaceuticals Australia Pty Ltd
 Allergan Australia Pty Ltd
 Amgen Australia Pty Ltd
 AstraZeneca Pty Ltd
 Baxter Healthcare Pty Ltd
 Bayer Australia Pty Ltd
 Biogen Idec Australia Pty Ltd
 Boehringer Ingelheim Pty Ltd
 Bristol-Myers Squibb Australia Pty Ltd
 Celgene Pty Ltd
 CSL Limited
 Eli Lilly Australia Pty Ltd
 Gilead Sciences Pty Ltd
 GlaxoSmithKline Australia Pty Ltd
 Ipsen Pty Ltd
 Janssen Pty Ltd
 Lundbeck Australia Pty Ltd
 Merck Serono Australia Pty Ltd
 MSD Australia Pty Ltd
 Mundipharma Pty Ltd
 Novartis Pharmaceuticals Australia Pty Ltd
 Novo Nordisk Pharmaceuticals Pty Ltd - Australia
 Nycomed: A Takeda Company
 Pfizer Australia Pty Ltd
 Roche Products Pty Ltd
 sanofi-aventis Australia Pty Ltd
 Servier Laboratories (Aust) Pty Ltd
 Shire Australia Pty Limited
 UCB Australia Pty Ltd

CLASS TWO

Fresenius Kabi Australia Pty Ltd
 Genzyme Australasia Pty Ltd
 iNova Pharmaceuticals Pty Ltd
 Invida Australia Pty Ltd
 Norgine Pty Limited
 Smith & Nephew Pty Ltd

CLASS THREE

Astellas Pharma Australia
 FIT-BioCeuticals Ltd
 IDT Australia Ltd
 Leo Pharma
 Vifor Pharma Pty Ltd

CLASS FOUR

Andrew's Refrigerated Transport
 Commercial Eyes Pty Ltd
 Covance Pty Ltd
 IMS Health Australia Pty Ltd
 IQnovate
 Iris Interactive Pty Ltd
 Kendle Pty Ltd
 KMC Health Care
 Pretium Pty Ltd
 PricewaterhouseCoopers
 Princeton Publishing Pty Ltd
 Quintiles Australia Pty Ltd



¹ Then Medicines Australia chairman Will Delaat, Consumers Health Forum chief executive officer Carol Bennett and Generic Medicines Industry Association chairman Martin Cross met with Prime Minister Julia Gillard on 5 October 2011 to discuss the deferral by Cabinet of the listing of medicines on the Pharmaceutical Benefits Scheme (PBS). Photo courtesy of the Consumers Health Forum.

KEY ISSUES

IMPROVING TIMELY ACCESS TO MEDICINES FOR AUSTRALIANS

2011-2012 continued to deliver challenges for access to medicines in Australia. The policy and regulatory issues in providing Australians access to medicines are many and varied. Through the year Medicines Australia and its member companies worked to resolve a number of issues.

Memorandum of Understanding

The policy changes introduced within the Memorandum of Understanding (MoU) with the Commonwealth in 2010 were designed to improve stability and speed time to listing. During this second year of the MoU some effort was spent in monitoring the implementation and effect of these policies, as industry and the Government became more familiar with the workings of them and the mutual benefits. However, the uncertainty introduced by the Cabinet decision to defer a number of new PBS listings recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) last year unravelled industry confidence in a predictable operating environment.

Over the last twelve months, members have continued to make use of the parallel TGA/PBAC processing provision, with 41 per

cent of major submissions in the 2011-2012 year selecting this route. The Therapeutic Goods Administration (TGA) have gathered data on the timeframes for registration decisions, showing reasonable average timeframes, but still a lack of certainty in the process. Planning the timing of parallel submissions with sufficient interval to receive the relevant TGA documentation has, therefore, remained challenging.

There are other successes to be reported with the processes implemented from the MoU. Short term horizon scanning and assessment of PBAC anticipated workflow has assisted in planning for both the companies and the PBAC. Since September 2011, Cabinet decisions on new PBS listings recommended by the PBAC have been achieved consistently within six month timeframes. The 12 month moratorium on cabinet deferrals is due to expire on 30 September 2012, although it is as yet unclear whether the post moratorium environment will alter significantly. Medicines Australia is also being provided with data on timeframes from pricing agreement to PBS listing. This is useful information to influence more timely access to medicines in the future.

Government PBS Deferrals

After the disappointment of the February 2011 decision by the Government to defer the listing of a number of new medicines on the PBS, 2011-2012 saw the issue at least temporarily resolved. In September 2011 Medicines Australia, together with the Generic Medicines Industry Association and the Consumers Health Forum, reached an agreement with the Government on a way forward. The Government agreed to list immediately all deferred medicines and not to defer medicines



2 Pharmaceutical Benefits Advisory Committee Chair Suzanne Hill speaking at the Medicines Australia managing directors dinner on 23 May 2012.

costing less than \$10million a year. In return, Medicines Australia and the other two groups agreed to discuss a number of future PBS policy topics. By the end of 2011-2012, no further medicines had been deferred and the parties had agreed to start discussions about the PBS policy environment after the MoU expired on 30 June 2014. At the Medicines Australia Parliamentary Dinner in February 2012, Prime Minister Julia Gillard made the point of acknowledging the constructive and professional way Medicines Australia and its member companies engaged with the Government to resolve a difficult policy problem in the deferrals issue.

Therapeutic Goods Administration and regulatory reform

The TGA are continuing to work with the industry to resolve the difficulties in meeting predictable regulatory timelines to further assist companies in planning for early submission to the PBAC. The burdensome program of regulatory reform announced in 2011 and scheduled for implementation over the next four years will continue to exert pressure on their resource capacity. In particular, the TGA's business process reforms for evaluating prescription medicines are key and the industry will continue to work with the TGA to complete their implementation.

Co-dependent technologies

Short term horizon scanning and assessment of PBAC anticipated workflow has also been useful for improving discussions with the Medicare Benefits Division in the development of co-dependent technologies pathways. The improved communication has helped to deliver a single evaluation process for co-dependent technology pairings. However, there is much work still to be done in this area. Creating flexibility in the submission process, and transparency of decision making and listing timeframes from Medical Services Advisory Committee (MSAC) recommendations, needs development.

PBS listing process

Medicines Australia continued to engage with the policy and administrative processes in the PBS. The new Chair of the Pharmaceutical Benefits Advisory Committee, Dr Suzanne Hill, took up her appointment in late 2011. Medicines Australia has worked with Dr Hill as she has settled into this important role. Medicines Australia also farewelled outgoing PBAC Chair Professor Lloyd Sansom who served in the role for a decade.

Through 2011-2012, Medicines Australia and its member companies progressed a number of engagements with the Government on PBS policy, including the 3rd Joint Medicines Policy Conference, which focussed on health technology assessment, and the annual Medicines Australia-PBAC meeting. Medicines Australia also continued its work on the PBAC subcommittees and the Pharmaceutical Benefits Pricing Authority.

Medicines Australia has continued to meet regularly with the central agencies and economic departments of Government to discuss the broader value of medicines within the health system and the understated savings that are currently derived.

However, it is important to note that the overriding fiscal pressures that Government is currently bringing to bear will remain, and will continue to compel the need for measures to assist in predicting and managing PBS expenditure and growth.

Medicines Australia will continue to work with the Commonwealth and stakeholders to determine the most favourable environment for access to medicines. It is clear that the industry will face a number of challenges in the coming year with continued pressure from the government for fiscal security. This will continue to challenge business certainty and transform the role of other stakeholders when negotiating with Government.

KEY ISSUES

IMPROVING THE
INVESTMENT
ENVIRONMENT**R&D Tax Credit**

On 24 August 2011, after nearly three years of debate and negotiations, the Australian Parliament passed legislation to implement the new R&D Tax Credit system. Medicines Australia was one of the earliest and strongest advocates of the new system, and we enthusiastically welcomed its introduction. The new R&D Tax Credit system makes access to tax benefits more predictable and helps reduce the cost of conducting eligible R&D in Australia by up to 10 per cent. In addition, there is no requirement under the new system for companies to demonstrate year-on-year growth in R&D expenditure in order to claim a tax benefit, nor is there a requirement for intellectual property from an eligible R&D project to be held in Australia. Above all, the new system provides a globally competitive tax incentive for conducting R&D activities in Australia. In fact, following the R&D Tax Credit system's implementation, a report by KPMG placed Australia at the top of its ranking of the most competitive locations for R&D investment, ahead of countries like Canada, the United Kingdom, France, Germany and Japan.

Gene Patents

In early 2011, a group of MPs and Senators introduced a Private Members' Bill seeking to ban patents on all biological and genetic materials. The Bill was immediately referred to the Senate Legal and Constitutional Affairs Committee for review.

Medicines Australia urged the Committee, in two [submissions](#) as well as in public testimony, to recommend that the Private Members' Bill be rejected and that Parliament investigate other, more meaningful ways to achieve the Bill's goals, which were to:

- improve Australian patients' access to new health technologies; and
- ensure that Australian scientists are free to conduct research on patented inventions, so long as it is not their intention to infringe valid patents by selling these inventions without the inventors' permission.

On 22 September 2011, the Committee released a report calling on Parliament to reject the Private Members' Bill. This was the fourth time a Federal inquiry found no grounds for a ban on patents on biological and genetic materials.



1 Medicines Australia launched a paper on clinical trial activity in Australia at a Parliamentary Friends of Medicines event in November 2011; (left to right) Shayne Neumann MP, Medicines Australia chief executive Brendan Shaw, AstraZeneca managing director Mark Fladrich, John Alexander MP, FIT Bioceuticals technical director Evan Hayes, Sanofi general manager Jean Monin, Eli Lilly general manager Chris Miskel, and Shire vice president and general manager Dominic Barnes.

Raising the Bar

On 20 March 2012, following three years of consultation, during which time Medicines Australia made numerous submissions, Parliament passed the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* aimed at overhauling Australia's patent system.

Medicines Australia strongly supported the Bill's implementation because it would help elevate the standard of Australian patents and codify an explicit research-use exemption which directly addresses concerns among certain stakeholders that patents on biological materials have the potential to stifle scientific research.

Medicines Australia was also pleased the Bill passed by Parliament incorporated relatively lenient transitional arrangements, including a provision that would allow existing patent applications to be judged against existing criteria, both at the time of application as well as during any subsequent defence or revocation proceedings.

Carbon Tax

Under the Australian Government's Clean Energy Future Plan, a new tax applies to most products containing synthetic greenhouse gases covered by the Kyoto Protocol. These gases include HFC 227, HFC 134a and other types of hydrofluorocarbons and perfluorocarbons which are commonly used as propellants in certain medicinal products like metered dose inhalers.

Medicines Australia worked with the Department of Sustainability & Environment and the Treasury to secure an exemption for all medicinal products from the new tax. It was estimated that, without an exemption, the new tax would cost affected companies around \$1.34 per unit (or, based on existing usage rates, just over \$65 million per year combined).



1 Members vote on the Code of Conduct at a General Meeting on 26 June 2012.

2 Chair of the Code Review Panel: Medicines Australia Board member James Cain.

KEY ISSUES

REVIEWING THE CODE OF CONDUCT

In May 2012, Medicines Australia was formally advised that the Australian Government had agreed with our proposal to exempt from the carbon tax all products used for medical, veterinary, health and safety purposes, including metered dose inhalers. However, the Government also established some new licensing and reporting requirements. Despite this, the exemption represents a significant saving for companies marketing medicinal products containing synthetic greenhouse gases in Australia.

Clinical Trials

The Australian Government in 2009 established the Clinical Trials Action Group, which released its final report in March 2011, making over 20 recommendations, aimed mostly at improving patient recruitment and making the process of initiating and conducting clinical trials in Australia significantly more efficient and cost effective.

In July 2011, to facilitate the implementation of these recommendations, the Federal Government established the CTAG Coordination Group, which consists of representatives from industry, state and Federal departments of health and industry, the National E-Health Transitional Authority and the National Health and Medical Research Council. Despite consistent efforts by some of the relevant parties, progress on the implementation of the Action Group's recommendations has been frustratingly slow over the past 12 months.

The number of new clinical trials declined by an alarming 34 per cent between 2008 and 2010 and despite a small increase in 2011, there were still around 26 per cent fewer clinical trials initiated in 2011 compared to 2007.

Code of Conduct Review

In August 2011 Medicines Australia commenced the three-yearly review of the Code of Conduct. The primary purpose for each triennial review is to ensure that the provisions of the Code and its administration remain appropriate and relevant to the Australian and international environments, taking into consideration the interests of consumers, government, healthcare professionals and the industry. Through regular consultation with all interested stakeholders as part of the review and revising the Code, it is intended that the Code will keep pace with changing standards and community expectations.

As with the last review of the Code, Medicines Australia once again appointed an independent auditor, the St James Ethics Centre, to oversee the process. The role of the auditor was to ensure that the review was comprehensive, effective, responsive and transparent.

To ensure that we captured the views of consumers in the Code review, Medicines Australia once again held facilitated workshops which enabled individuals and organisations to actively participate in the review. These workshops were held in Sydney, Perth and Melbourne in March 2012 and provided a valuable opportunity for consumer views to be voiced and heard by the Code Review Panel.

Medicines Australia received 61 submissions from state and Commonwealth government departments, health consumer organisations, peak industry bodies, peak healthcare professional organisations, businesses working with the

pharmaceutical industry, pharmaceutical companies and individuals. The number of submissions received represents a significant increase on the previous review in 2008/2009, where 46 submissions were received.

Edition 17 of the Code of Conduct was adopted at a general meeting of the Medicines Australia Membership on 26 June 2012. Following that adoption, Medicines Australia lodged an application for authorisation of the new Code with the Australian Competition & Consumer Commission (ACCC). It is anticipated that the ACCC will make a final determination by December 2012, and if the Code is authorised, Edition 17 of the Code of Conduct will take effect from 1 January 2013.

Medicines Australia remains committed to the continuous improvement of ethical conduct in the industry. This is evident in the recommendations of the Code Review Panel committing to transparency measures that will see a transformation in the disclosure of arrangements between the industry and healthcare professionals.

Continuing Education Program (CEP)

The Medicines Australia Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. It is also intended to educate other company personnel about the Medicines Australia Code of Conduct.

At the expiration of the contract with the previous provider of the Medicines Australia CEP, Medicines Australia commenced a tender process for the ongoing management and delivery of the CEP. Following a thorough tender process, which included a rigorous selection and interview process, the University of Tasmania was awarded a four year contract to provide the CEP. The CEP will be provided through the Unit for Medical Research and Education (UMORE) in the University's School of Pharmacy.

Principles of Ethical Conduct

The Working Group on the Promotion of Therapeutic Goods, established by the former Parliamentary Secretary for Health, Mark Butler MP, in mid-2010, delivered its Report to the current Parliamentary Secretary, Catherine King MP, in March 2011. The Government responded to the report in December 2011, as part of its response to several reviews, by releasing "TGA Reforms: A blueprint for TGA's future". Whilst the Government endorsed many of the Working Group on Promotion's recommendations, it fell short of taking positive action on several key recommendations that would ensure all companies that supply therapeutic goods in Australia adhere to an industry code of conduct.

However, in the May 2012 Federal Budget the Government allocated \$1.4 million over four years "to assist the therapeutic goods industry to develop strong, consistent and enforceable codes of conduct based on a common framework of high level principles, better communication mechanisms and shared systems for complaints reporting."

While the Government did not accept all of the Working Group's recommendations, Medicines Australia's incorporated all relevant recommendations into the 17th edition of the Code of Conduct, including the high level principles for ethical conduct developed by the Working Group.

Educational Event Reports

Member companies continued to report all educational meetings and symposia that they organise or sponsor. These reports are published every six months on the Medicines Australia [website](#). Companies have consistently demonstrated a high level of compliance with the Code and ongoing commitment to improved transparency of these interactions with healthcare professionals, which deliver and support valuable education about the treatments available to Australians.

In December 2011 and June 2012 Medicines Australia published educational event reports for the periods April - September 2011 and October 2011 - March 2012 respectively. There were over 18,000 events reported for April - September 2011 and almost 14,000 events reported for October 2011 - March 2012. The lower number of events in this period most likely reflects the fact that it includes the December-January holiday period.

The Monitoring Committee will complete its review of three randomly selected months from the last 12 months of reports in July and August 2012. The outcomes of this review will be published at the completion of that review.

Reporting educational events is now standard good business practice for Medicines Australia member companies. We are pleased to see that Generic Medicines Industry Association members continue to report the events that they organise or sponsor for health professionals, as required under the GMiA's Code of Practice.

How we performed

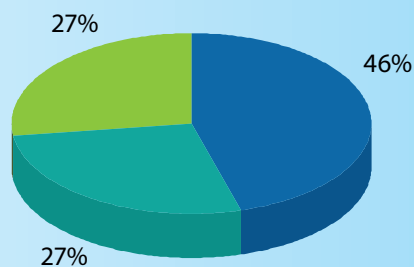
In 2011-2012 member companies maintained a high level of compliance with the Code.

During the year 12 new complaints were received, which is a small decrease from 2010-2011 when 14 new complaints were submitted to Medicines Australia. Four of the new complaints received this year were from pharmaceutical companies, with the balance from healthcare professionals (six complaints) and the Monitoring Committee (two complaints). Of the new complaints received, one remains outstanding as at 30 June 2012. Of the finalised complaints, five were found not in breach of the Code and six were found to be in breach in relation to some or all of the alleged breaches. Details of the complaints considered and finalised in 2011-2012 and the outcomes are reported in the [Code of Conduct Annual Report](#), which is published on the Medicines Australia website.

The Monitoring Committee undertook a substantial number of reviews of company promotional materials and other activities during the year. In 2011-2012 the Monitoring Committee undertook five reviews of materials associated with particular therapeutic areas as well as reviews of patient education materials and patient support programs, media releases directed to consumer media, disease education activities in any media and websites directed at healthcare professionals. The reviews of patient education materials and patient support programs and websites directed to healthcare professionals were particularly extensive, each taking two meetings of the Committee to complete its examination of materials and responses from companies to questions raised by the Committee.

CODE OF CONDUCT PERFORMANCE IN 2011-12: A SNAPSHOT

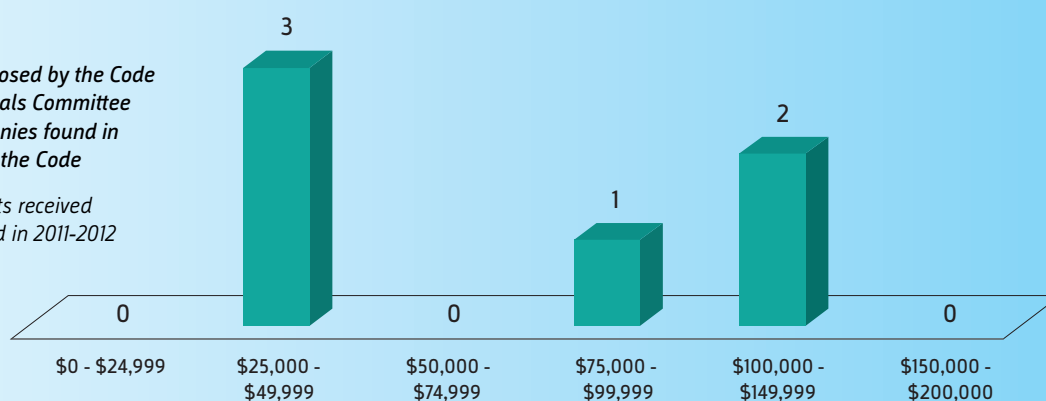
*Outcomes of complaints
received and finalised
in 2011-2012*



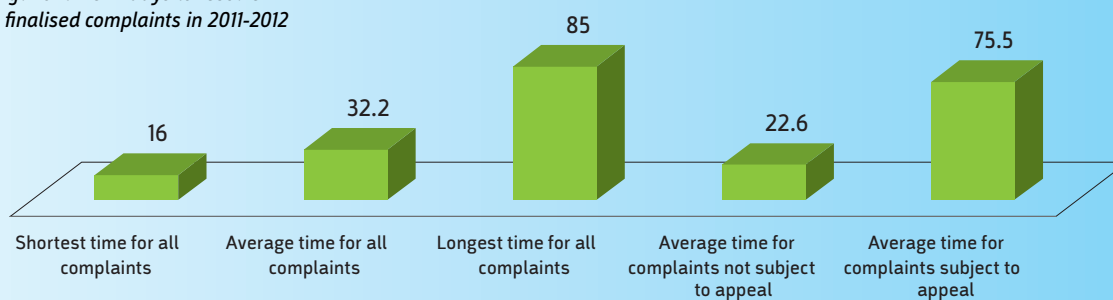
- Where no aspects of a complaint were found to be in breach N = 5
- Where all aspects of a complaint were found to be in breach N = 3
- Where some aspects of a complaint were found to be in breach N = 3

*Fines imposed by the Code
and Appeals Committee
on companies found in
breach of the Code*

*Complaints received
& finalised in 2011-2012*



*Length of time in days to resolve
all finalised complaints in 2011-2012*





- *Driven by discovery*
- *Supporting Australian science*
- *Delivering Australian clinical trials*
- *Acting with integrity*
- *Committed to Australia*



The Prime Minister of Australia Julia Gillard played a part in getting the industry message out when she said, "I...acknowledge this industry and its magnificent contribution to the health of our people and the productivity of our nation...You are a great success story...employing 14,000 people and sending abroad exports worth \$4billion a year...I want this industry to succeed and thrive" at the Medicines Australia Parliamentary Dinner on 29 February 2012.

KEY ISSUES

PROMOTING THE AUSTRALIAN MEDICINES INDUSTRY

This year Medicines Australia commenced a public awareness campaign to get Australians thinking about our industry's contribution to the health and wealth of the nation.

The Australian Medicines Industry brand is the collective face of the industry for the general public.

Our brand promise:

- We deliver and support innovative medicines and vaccines that all Australians need to live healthier, longer and more fulfilling lives.

Key messages conveyed were that the Australian Medicines Industry:

- Invests \$1billion a year in R&D
- Exports more in value than the wine and car industries – around \$4billion per annum
- Employs around 14,000 high wage, highly skilled people
- Is a great success story and worth supporting because we support the health and wealth of the nation.

Advertisements were placed in *The Weekend Australian* magazine, and *The Australian* newspaper from July to October 2011 and the *Daily Telegraph*, *Herald Sun*, *Courier Mail*, *The Advertiser*, *Sunday Times* and *Canberra Times* from March to June 2012. Advertising was also placed in a custom magazine entitled, 'The Health of The Nation' produced by The Weekend Australian's journalists and 10,000 copies were distributed to industry employees. The gross reach of advertising in News Ltd press was 4.2 million people with a projected audience of 988,000 and a frequency of 6.56 times with the target audience.

Campaign messaging had cut-through with the key audience tested in independent tracking research undertaken pre and post advertising placements conducted by Environmetrics Pty Ltd for Medicines Australia (wave 1 was completed in week ending 25 July 2011; wave 2 was completed week of 31 October 2011 with 1000+ participants).

Some of the advertisements for The Australian Medicines Industry



Australian medicines exports exceeded \$4 billion last year

Not without a little help from Andrew and his medicines industry colleagues

Andrew Leggett is a busy man. Between his gigs (Medicines Australia and the ABC) and coping with puppy issues, Andrew hardly ever gets out in his regular life. But that he needs to make time for his job as a pharmaceutical company's public relations officer is a testament to the industry's importance to the nation's health.

Andrew Leggett is a busy man. Between his gigs (Medicines Australia and the ABC) and coping with puppy issues, Andrew hardly ever gets out in his regular life. But that he needs to make time for his job as a pharmaceutical company's public relations officer is a testament to the industry's importance to the nation's health.

Everyone involved is proud to be part of The Australian Medicines Industry, and it's a privilege to be part of it. Andrew's passion is to ensure that the medicines industry is seen for what it is: a vital part of the nation's health.

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the Australian medicines INDUSTRY
Supporting Australia's health

If this story has got you thinking visit www.ausmedindustry.com.au to find out more about the medicines industry in Australia



The Australian Medicines Industry invested \$1 billion in research in 2010

So Anne De Luca and her colleagues could keep trailing new medicines for diseases like cancer

For Anne, the weekend is a familiar sight of a scientist, wearing a lab coat and gloves, working in a lab. But during the week, she's a mother of two, a wife, and a professional. Anne De Luca is a scientist at a pharmaceutical company, and she's also a mother of two, a wife, and a professional.

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the Australian medicines INDUSTRY
Supporting Australia's health

If this story has got you thinking visit www.ausmedindustry.com.au to find out more about the medicines industry in Australia



Since 2000 The Australian Medicines Industry has released over 200 new medicines

And people like Ian help keep our healthcare professionals up to date

Ian Gilchrist is a busy man. Between his gigs (Medicines Australia and the ABC) and coping with puppy issues, Ian hardly ever gets out in his regular life. But that he needs to make time for his job as a pharmaceutical company's public relations officer is a testament to the industry's importance to the nation's health.

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the Australian medicines INDUSTRY
Supporting Australia's health

If this story has got you thinking visit www.ausmedindustry.com.au to find out more about the medicines industry in Australia

A snapshot of the website at www.ausmedindustry.com.au

A website featuring sections which include 'Making Medicines', 'Using Medicines', 'Careers', and 'Supporting the Community' received over 80,000 visits from people in 142 countries, and Medicines Australia serviced 123 requests arising from the website from members of the public. Interest from other industry associations was received from Belgium, Canada, the UK and US.

In addition to print advertising and digital advertising, there were regular blogs and updates to the consumer website, e-newsletters and a number of PR initiatives including feature placements, the discussion of polling results on Australians' attitudes to vaccines and a *Medicines Memories* patient stories project.



the Australian medicines INDUSTRY
Supporting Australia's health

WELCOME

Welcome to The Australian Medicines Industry website. We are the companies that produce and supply the medicines and vaccines that you use every day. We also discover, research and develop the new medicines and vaccines that you'll be using in the future. In doing this we play an important role in supporting both the health and the wealth of the nation. Let us introduce you to some of the people who work for us and help you find out more about what we do.

MAKING MEDICINES

The process, the costs, the timeline – making new medicines available to the Australian general public is one of The Australian Medicines Industry's primary goals. It's a highly complicated business – but here's a simple overview of the whole process. [Learn more...](#)

USING MEDICINES

From your initial prescription through to disposing of unwanted medicines and every step along the way, The Australian Medicines Industry plays its part – investigate our role by following this interactive timeline. [Learn more...](#)

HISTORY

From original medicines up to the present day, follow the story as it evolved and you will begin to see the extent of the change that medicines have helped to deliver in Australia – with some interesting facts and excellent links to more information if you are interested. [Learn more...](#)

Healthcare Blog

Careers

[Home](#) [Privacy Policy](#) [Terms of Use](#) [Sitemap](#) [Links](#) [Contact Us](#)

Digital banner advertising for The Australian Medicines Industry (below)



Australian medicines exports were \$4 billion last year

Not without a little help from Andrew and his medicines industry colleagues

If this has got you thinking click through to www.ausmedindustry.com.au

the Australian medicines INDUSTRY
Supporting Australia's health

The campaign is a project which has been assisted by many people from our industry including

- stewardship from members of the Medicines Australia Image Strategic Committee
- brand champions from member companies
- industry employees who stepped forward to share their stories and start our public conversation, in particular: Wayne Adcock, CSL Biotherapies / Alan Brnabic, Eli Lilly / Ian Gillespie, Sanofi / Andrew Legro, GSK / Anne De Luca, Pfizer / Karen Smith, Merck Serono / Carolyn Winkler, Mundipharma
- Managing Directors who continue to engage publicly to improve the understanding of The Australian Medicines Industry among the general public.

KEY EVENTS DIARY

JULY 2011

- Medicines Australia made a [submission](#) to the Senate Finance and Public Administration References Committee inquiry into the Government's administration of the Pharmaceutical Benefits Scheme. Representatives from Medicines Australia and a number of member companies appeared before the Committee.
- The Australian Medicines Industry Brand was launched to the public through a range of activities including a public [website](#), the *Health of the Nation* initiative in *The Weekend Australian* newspaper, and advertisements *The Weekend Australian* magazine.
- Over 300 delegates attended the third Joint Medicines Policy Conference, co-hosted by Medicines Australia and the Department of Health and Ageing. Health Minister Nicola Roxon MP opened the Conference which featured 32 speakers and was attended by representatives from industry, government, academia, patient groups and other stakeholders. Transcripts and audio recordings of conference presentations are available [here](#).
- Medicines Australia and the Consumers Health Forum co-hosted a forum for consumers on *Medicines, Health Technologies and Reform* prior to the Joint Medicines Policy Conference.

AUGUST

- Medicines Australia lodged a [submission](#) with the Department of Health and Ageing regarding the Personally Controlled Electronic Health Records Legislation Issues Paper.
- Will Delaat met with Prime Minister Gillard to discuss Cabinet's decision to defer the listing of some medicines on the PBS. He was joined at that meeting by Carol Bennett of the Consumers Health Forum and Martin Cross from the Generic Medicines Industry Association.
- Will Delaat hosted a members-only industry lunch with Health Minister Nicola Roxon MP.
- Medicines Australia lodged a [submission](#) to the Department of Innovation, Science and Research on the R&D Tax Credit Exposure Draft Regulations and Decision Making Principles.
- Will Delaat visited the communities of Beswick and Barunga (near Katherine, NT) to experience first-hand the Uncle Jimmy Thumbs Up Program being funded by the Medicines Australia [Special Purpose Fund](#). The visit included demonstrations of classroom workshops, community festivals and a meeting with Outback Stores representatives.
- After two years of debate, the Australian Parliament passed legislation to implement the new R&D Tax Credit system. Medicines Australia strongly supported the implementation of the new system.
- The Medicines Australia-Department of Health and Ageing Access to Medicines Working Group met.
- Brendan Shaw attended The National Party Federal Council and met with a number of Members of Parliament.
- Medicines Australia and the Department of Health and Ageing co-hosted a technical symposium on the use of observational data sets and possible confounders.

SEPTEMBER

- The Code Review Panel, chaired by Medicines Australia Board member Jim Cain, held its first meeting, officially commencing the review of Edition 16 of the [Code of Conduct](#).
- The Senate Legal and Constitutional Affairs Committee released its report rejecting the Private Members Bill that sought to ban patents on biological materials. The bipartisan report quoted extensively from Medicines Australia's submission and vindicated the industry's position that passing the Bill would harm patients, researchers and the pharmaceuticals industry in Australia.
- Medicines Australia attended a Therapeutics Goods Administration (TGA) Industry Consultative Committee meeting to discuss the changing face of the TGA and its reform program.
- Will Delaat spoke about the Australian medicines industry at the 2011 PRIME Awards which celebrate excellence in the pharmaceutical industry.
- The Government, Medicines Australia, the Generic Medicines Industry Association and Consumers Health Forum reached agreement on a Statement of principles of commitment between stakeholders relating to Pharmaceutical Benefit Scheme (PBS) deferrals.

OCTOBER

- Will Delaat, Brendan Shaw and several Board members met with Health Minister Nicola Roxon MP and Finance Minister Senator Penny Wong to discuss the sustainability of the PBS and longer-term questions of healthcare expenditure.
- Medicines Australia met with the new chair of the Pharmaceutical Benefits Advisory Committee (PBAC) Dr Suzanne Hill and representatives from the Department of Health and Ageing to discuss the agenda for the annual Medicines Australia-PBAC meeting scheduled for November.
- Medicines Australia met with Shadow Minister for Innovation, Industry and Science Sophie Mirabella MP for consultations as part of the Coalition's 'Industries for Australia's Future' review.
- The Medicine Memories programme, an initiative of The Australian Medicines Industry, was launched. The programme invited Australians to share their stories of improved health through medicines.
- The Medicines Australia Board met in Sydney. The Secretary of the Department of Health and Ageing Jane Halton addressed the meeting.
- The Medicines Australia Annual General Meeting took place in Sydney. Medicines Australia's 2010-11 Financial Report and Annual Report were tabled at the meeting and Board members for 2012-13 were announced.
- The Parliamentary Friends of Medicine Group was formed under the sponsorship of Member for Bennelong, John Alexander MP, and Member for Blair, Shayne Newmann MP. Medicines Australia sponsored an inaugural Parliamentary Friends of Medicines event at which a Medicines Australia [occasional paper](#) titled *Keeping Clinical Trials in Australia: Why action is needed now* was launched.
- Minister for Health and Ageing Nicola Roxon MP presented the Excellence in Health Journalism Awards, sponsored by Medicines Australia. The 2011 National Press Club Health Journalist of the Year Award went to Sonya Pemberton for the story "Immortal".
- Medicines Australia lodged a [submission](#) to the Federal Coalition's Industries for Australia's Future review. The review examined factors affecting the expansion and contraction of industry sectors under the influence of the mining boom, and how policy makers should best respond.
- The Annual Joint Medicines Australia-Pharmaceutical Benefits Advisory Committee (PBAC) meeting was held, the first with new PBAC Chair Dr Suzanne Hill.
- Medicines Australia held information workshops for Medicines Australia [Continuing Education Program](#) (CEP) Coordinators in Sydney and Melbourne to introduce new CEP provider University of Tasmania. The University was awarded the contract for the CEP course in 2011 after a lengthy tender process. The course was transferred from the University of Queensland. The workshops included an update on the transition to the new course in 2012.

NOVEMBER

- Brendan Shaw delivered a National Press Club address to a live national television audience. The address was titled 'Where do your medicines come from and why you should care'. A transcript is available on the Medicines Australia website [here](#)
- The Medicines Partnership of Australia released its PBS scorecard.
- Medicines Australia Board members attended a Pharmaceutical Industry Working Group (PIWG) meeting. Agenda topics included Clinical Trial Action Group (CTAG) recommendations, biologics and biosimilars reimbursement, progress on implementation of the MoU and PBS growth. The PIWG was co-chaired by the then Minister for Innovation, Industry Science and Research Senator Kim Carr and then Minister for Health and Ageing Nicola Roxon MP.
- The Pharmaceuticals Industry Council (PIC) hosted an overview of the pharmaceutical industry titled '*From discovery to off-patent: What are the implications for policy makers?*' for officials from the Departments of Prime Minister and Cabinet, Treasury, Innovation and Finance and Deregulation.
- Medicines Australia hosted a dinner for managing directors with former Pharmaceutical Benefits Advisory Committee (PBAC) chair Professor Lloyd Sansom.

DECEMBER

- Nicola Roxon MP was replaced by Tanya Plibersek MP as Minister for Health and Ageing in a Federal Cabinet Reshuffle. Greg Combet MP replaced Senator Kim Carr as Minister for Innovation.
- The Medicines Australia Board met with the Code of Conduct Panel of Chairs to discuss Code processes. The Code chairs meet with the Board every six months.
- Will Delaat, Board member John Latham, and Brendan Shaw attended the launch of the Medicines Australia-funded mobile renal dialysis unit for the Western Desert (The Purple Truck) in Alice Springs. Minister for Indigenous Health, Warren Snowdon, launched the truck.
- Education Event Reports for the period April – September 2011 were released on the Medicines Australia [website](#). Summary statistics for the period were broadly in line with the same period last year.
- The Department of Health and Ageing released the results of the 'super' round of price disclosure cuts for the PBS scheduled for 1 April 2012. The cuts were negotiated as part of the MoU between Medicines Australia and the Government.

JANUARY

- Medicines Australia lodged a [submission](#) to the 2012-13 Federal Budget.
- Medicines Australia completed its partnership with the Jimmy Little Foundation to educate indigenous children about healthy eating. The Jimmy Little Foundation received funding from the Federal Government to continue its work.

FEBRUARY

- Will Delaat retired as independent chairman of Medicines Australia after 14 years on the Medicines Australia Board including six as chairman.
- Brendan Shaw and the Medicines Australia Board met with Health Minister Tanya Plibersek MP to introduce her to the industry and discuss a range of issues including the future of the PBS, PBS growth, the Memorandum of Understanding and the operation of the Code of Conduct.
- The University of Tasmania opened enrolments for the Medicines Australia [Continuing Education Program](#) 2012 Academic year.
- Speaking in Parliament, Shadow Minister for Health Peter Dutton MP highlighted the importance of the medicines industry to the Australian economy and criticised Government policies that have led to uncertainty in the listing process.
- Medicines Australia held a Members-Only Strategic Conference in Sydney to consider the association's strategic priorities. More than 130 people from member companies participated in the conference.
- Medicines Australia lodged a [submission](#) to the Independent Hospital Pricing Authority (IHPA) in response to the consultation document 'Activity based funding for Australian public hospitals: Towards a Pricing Framework.'
- Brendan Shaw hosted a media briefing on clinical trials and research and development (R&D) at The George Institute. Journalists from news organisations including *The Australian Financial Review*, *BRW* and *The Australian* heard presentations from key speakers on different aspects of R&D.
- Approximately 300 guests attended Medicines Australia's Annual Parliamentary Dinner, including around 35 Members of Parliament. Prime Minister Gillard delivered the opening address in which she lauded the industry for its contribution to the economy and to the health of all Australians. GlaxoSmithKline global CEO Sir Andrew Witty delivered the keynote speech. Transcripts of the speeches are available on the Medicines Australia website [here](#).

MARCH

- The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* was passed by the Australian Parliament. Medicines Australia strongly supported the Bill's implementation.
- The Government's Report on the meeting of the Pharmaceutical Industry Discussion Group (PIDG) was tabled in Parliament.
- [Code of Conduct](#) Review Consumer Workshops were held in Sydney. The Workshops provided a valuable avenue for incorporating health consumer views into the Code of Conduct Review.
- Medicines Australia lodged a [submission](#) with the Government's *Australia in the Asian Century Review*.
- The Pharmaceuticals Industry Council (PIC) hosted a luncheon of the Parliamentary Friends of Medicines Group at Parliament House.
- Board members met with Minister for Industry and Innovation Greg Combet MP to introduce Medicines Australia to the new Minister and discuss policy issues and a program of engagement.
- Brendan Shaw participated in Pollie Pedal 2012, riding his bike from Geelong to Canberra. The medicines industry was well represented at the event which was hosted by Leader of the Opposition Tony Abbott MP and raised money for Carers Australia.
- Medicines Australia hosted Minister for Mental Health and Ageing Mark Butler MP at a lunch with industry representatives in Sydney.

APRIL

- Medicines Australia lodged a [submission](#) with the Government's Strategic Review of Health and Medical Research in Australia.
- Medicines Australia Board members gathered for a Board Retreat to discuss Medicines Australia's future strategic priorities. The Retreat built on input from the Members-Only Strategic Conference that was held in February.
- Brendan Shaw presented awards to fourteen high-achieving students at the 2011 Medicines Australia [Continuing Education Program](#) (CEP) awards ceremony.
- Brendan Shaw presented on the topic 'PBS Deferrals' at the Future of the PBS conference. A transcript of the speech is available on the Medicines Australia website [here](#).
- Medicines Australia briefed members on the progress of the [Code of Conduct](#) Review at separate sessions in Melbourne and Sydney.

MAY

- Medicines Australia's new Appointed Chairman, Mark Masterson, is announced. Members welcomed him at cocktail functions in Sydney and Melbourne. Mark spoke about the industry's achievements to date and his desire to build on that success through maintaining industry unity and collaboration.
- Medicines Australia hosted a Managing Directors' dinner with Pharmaceutical Benefits Advisory Committee (PBAC) chair Dr Suzanne Hill.
- Mark Masterson and Brendan Shaw attended a meeting of the Pharmaceutical Industry Working Group (PIWG). Agenda topics included Clinical Trial Action Group (CTAG) recommendations, biologics and biosimilars reimbursement, progress on implementation of the MoU and the R&D tax credit. The PIWG meeting was co-chaired by Minister for Innovation Greg Combet MP and Minister for Health Tanya Plibersek MP.
- The Australian Government agreed to exempt medicinal products containing synthetic greenhouse gases, such as metered dose inhalers, from the new carbon tax.
- The final draft of [Edition 17 of the Code of Conduct](#) was released to members. Member briefings were held in Melbourne and Sydney to outline the proposed changes to the Code.
- Medicines Australia lodged a submission to the Therapeutic Goods Administration (TGA) on the prototype Database of Adverse Events Notifications.
- Former Medicines Australia chairman Will Delaat was awarded a Member (AM) in the General Division in the Queen's Birthday honours list for services to the pharmaceutical industry.
- Brendan Shaw was invited to the Prime Minister's Economic Forum in Brisbane. Participants discussed the opportunities and challenges presented by structural changes occurring in the economy and opportunities emerging from major public policy reforms. The Forum highlighted the importance of building Australia's capabilities directly relevant to the medicines industry, such as R&D, innovation, exporting, and links with university and institute research institutes.
- The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2012 passed in Parliament.
- Medicines Australia members unanimously voted to adopt [Edition 17 of the Code of Conduct](#) at a General Meeting.

JUNE 2011

- Medicines Australia hosted a members-only dinner with Opposition Finance Spokesman Andrew Robb MP. The function was co-sponsored by the Bennelong Forum.
- Representatives from the Medicines Australia Regulatory Affairs Working Group attended the biannual TGA-Medicines Australia liaison meeting to discuss the ongoing regulator-industry partnership.
- Medicines Australia launched a new guide to the quality use of medicines. The booklet is available on the Medicines Australia website [here](#).
- Medicines Australia held webinars with industry stakeholders on proposed changes to the Code of Conduct. The webinars were attended by staff from communications and marketing agencies, legal firms, non-member companies and other key stakeholders who work with the pharmaceutical industry. More than 80 participants attended over three sessions.



1 Chief executive Brendan Shaw addresses the National Press Club.



2 Members discussing industry priorities at the Members-only Strategic Policy Conference.



3 Then Health Minister Nicola Roxon MP meets with Department of Health and Ageing deputy secretary David Learmonth (left) and Medicines Australia's then chairman Will Delaat (right) at the start of the 3rd Joint Medicines Policy Conference.

CONFERENCES AND EVENTS

3RD JOINT MEDICINES POLICY CONFERENCE

Over 300 delegates gathered in Canberra on 30 and 31 August for the third Joint Medicines Policy Conference, co-hosted by Medicines Australia and the Department of Health and Ageing.

The conference, titled *Health Technology Assessment for Future Generations*, attracted representatives from industry, government departments and consumer groups, as well as pharmacists, medical practitioners, medical researchers and the media.

More than 30 speakers participated in panel discussions on topics including data requirements for the future, data linkages and consumer engagement, the future relevance of the National Medicines Policy, access to medicines for aboriginal people, paediatric health, and investment decisions in drug development. Speaker [presentations](#) and conference [outcomes](#) are available on the [conference website](#).

A lively conference dinner included a farewell celebration for Professor Lloyd Sansom who had recently retired as chair of the PBAC.

Technical Symposium – Confounding in Datasets

There is global interest in using computerised databases for comparative effectiveness and medication safety studies. However, the data represents patients in practice. Patient and physician characteristics may affect the likelihood of receiving treatments. This creates the potential problem of confounding, which must be overcome to obtain robust results from observational studies.

Around 50 delegates met the day prior for a half-day technical symposium exploring the issue of confounding in Australian and international datasets. The methods to deal with confounding in observational studies were presented including: propensity scores; instrumental variables and the self-controlled case-series design.

MEDICINES AUSTRALIA-CONSUMERS HEALTH FORUM WORKSHOP

Medicines Australia and the Consumers Health Forum co-hosted a workshop on 29 August 2012, the day prior to the Joint Medicines Policy Conference. The workshop, titled *Medicines, Health Technologies and Reform*, considered recent health reforms and the review of health technology assessment, and identified consumer issues for discussion at the Joint Medicines Policy Conference.

THE CHIEF EXECUTIVE'S NATIONAL PRESS CLUB ADDRESS

Medicines Australia chief executive Brendan Shaw delivered an address to the National Press Club before a live television audience on 2 November.

In his address, titled *Where do your medicines come from and why should you care?*, Dr Shaw told the Press Club that with the right policy settings the medicines industry could offer Australia significant strategic and economic advantages in a post-mining boom future.



1 Delegates listen to Minister Roxon's opening address at the 3rd Joint Medicines Policy Conference.



2 GlaxoSmithKline managing director Deborah Waterhouse discusses access to medicines at the 3rd Joint Medicines Policy Conference.



3 Medicines Australia-Consumers Health Forum Workshop speakers: (left to right) Brendan Shaw (Medicines Australia), Anne Trimmer (Medical Technology Association of Australia), Rohan Hammett (then Therapeutic Goods Administration), Deborah Monk (Medicines Australia), Stephen Murphy (Consumers Health Forum), Wendy Babidge (Royal Australasian College of Surgeons), Carol Bennett (Consumers Health Forum), Ken Harvey (La Trobe University), John Aloizos (Australian Medical Association), and Will Delaat (then Medicines Australia).



4 Parliamentary Friends of Medicines Group chair John Alexander MP with AstraZeneca managing director Mark Fladrich.



5 Amgen Australia managing director Ian Thompson launching the Occasional Paper on clinical trials.

Dr Shaw said that the medicines industry "is a perfect industry for a country that is trying to develop a smart, high-wage, high-skill, innovative, low carbon economy" but warned that the industry was under challenge and needed supportive policy settings to thrive.

The address is available on the [Medicines Australia website](#).

PARLIAMENTARY FRIENDS OF MEDICINES GROUP INAUGURAL EVENT

Medicines Australia hosted an event at Parliament House on 22 November to celebrate the end of the parliamentary year.

The cocktail function was the inaugural event of the Parliamentary Friends of Medicines Group, a non-partisan forum through which members of the medicines industry can interact with parliamentarians to discuss issues affecting industry and patients. Members of Parliament John Alexander and Shayne Neumann co-chair the Group. Approximately 85 guests were in attendance, including 15 Members of Parliament.

Medicines Australia's Occasional Paper titled *Keeping clinical trials in Australia: why action is needed now* was launched at the event. The paper is available on the [Medicines Australia website](#).

MEDICINES AUSTRALIA MEMBERS ONLY STRATEGIC POLICY CONFERENCE

On 23 February 2012, more than 130 members attended the Members Only Strategic Policy Conference in Sydney. The conference sessions included an overview of industry's priorities for 2012-2013, Medicines Australia's strategic plan, an environmental scan and key implications for the future of the industry.

Key speakers for the conference were John Cannings of PricewaterhouseCoopers and Grahame Morris of Barton Deakin. Mr Cannings provided an internal environmental scan on the pharmaceutical industry, exploring international trends, implications of changes in markets, policy, research, regulatory environments and access regimes. Mr Morris provided an external environmental scan and outlined his observations of the current political environment and how the industry can engage with this.

The Members only conference was a successful event in which members mapped the future strategic direction of Medicines Australia and the pharmaceutical industry. The outcomes of the conference informed the Medicines Australia Board's deliberations at its Strategic Retreat held in April 2012.



1 Prime Minister Julia Gillard delivers the opening address at the 2012 Medicines Australia Parliamentary Dinner.



2 GlaxoSmithKline global chief executive officer Sir Andrew Witty speaks about opportunities and challenges for the medicines industry.



3 Dinner guests listen to the keynote speech.



4 Prime Minister Gillard acknowledges retiring Medicines Australia chairman Will Delaat's service to the medicines industry.



5 Medicines Australia chairman Mark Masterson (center) and chief executive Brendan Shaw (right) chat with Pharmaceutical Benefits Advisory Committee chair Suzanne Hill at the Medicines Australia managing directors dinner on 23 May 2012.

MEDICINES AUSTRALIA PARLIAMENTARY DINNER

Three hundred guests from industry, parliament, Government and the broader healthcare sector gathered in the Great Hall at Parliament House for Medicines Australia's Annual Parliamentary Dinner on 29 February 2012.

Around 35 parliamentarians attended the dinner which explored the theme *Securing Health for Future Generations*. Prime Minister Gillard delivered the opening address in which she lauded the industry for its contribution to the economy and to the health of all Australians. She also paid tribute to the long history of the Pharmaceutical Benefits Scheme and acknowledged retiring Medicines Australia chairman Will Delaat's many years of exemplary service to the industry and public policy.

GlaxoSmithKline global CEO Sir Andrew Witty delivered the keynote speech in which he spoke passionately about the industry's importance in raising standards of living across the globe. He also discussed the challenges facing the industry and future opportunities for new kinds of transparency and dialogue with governments on access and payment issues.

Transcripts of the speeches by Prime Minister Gillard and Sir Andrew Witty are available on the [Medicines Australia website](http://www.medicinesaustralia.gov.au).

MANAGING DIRECTORS DINNERS

Medicines Australia held four Managing Directors dinners during the year.

The first two dinners, held in Melbourne and Sydney respectively on 18 and 20 July 2011, gave Medicines Australia managing directors the opportunity to discuss with their colleagues current issues and likely future trends in the industry. The dinners were themed "How the industry is positioned today in Australia and Medicines Australia's position in the sector".

Emeritus Professor Lloyd Sansom, former Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), addressed managing directors on 16 November 2011. Professor Sansom reflected on the health system, the role of medicines in society, his views on how the PBS evaluation system is evolving and how companies and the industry can contribute to future development of the system.

On 23 May 2012, Dr Suzanne Hill, the current Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), addressed managing directors and provided insights into the current PBS evaluation system. Dr Hill spoke of her experience in the Department of Medicines Policy and Standards at the World Health Organization in Geneva. She also discussed issues for future discussion with industry, including the impact of falling generic prices on listing of new medicines and parallel processing of Therapeutics Goods Administration (TGA) and PBAC submissions.



1 Neil Byrne collects the Health Journalist of the Year Award from former Health Minister Nicola Roxon MP on behalf of Sonya Pemberton.

3 Code of Conduct Award winner, Wendy Carroll from Sanofi, receives her award from Medicines Australia chief executive Brendan Shaw at the Continuing Education Program (CEP) Awards Dinner.

2 Medicines Australia's former chairman Will Delaat (left) and Board member Graeme Blackman (right) with Pat Clear Award recipient Fiona Palmer from Gilead. Ms Palmer accepted the award on behalf of the Collaboration for Health in PNG.

4 Recipients of the 2011 Medicines Australia Continuing Education Program Awards.



AWARDS

2011 PAT CLEAR AWARD

The Collaboration for Health in PNG, a consortium of pharmaceutical companies, was the recipient of the Pat Clear Award in 2011 for its work combating the rise of HIV/AIDs in Papua New Guinea.

Fiona Palmer from Gilead accepted the award on behalf of the consortium at Medicines Australia's Annual General Meeting on 25 October 2011. The consortium has been represented by a number of Medicines Australia member companies throughout its ten year history. Currently, it includes Boehringer-Ingelheim, Gilead, Janssen, MSD, Pfizer and Viiv Healthcare.

Through the collaboration more than 50,000 people in Papua New Guinea have accessed professional counselling and 3000 have received HIV care. In addition the collaboration has provided workshops for 250 doctors, nurses, health administrators, counsellors and lab technicians.

The Pat Clear Award recognises outstanding levels of commitment by an individual, group or team for the benefit of the Australian medicines industry. The award was established in 2002 to commemorate the substantial contribution Mr Clear made to the medicines industry in Australia during his 40-year career.

For more information on the Pat Clear Awards, visit the [Medicines Australia website](#).

EXCELLENCE IN HEALTH JOURNALISM AWARDS

The annual Excellence in Health Journalism Awards were presented by then Minister for Health Nicola Roxon MP at the National Press Club on 22 November 2012.

Medicines Australia is the principal sponsor of the awards which honour journalists who have contributed the best work on health and health science each year. The prize for category winners is \$1000 in cash. The prize for the Health Journalist of the Year is \$1000 in cash and an international study tour.

Documentary filmmaker Sonya Pemberton was named Health Journalist of the Year in 2012 for her film *Immortal*. The film explores Australian scientist Elizabeth Blackburn's research into an enzyme key to the ageing process. Other Award winners were:

- Best News Feature, Article or Presentation; Health, Health Sciences or Innovation: Dr Maryanne Demasi for ABC TV *Catalyst* program 'Corneal Stem Cells – Window to the Eye'.
- Best Documentary or Documentary Series; Health, Health Science or Innovation: Sonya Pemberton for December Media & Pemberton Film documentary 'Immortal'.
- Best Feature, Article or Presentation; Health Policy, Health Economics and Health Business: Les Pearson (*Riverland Weekly*) for the 'Yuendumu' series, and Paul Smith (*Australian Doctor*) for the 'AMI impotency clinics' series.

- Best News Feature, Article or Presentation: Health, Health Science or Innovation directed to Medical Professionals: Peter Waterman (*Australian Pharmacist*) for 'Even Accidental Counsellors Have to be Brave'

Special Commendations went to:

- Jill Margo (*Australian Financial Review*) for 'Why are we taking so much Vitamin D'
- Ellen Fanning (*60 Minutes*) for 'Getting the Point'

For more information on the Awards, visit the [Medicines Australia website](#).

CONTINUING EDUCATION PROGRAM AWARDS

Thirteen sales representatives from Medicines Australia member companies received the industry's top accolade for ethical sales and marketing at the Continuing Education Program Awards ceremony in Sydney on 4 April 2012.

The CEP awards are presented annually to sales representatives who achieve maximum marks in their compulsory ethics education program.

UQ Health Insitu Active Learning Prize

Based on the level and quality of participation in group discussions and personal reflections in the online tutorials, the winners are selected by a panel from the University of Queensland.

UQ Health Insitu Active Learning Awards were presented to:

- Joanna Campbell (Novartis)
- Kimberly Varga (Amgen)

Code of Conduct Award

To be eligible for this award, a student must achieve a final mark of 100 per cent for the Code of Conduct module. The Code of Conduct Award was presented to:

- Wendy Carroll (Sanofi)

CEP Achievement Awards

The winners of these awards are the students who achieve the 10 highest aggregated marks for the five core programs (out of a possible aggregate of 500).

CEP Achievement Awards were presented to*:

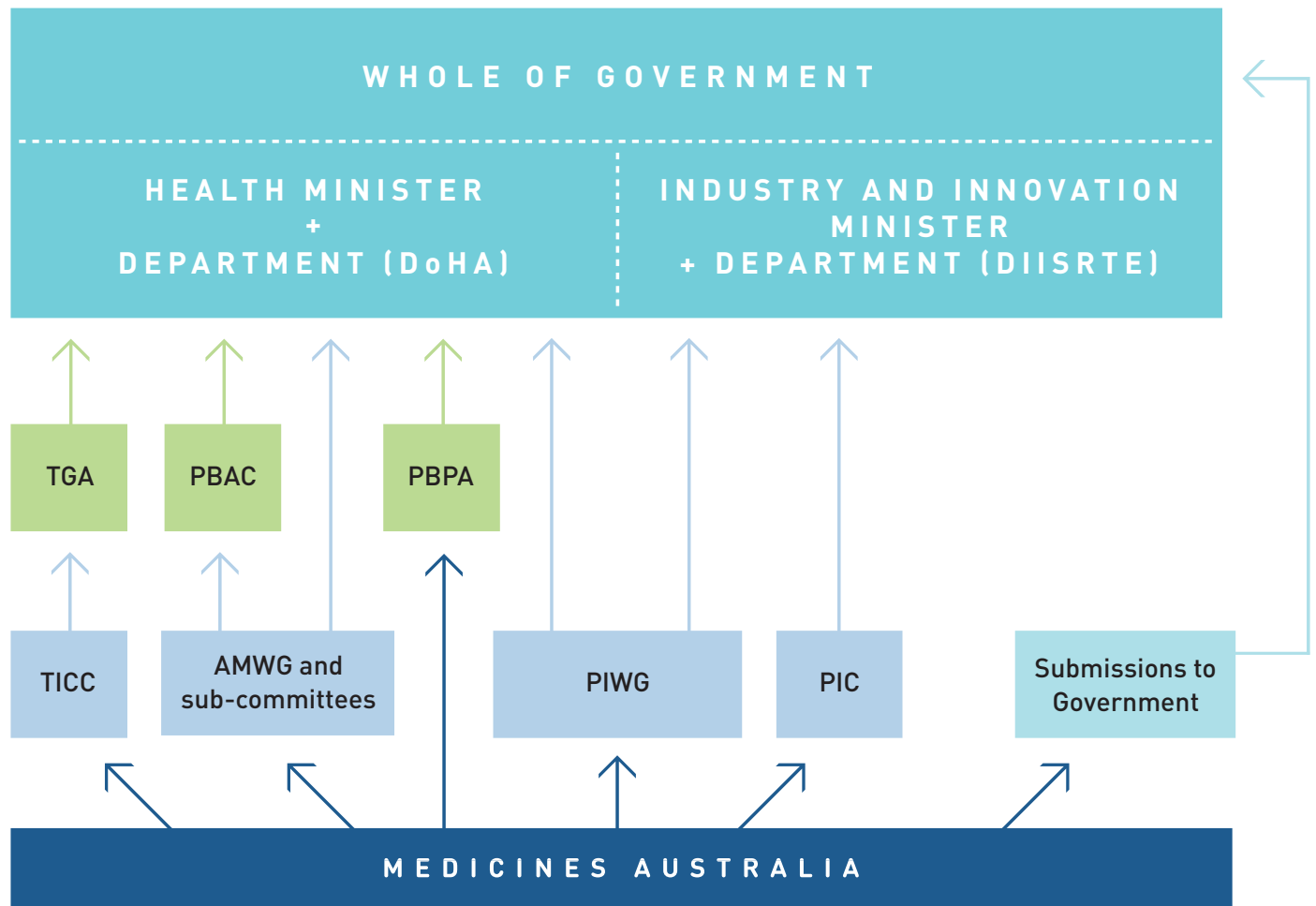
- Margaret De Jong (AstraZeneca)
- Martin Kelly (Novartis)
- Sean Lim (Pfizer)
- Natalie McLean (Boehringer Ingelheim)
- Lucy Nicholson (AstraZeneca)
- Maria Lizbeth Piedad (MSD)
- Carla Silvestri (MSD)
- Neil Stilgoe (Boehringer Ingelheim)
- Kristen Viero (AstraZeneca)
- Lauren Weiher (Abbott)

* Award recipients' companies were correct at time of completion of the CEP. Some award recipients may have since moved to other companies or roles outside industry.

For more information on the Continuing Education Program, visit the [Medicines Australia website](#).

INDUSTRY REPRESENTATION ON GOVERNMENT BODIES AND FOR OTHER ORGANISATIONS

This chart summarises Medicines Australia's engagement with the Federal Government on regulation, reimbursement and industry issues, through formal committees and working groups.



TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Access to Medicines Working Group (AMWG) and sub-groups	Provides strategic oversight of joint activities by Medicines Australia and DoHA to enhance PBS processes.	Will Delaat (until February 2012), Brendan Shaw, Mendel Grobler (Pfizer), David Grainger (Eli Lilly), Ian Noble (Amgen), Andrew Bruce, Jim Crompton
Medicines Partnership of Australia – MPA	Represents key members in the supply chain that deliver medicines and pharmacy expertise to Australian consumers.	Will Delaat (until February 2012) Brendan Shaw Others by invitation (Elizabeth de Somer for Labelling and packaging)
TGA Industry Consultative Committee (TICC)	High-level forum to discuss TGA broad policy, resource allocation and program performance issues.	Brendan Shaw, Elizabeth de Somer
Pharmaceutical Benefits Pricing Authority (PBPA)	Makes recommendations to the Minister for Health and Ageing on prices of PBS and NIP programs.	Brendan Shaw, Andrew Bruce Jim Crompton (observer)
Economic Sub-Committee of the PBAC (ESC)	Reviews, interprets and advises the Pharmaceutical Benefits Advisory Committee on economic analyses of medicines submitted for listing on the PBS.	Jim Crompton
Drug Utilisation Sub-Committee of the PBAC (DUSC)	Collects and analyses information on drug utilisation patterns in Australia, and contrasts such information with observations internationally.	Jim Crompton
Paediatric Medicines Advisory Group	Advises the PBAC and DoHA on paediatric medicines issues. Identifies and prioritises medicines which may be useful in a paediatric setting.	Andrew Bruce
Clinical Advisory Group on PBS Access for Refugees and Humanitarian Entrants	Provides information to the PBAC about disease trends and medications specific to the refugee and humanitarian entrant population.	Andrew Bruce
Palliative Medicines Working Group	Provides clinical and technical support and advice to DoHA on how to improve access to and quality use of palliative care medicines in the community.	Jim Crompton
Palliative Care Clinical Collaboration Management Advisory Board	Manages a group of palliative care units and conducts scientific research into the safety and efficacy of use of certain medicines in a palliative setting.	Jim Crompton
PBAC Guidelines Working Group	Monitors and implements any changes necessary to the PBAC Guidelines.	Greg Cook (BMS), Ian Noble (Amgen), Richard de Abreu Lourenco (Covance), Jim Crompton

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Annual Medical Oncology Group of Australia Drugs Roundtable Meeting	The annual roundtable held by the PBAC with the oncology specialist society.	Elizabeth de Somer, Jim Crompton
Australian Commission on Safety and Quality in Healthcare (ACSQHC) – Medication Reference Group	Provides advice to ACSQH on national strategies and priorities for medication safety and quality.	Elizabeth de Somer, Kristin Trace
TGA-Industry Working Group for Reforms	Assists the TGA in the development of a streamlined submission and effective business process reform package and provide subsequent implementation and transition advice and support.	Sue Alexander (Roche), Tony Whittaker (Commercial Eyes), Mark Rowland (Amgen), Kirpal Kaur (Bristol-Myers Squibb), Duncan Purvis (Janssen), Helen Critchley (Sanofi), Brian Hewitt (Pfizer), Mandy Cooke (GSK), Elizabeth de Somer, Rory Graham (CSL), Warren Back (MSD)
Horvath Review Working Party of Experts (HRWPOE)	Implementing recommendations for the Horvath review into adverse events following immunisation.	Elizabeth de Somer
TGA Labelling and Packaging External Reference group	Reviewing Regulatory guidelines and standards for labelling and packaging of medicines.	Elizabeth de Somer
TGA technical working groups (sterile TWG and non-sterile TWG)	Represents industry on manufacturing technical quality and standards groups.	David Peacock (Pfizer), Graham Garside (iNova)
Precursor Chemicals Industry Reference Group (PIRG)	Provides industry advice on regulation of precursor chemicals that may be diverted for illicit use and organised crime.	Elizabeth de Somer
National Industry Reference Group (NIRG) for Chemicals of security concern	Provides industry advice on regulation of chemicals that may be diverted for illicit use and organised crime.	Elizabeth de Somer
GS1 Australia – Healthcare Recall Portal Advisory Council	Provides industry advice on development of electronic medicines recall portal.	Elizabeth de Somer
Health Sector Group (HSG)	Provides advice to its members and to the Federal Government in the areas of critical infrastructure resilience and interface with the public sector (such as supply chain and essential medicines).	Elizabeth de Somer (Chair)
Critical Infrastructure Advisory Council (CIAC)	Provides advice to the Attorney-General on matters related to crises affecting nationally significant critical infrastructure (such as supply chain and essential medicines).	Elizabeth de Somer
National Prescribing Service RADAR Editorial Group	Produces information for healthcare professionals about new medicines listed on the PBS.	Deborah Monk

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
National Prescribing Service Consumer New Medicines Editorial Group	Produces Medicines Update, which is information for consumers for new medicines on the PBS.	Deborah Monk
Pharmaceuticals Industry Working Group (PIWG)	High-level forum, co-chaired by the Federal Ministers for Health & Ageing and Innovation & Industry, for wide-ranging discussions between industry leaders and Government.	Will Delaat (2011), Mark Masterton, two Board representatives (on rotation), Brendan Shaw
CTAG Coordination Group	This group was formed in 2011 to help facilitate the implementation of the Clinical Trials Action Group's recommendations.	Mitch Kirkman (Novartis), David Lloyd (Southern Star Research), Deborah Monk
Pharmaceuticals Industry Council (PIC)	Brings together representatives from the biotech, generic and innovative medicines sectors to advise Government on issues affecting the Australian pharmaceuticals industry.	Will Delaat (Chair, retired February 2012), Brendan Shaw, Sara Pantzer (Amgen), Jeff Davies (CSL), Deborah Monk, Omar Ali Khan
Research & Development Taskforce	Develops strategies to improve the business environment for clinical research in Australia (working group of the Pharmaceuticals Industry Council).	Annette Jones (Boehringer Ingelheim), Kaylene O'Shea (Celgene), Carlo Maccarrone (GlaxoSmithKline), Mitch Kirkman (Novartis), Stefan Krug (Amgen), Michael Daly (Bristol-Myers Squibb), Linda Nielsen (Sanofi -aventis), Cheryl Townsend (Merck Serono), Deborah Monk, Omar Ali Khan
Industry Development Taskforce	Develops strategies to improve the business environment for clinical research in Australia (A working group of the Pharmaceuticals Industry Council).	Sara Pantzer (Amgen), Deborah Monk, Omar Ali Khan

WORKING WITH OUR MEMBERS

This chart summarises Medicines Australia's engagement with our members through strategic committees and working groups.



WORKING WITH OUR MEMBERS

STRATEGIC COMMITTEES AND WORKING GROUPS

** Committee and working group representative companies are current at 30 June 2012. Some representatives may have since moved to other companies or roles outside industry.*

ACCESS STRATEGIC COMMITTEE

Key capabilities:

- Provides high-level PBS policy, pricing, registration reimbursement, health economics, access and regulatory advice, undertakes discrete research projects and provides other assistance
- Has Working Groups on: Health Economics, International Policy Scanning, PBS Reform Access, Regulatory Affairs and Vaccines.

Members at 30 June 2012:

- Michelle Burke Bristol-Myers Squibb, Co-Chair
- Andrew Bruce Medicines Australia, Co-Chair
- Mark Fladrich AstraZeneca, Board sponsor
- Ian Thompson Amgen, Board sponsor
- Sue Alexander Roche
- Andrew Carter Commercial Eyes
- Steve Crowley Janssen
- Mendel Grobler Pfizer
- David Herd GlaxoSmithKline
- Sara Pantzer Amgen
- Christian Sellars MSD
- Peter Vermeer Eli Lilly
- Charles Waterfield AstraZeneca
- Cammy Yuen Abbott

The following were also members for part of 2011-2012:

- Frederic Guerard Novartis, Board sponsor
- Jean Monin Sanofi, Board sponsor
- Deborah Waterhouse GlaxoSmithKline, Board sponsor
- Rory Graham CSL
- Nicol Kurstjens Novartis
- Michael Rasmussen Boehringer Ingelheim

Regulatory Affairs Working Group (RAWG)

Key capabilities:

Shapes and maintains a sustainable and competitive registration environment to result in timely access to innovative prescription medicines for all Australians.

Members at 30 June 2012:

- Sue Alexander Roche, Co-Chair
- Elizabeth de Somer Medicines Australia, Co-Chair
- Mandy Cooke GlaxoSmithKline
- Helen Critchley Sanofi
- Brian Hewitt Pfizer
- George Lillis Novartis
- Michael Parker AstraZeneca
- Duncan Purvis Janssen
- Mark Rowland Amgen
- Ron Sinani Shire
- Elizabeth Thompson Abbott
- Tony Whittaker Commercial Eyes

The following were also members for part of 2011-2012:

- Sarah Lam Baxter
- Kirpal Kaur Bristol-Myers Squibb
- Anna Pohl Boehringer Ingelheim
- Rory Graham CSL
- Mary Flannery Eli Lilly

Health Economics Working Group (HEWG)

Key capabilities:

Provides expertise on improving the registration and reimbursement requirements for pharmaceutical products, and generates information and resources to inform and influence stakeholders.

Members at 30 June 2012:

- Greg Cook Bristol-Myers Squibb, Co-Chair
- Jim Crompton Medicines Australia, Co-Chair
- Alissa Brown Pfizer
- Susan Phillips GlaxoSmithKline
- Peter Germanos Boehringer Ingelheim
- Fernando Gonzalo Sanofi
- Louise Graham Amgen
- Gary Hamann Servier
- Andrew Manton Commercial Eyes
- Jost Reinhard Bayer
- Jodie Thomas Eli Lilly
- Alison Wright Janssen

The following were also members for part of 2011-12:

- Cammy Yuen Abbott
- Beth O'Leary Covance
- Mirella Daja Novo Nordisk
- Grace Malanos Roche
- Delia Schaffer Takeda

PBS Reform Access Group (PRAG)**Key capabilities:**

Provides policy advice and support to the Medicines Australia members of the Access to Medicines Working Group (AMWG).

Members at 30 June 2012:

- Mendel Grobler Pfizer, Co-Chair
- Andrew Bruce Medicines Australia, Co-Chair
- Greg Cook Bristol-Myers Squibb
- Jim Crompton Medicines Australia
- Steve Crowley Janssen
- David Grainger Eli Lilly
- David Herd GlaxoSmithKline
- Ian Noble Amgen
- Christian Sellars MSD
- Mike Smith AstraZeneca

International Policy Scanning Working Group (IPSWG)**Key capabilities:**

Provides a general overview of the international policy landscape pertaining to the provision of medicines. International evidence and advice relevant to the priority areas of Medicines Australia's strategic committees is a core responsibility of the IPSWG. IPSWG consolidates this information to provide context for discussions of current healthcare related policy in Australia and guidance for the identification of potential future policy trends in Australia.

Members at 30 June 2012:

- Alissa Brown Pfizer, Co-Chair
- Amish Chaturvedi Medicines Australia, Co-Chair
- Andrew Wheatley Janssen
- Jodie Wilson Abbott
- Steve Quinn Amgen
- Michael Haberl GSK
- Jonathan Tan Allergan
- Charles Stratton Sanofi
- Carolyn Cameron Novartis

The following were also members for part of 2011-2012:

- Lesley Chim AstraZeneca
- Michelle Frost Allergan
- Fernando Gonzalo Sanofi
- Beth O'Leary Covance
- Susan Phillips GlaxoSmithKline
- Natalia Price Abbott
- Peter Dean Sharpe Eli Lilly
- Kristin Trace Medicines Australia

Medicines Australia Vaccine Industry Group (MAVIG)**Key capabilities:**

Provides advice to the Access Strategic Committee and Medicines Australia relating to the provision of vaccines under the National Immunisation Program (NIP) and advice on policy regarding other vaccine issues.

Members at 30 June 2012:

- Louise Carter GlaxoSmithKline, Co-Chair
- Elizabeth de Somer Medicines Australia, Co-Chair
- Helen Concilia CSL
- Lauren Conyer Pfizer
- Russell Jacobson Sanofi
- Christoph Kaufmann Novartis
- Tony Shelton Baxter
- Paul Vilner Abbott

The following were also members for part of 2011-2012:

- John Anderson CSL
- Christine Apostopoulos Novartis
- Brent MacGregor Sanofi
- Glen Mason Sanofi
- Sheryl Page GlaxoSmithKline
- Scott Williams Pfizer
- Jodie Wilson Abbott

IMAGE STRATEGIC COMMITTEE**Key capabilities:**

Provides reputation management, communication strategy, issue and crisis management, message formation and delivery, stakeholder management and advocacy advice to achieve credibility with, and obtain the trust of, key stakeholders for industry. Demonstrates the commitment of the industry to healthcare in Australia. Expertise to:

- build community and stakeholder perceptions about the industry;
- harness some of the positive images associated with the broader health sector; and
- inform consumers about the benefits the industry provides for individuals, families, the community and the Australian economy.

Members at 30 June 2012:

- Libby Day Baxter, Co-Chair
- Donna Edman Medicines Australia, Co-Chair
- Dominic Barnes Shire, Board sponsor
- John Latham Pfizer, Board sponsor
- Stuart Englund Eli Lilly
- Robert Gunning AstraZeneca
- Sharon McHale CSL
- Lee McKerracher Pfizer

- Lisa Maguire GlaxoSmithKline
- Duncan O'Brien Janssen
- Maida Talhami MSD
- Belinda Wood Commercial Eyes

The following were also members for part of 2011-2012:

- Jane Orr MSD, Board sponsor
- Dean Phizacklea Abbott, Board sponsor
- Karen Barfoot Bristol-Myers Squibb
- Rowena Cowan Sanofi
- Helen Craig MSD
- Glenn Montgomery Merck Serono
- Adam Roach Janssen
- Jude Tasker Pfizer
- Jackie Wilson Abbott

Government Working Group (GWG)

Key capabilities:

Provides political intelligence and political engagement strategies to manage issues and identify approaches within government that can affect our industry.

The Group acts as a conduit for political advocacy and policy message delivery to increase the value of the relationship of Medicines Australia and its members with elected officials.

Members at 30 June 2012:

- Sara Pantzer Amgen, Co-Chair
- Andrew Simpson Medicines Australia, Co-Chair
- Karen Barfoot Bristol-Myers Squibb
- Sam Crosby Janssen
- Stuart Englund Eli Lilly
- Jodie Jansen GSK
- Cameron Milliner Abbott
- Andrew Plumley Pfizer
- Kieran Schneemann AstraZeneca
- Todd Stephenson Roche
- Patrick Tung Merck Serono

The following were also members for part of 2011-2012:

- Rowena Cowan Sanofi
- Helen Craig MSD

Health Consumer Organisation Working Group (HCOWG)

Key capabilities:

Provides expertise on issues relating to health consumer and patient groups, especially organisations which demonstrate a willingness to partner with industry and support for issues of shared interest.

Provides advice on key principles in establishing successful HCO partnerships between the non-profit and commercial sectors.

Current members as at 30 June 2012:

- Diana Terry Medicines Australia, Co-Chair
- Neil Wildman Pfizer, Co-Chair
- Duncan O'Brien Janssen
- Zarli French MSD
- Holly Kania Roche
- Monique McLaughlin Amgen
- Arli Miller Eli Lilly
- Peter Murphy Novartis
- Jennifer Stevenson Abbott
- Rebecca Willocks Sanofi
- Anna Karelis Bayer Healthcare

The following were also members for part of 2011-2012:

- Deborah Chan Janssen

Media Working Group (MWG)

Key capabilities:

Provides strategic media communications advice and tactical planning for all issues across the industry.

Provides advice on expected media reaction, message development, risk management, media engagement, training, measurement, monitoring and analysis.

Current members as at 30 June 2012:

- Lisa Maguire GlaxoSmithKline, Co-Chair
- Jamie Nicholson Medicines Australia, Co-Chair
- Libby Day Baxter
- Adrian Dolahenty Bayer
- Helen Corcoran Pfizer
- Joanne Galea Janssen
- Robert Gunning AstraZeneca
- Lisa Julian Eli Lilly
- Emma Keogh Boehringer Ingelheim
- Petra Rosen Abbott

The following were also members for part of 2011-2012:

- Will Collie Sanofi
- Loucineh Mardirossian Abbott
- Adam Roach Janssen
- Maida Talhami MSD

Quality Use of Medicines Working Group

Reported to both the Access and Image Strategic Committees. The term of the Working Group ran to 30 September 2011.

Key capabilities:

Provided high-level strategic, policy and technical advice on matters pertaining to the quality use of medicines.

Members at 30 September 2011:

- Andrew Carter Commercial Eyes, Co-Chair
- Jude Tasker Pfizer, Co-Chair
- Helen Craig MSD
- Elizabeth de Somer Medicines Australia
- Stephen Gray Sanofi
- Kristin King Baxter
- Joyce Lloyd Pretium
- Lee McKerracher Pfizer
- Diana Terry Medicines Australia
- Cammy Yuen Abbott

The following were also members for part of 2011-2012:

- Malcolm Handel Janssen

Patents Working Group**Key capabilities:**

Designs and implements measures to ensure fair and balanced protection of intellectual property rights in Australia.

Ensures Australia maintains equity with the highest international standards and its bilateral Australia-US Free Trade Agreement (AUSFTA) and Trade Related Intellectual Property Rights (TRIPS) commitments.

Members at 30 June 2012:

- Deborah Monk Medicines Australia, Chair
- Rebecca Allsopp Sanofi
- Shahnaz Irani Spruson & Ferguson
- Omar Ali Khan Medicines Australia
- Sara Pantzer Amgen
- Sana Rasool Pfizer

INNOVATION STRATEGIC COMMITTEE**Key capabilities:**

Develops and implements policy and program measures for continuing industry development, growth in investment in research and development, and protection of intellectual property.

Members at 30 June 2012:

- Tim Murphy GlaxoSmithKline, Co-chair
- Deborah Monk Medicines Australia, Co-chair
- Graeme Blackman IDT Australia, Board sponsor
- Bruce Goodwin Janssen, Board sponsor
- Chris Miskel Eli Lilly, Board sponsor
- Alex Condoleon Sanofi
- Luke Cornish MSD
- Tim Donald PricewaterhouseCoopers
- Beata Niechoda Shire
- Ian McKnight Leo Pharma
- Duncan Purvis Janssen
- Bill Ketelbey Pfizer
- Omar Ali Khan Medicines Australia
- Joyce Lloyd Pretium
- Dieter Torheiden Abbott

The following were also members for part of 2011-2012:

- Frederic Guerard Novartis, Board sponsor
- Mark Fladrich AstraZeneca, Board sponsor
- Paul Dale Eli Lilly
- Simon Fisher AstraZeneca



1 Uncle Jimmy Thumbs Up! website launch at Miliner Primary School, Darwin.



2 Will Delaat and Medicines Australia's Director of Corporate Services Katie Whitehead give a thumbs up to the school workshop in Beswick, Northern Territory.



3 Classroom activities at the website launch.

WORKING WITH THE COMMUNITY

MEDICINES AUSTRALIA SPECIAL PURPOSE FUND

Medicines Australia's [Special Purpose Fund](#) was established in 2008, to support not-for-profit organisations committed to improving indigenous health outcomes.

In 2010, Medicines Australia announced its support for the Jimmy Little Foundation *Thumbs Up!* healthy eating program and the Western Desert Mobile Renal Dialysis unit – the Purple Truck. Both these projects concluded in the 2011-2012 financial year.

Medicines Australia continues to support two indigenous students of medicine through the Shalom Gamarada Residential Scholarship Program, which it has supported since 2010.

In April 2012, the Board committed the final amount remaining in the fund and agreed to support the following organisations:

- \$100,000 over two years will be provided for maintenance and on-costs for the Purple Truck
- \$30,000 over five years is committed to the Shalom Gamarada Residential Scholarship Program to support a further two indigenous students, taking the total number of students supported by Medicines Australia to four
- \$165,000 over two years will augment diabetes education and allied health professional services in central Australia, provided by Baker IDI.

UNCLE JIMMY THUMBS UP!

Medicines Australia was involved in some key activities in the final year of the *Thumbs Up!* program.

On 15 August, The Jimmy Little Foundation launched its *Thumbs Up!* website. This event, held at Miliner Primary School in Darwin, was attended by Northern Territory Education Minister Chris Burns. Medicines Australia was represented by Katie Whitehead, Director of Corporate Services, who is responsible for the management of the Special Purpose Fund.

Later that month, Medicines Australia chairman Will Delaat and Ms Whitehead visited the remote community of Beswick in the Northern Territory to see first-hand the *Uncle Jimmy Thumbs Up!* program in action. They attended classroom activities and visited the Beswick Outback Store to discuss the healthy eating awareness program in-store and view the *Uncle Jimmy Thumbs Up!* shelf talkers and other promotional material.

While in Darwin, Mr Delaat met with CEO of the Arnhem Land Progress Association Alistair King, CEO Outback Stores Steve Moore, and Jimmy Little Foundation CEO Graham Bidstrup. As part of the *Thumbs Up!* program, the Jimmy Little Foundation has secured a Memorandum of Understanding with these retail organisations to promote the *Uncle Jimmy Thumbs Up!* messages in-store.

Throughout the term of the project, Medicines Australia provided significant in-kind support to the Jimmy Little Foundation, assisting in project management, capacity building and governance arrangements. In addition, Medicines Australia funded external assistance for project management provided by SGS Economics and Medicines Australia member, PricewaterhouseCoopers, provided *pro bono* services.



1 Jimmy Little AO: a passionate advocate for indigenous health.



2 A patient receiving dialysis in the Papunya.



3 The Purple Truck, which is now dialysing patients throughout the Western Desert region.

A key achievement of the Jimmy Little Foundation is the Federal Department of Health and Ageing support through the *Local Community Campaign*. The Foundation received \$500,000 to continue the program established with Medicines Australia funding.

Medicines Australia's involvement in the *Uncle Jimmy Thumbs Up!* program concluded in January 2012. Medicines Australia contributed \$773,000 to the *Uncle Jimmy's Thumbs Up!* program.

VALE JIMMY LITTLE AO

Medicines Australia was saddened by the passing of Jimmy Little AO on 2 April 2012. Jimmy was not only a legendary and talented musician and entertainer, but also a passionate advocate for indigenous health. While his passing is extremely sad, the Jimmy Little Foundation is a fitting monument to a lifetime devoted to helping other indigenous Australians. Medicines Australia is proud to be part of that story. Medicines Australia chairman Mark Masterson, and Director of Corporate Services Katie Whitehead, attended the State Memorial Service for Jimmy Little on 3 May 2012.

THE PURPLE TRUCK

The Purple Truck was launched in Alice Springs on 12 December 2011 by the Federal Minister for Indigenous Health Warren Snowdon MP, who handed it over to the communities of the Western Desert, where it is now dialysing patients throughout that region and beyond.

The launch was attended by 120 people representing the industry, the Federal and Northern Territory governments, the broader healthcare sector, patient groups, academics, local business people, and media. Special guests included Shadow Parliamentary Secretary for Regional Health Services & Indigenous Health Andrew Laming MP; Northern Territory Minister for Central Australia Karl Hampton MLA; CEO of the Papunya Tula Artists Paul Sweeney (providers of the Truck artwork); Albert and Christian Albertini of GSV Adelaide (the truck builders); and CEO of Fresenius Medical Margot Hurwitz. Fresenius Medical supplied the dialysis equipment and will provide ongoing maintenance of the equipment.

The day after the launch, the truck went on its maiden trip to Papunya. Since then it has travelled to Warburton – Australia's most remote community – Mutitjulu, and Docker River, to name a few. It travelled back to Adelaide in June 2012 for its first major service and alterations. You can follow the [Purple Truck](#) on Facebook.

Medicines Australia contributed \$483,000 to the construction and maintenance of the Purple Truck.



1 Laura Fitzgerald (left) and Brylie Frost, students in the Shalom Gamarada Residential Scholarship Program

2 Cancer Council chief executive officer Ian Olver at the Medicines Australia Parliamentary Dinner in February 2012.

SHALOM GAMARADA NGIYANI YANA RESIDENTIAL SCHOLARSHIP PROGRAM

Medicines Australia is supporting four indigenous medical students through the Shalom Gamarada Ngiyani Yana Residential Scholarship Program. The students are: Laura Fitzgerald, Brylie Frost, Maiysha Craig and Luke Walker.

In October 2011, Laura and Brylie attended a Medicines Australia Board dinner to give an account of why the scholarship is important to them and to thank Medicines Australia for its support.

BAKER IDI

In April, the Medicines Australia Board agreed to support Baker IDI to conduct its fourth Health Care Education symposium in Darwin in October 2012 aimed at expanding knowledge-based care options for health care workers in the Top End, reviewing what care and preventative health program initiatives are feasible in remote communities, and to creating local champions for the management and treatment of diabetes.

Medicines Australia funding will also provide support for allied health professionals over the next two years, to provide for a full time chronic disease and diabetes screening nurse to work in the Alice Springs town camps in conjunction with Tangentyere Council. This will augment the federally funded government program of diabetes clinical service delivery by Baker IDI in remote areas of the Northern Territory.

This work aligns to the three existing projects supported by the Special Purpose Fund.



1 Consumers Health Forum chief executive officer Carol Bennett speaking at the Joint Medicines Policy Conference in August 2011.

2 Medicines Australia's stakeholder relations manager Diana Terry and chief executive Brendan Shaw get to grips with the challenges faced by those living with arthritis at a Parliamentary Friends of Arthritis function in March 2012.

ENGAGEMENT WITH HEALTH CONSUMER ORGANISATIONS

Health consumer organisations (HCOs) and the industry have collaborated for many years in areas of mutual interest with regard to the needs of health consumers and improving health outcomes. The voice of the health consumer is widely acknowledged as contributing valuable insights into the health policy debate, reinforced by public comments, funding, and engagement from government.

The level of interaction and engagement between the health consumer sector, and the industry, exhibits a broad spectrum of relationships and capabilities. The willingness to engage with members of the industry or Medicines Australia often reflects the level of understanding and trust in the practices of this industry.

The greater rigour now being applied to how these relationships are being established (based on the [Working Together Guide](#)) is a positive step. The *Working Together Guide* contains the basic framework from which industry should engage with consumer groups and organisations. The key principles for any engagement are: honesty, integrity, trust, and respect. Underpinning these principles is:

- Respect for independence
- Achieving and maintaining public trust
- Fairness
- Openness and transparency
- Accountability

Fostering greater collaboration between HCOs and the industry, and identifying emerging trends and issues from HCOs that may impact the industry's operating environment has never been more relevant.

Over the past year the Medicines Australia HCO working group has been in contact with many HCOs delivering key messages on behalf of the industry, and encouraging these organisations to take action on certain issues of mutual relevance to both the industry and health consumers, on issues such as PBS deferrals where concerns of access to medicines gained unprecedented unity from various groups.

With the aim of actively supporting the work of health consumer organisations, moving towards their strategic priorities of influencing the debate around public policy, Medicines Australia participates in initiatives ranging from Parliamentary Friends events, to National Press Club addresses, and supporting research such as the National Seniors Social Survey.

Health consumer organisations are invited to participate in conferences and forums such as the Joint Medicines Policy Conference, specifically to have consumer engagement firmly planted as central to the medicines policy debate. This has built a better understanding of Medicines Australia and the industry in its genuine attempts to have the consumer voice heard. Medicines Australia also supported a preceding consumer forum, to facilitate consumer participation in the Joint Medicines Policy Conference, further highlighting issues of importance to consumers and HCOs.



1-2 Board members, Strategic Committee co-chairs and secretariat discussing Medicines Australia's strategic priorities at the Board Retreat in April 2012



3 Medicines Australia chairman Mark Masterson speaking to members at a welcome event in May 2012

INSIDE MEDICINES AUSTRALIA

Medicines Australia Board meetings

Sixteen meetings of the Medicines Australia Board were held in 2011-2012:

6 September 2011, West Ryde
 16 September 2011, teleconference
 21 September 2011, teleconference
 26 September 2011, teleconference
 30 September 2011, teleconference
 5 October 2011, Canberra
 12 October 2011, email
 25 October 2011, Sydney
 6 December 2011, Melbourne
 7 February 2012, Sydney
 5 March 2012, email
 13 March 2012 teleconference
 2-3 April 2012, Canberra (Board Retreat)
 8 May 2012, Canberra (Federal Budget Night)
 24 May 2012, Sydney (Risk Management Workshop)
 26 June 2012, Sydney

In April, the Board also hosted its annual National Press Club dinner with a number of key political and health journalists from the Press Gallery. Discussions covered industry issues and trends and the political environment in Canberra.

Finance & Audit Committee

- Review the monthly financial statements of Medicines Australia Limited and provide advice and guidance to how finances are reported to the Board.

- Review the draft annual budget of Medicines Australia Limited as developed by the Secretariat and provide advice and guidance on how the annual budget is presented to the Board.
- Review the audited annual financial statements of Medicines Australia Limited and provide advice and guidance on how the annual financial statements are to be presented to the members at the Annual General Meeting.

The Committee also has the oversight of the Medicines Australia Special Purpose Fund.

Members:

Mr John Latham, Chair (from June 2007)
 Mr Bruce Goodwin (from June 2012)
 Mr Chris Miskel (from February 2012)
 Mr Frederic Guerard (until June 2012)
 Ms Jane Orr (February – May 2012)
 Mr Dean Phizacklea (until December 2011)

Meetings:

11 July 2011
 29 August 2011
 20 September 2011
 29 November 2011
 29 February 2012
 26 March 2012
 29 May 2012
 19 June 2012

Nominations Committee

- Identify and make available for Members in good time before elections the skill sets that are needed on the Board, what skill gaps need to be filled and the personal capabilities that are required for Directors to make an effective contribution to the Board.
- Identify suitable people who might be nominated for the Board or its Committees.



1-3 The Medicines Australia secretariat at work

- Develop the policy and procedures for determining when recruitment of a Selected Director is required and conduct the recruitment process for recommendation to the Board
- Ensure Members are aware of the duties and responsibilities that will be taken on by Directors, the time required to perform effectively and the range of legal liabilities applying to Directors that all need to be borne in mind when nominating people for election to the Board.

Members:

Dr Graeme Blackman, Chair (from February 2010)
Ms Deborah Waterhouse (until May 2012)
Mr Jim Cain (from May 2012)

Meetings:

9 August 2011
21 May 2012

Remuneration & Governance Committee

- Monitor and evaluate Board Performance including duties and responsibilities of Directors, the time required to perform effectively and the range of legal liabilities applying to Directors.
- Monitor and evaluate Chair performance and where there is an Independent Chair, make recommendations on the appropriate level of remuneration.
- Be a consultative body for the Chief Executive on matters he/she seeks advice and guidance that are specific matters delegated to the Chief Executive.
- Monitor and evaluate the Chief Executive performance and make recommendations on the appropriate level of remuneration.
- Approve the remuneration of senior managers who are direct reports to the Chief Executive.

Members:

Mr Mark Masterson, Chair (from May 2012)
Mr John Latham (from February 2010)
Mr Ian Thompson (from September 2011)
Mr Will Delaat, Chair (until February 2012)
Mr Bruce Goodwin (interim member from February 2012 – May 2012)

Meetings:

30 May 2012
27 June 2012

Medicines Australia Member meetings

There were two meetings of members in the 2011-2012 financial year.

- The Annual General Meeting was held on 25 October 2011, AstraZeneca Conference Centre, North Ryde.
 - There were three separate meetings of Class 1, Classes 2 and 3, and Class 4 members in order to consider separately the change in voting entitlements. The amendments to the Constitution were agreed by members and Class 4 members are now entitled to vote at General Meetings of the company.
 - Moore Stephens was appointed as Company Auditor, replacing PricewaterhouseCoopers (formerly Walter Turnbull).
 - The Board for the 2012-2013 term was announced at the AGM
 - CHPNG was awarded the Pat Clear Award
- A General Meeting of members was held on 26 June 2012, to consider the Draft Edition 17 of the Medicines Australia Code of Conduct. The draft Code was unanimously agreed by the members. The members also agreed to lead the establishment of a sector-wide Transparency Working Group with relevant key stakeholders.

Secretariat**Departing staff:**

Ms Larissa Karpish
Ms Romina Bognolo
Ms Juanita Wall

New staff:

Ms Rochelle Pelaez
Mr James Turnley
Ms Zoe Morton (contract)

The Policy and Research Officer in the Access Team has not been filled since the promotion of Ms Kristin Trace to Policy Manager.

Records Management

Medicines Australia has developed a business classification scheme and retention authority for disposal of records. A review of work practices was undertaken in order to make an assessment of the type and value of documents Medicines Australia creates, including a series of interviews conducted with staff members.

The document assists the Secretariat in managing the records of Medicines Australia in an informed and systematic manner. In determining the business classification and retention authority, consideration has been given to legal requirements for the retention of documents; well-established disposal authorities based on industry best practice; and the nature of business activities conducted by Medicines Australia.

Risk Management and Internal Control Audit

In the interest of good governance and transparency, the Medicines Australia Board has embarked on a review of its risk management framework and internal controls. In May, the Company Auditor, Moore Stephens, conducted a workshop with the Board as the first step in a thorough review and development of Medicines Australia's Risk Management Framework and management plan. Through this process, the Board has affirmed its commitment to ensure appropriate governance and management of our members' organisation.

Work Health and Safety Act

Medicines Australia undertook a thorough review of its occupational health and safety policies in the latter half of 2011. The policies align with the national harmonisation legislation and commensurate ACT Work Health and Safety Act, which came into effect on 1 January 2012.

Medicines Australia Strategic Committee Guidelines

In July 2011, the Secretariat undertook a comprehensive review of the strategic committee roles, objectives and meeting processes. The Medicines Australia Strategic Committee Guidelines review process was as follows:

- 1 Co-Chairs sought feedback from Board Sponsors on effectiveness, role, composition and conduct of strategic committees
- 2 The Secretariat conducted an audit of committees and working groups to measure company representation across committee structure and attendance records
- 3 Individual strategic committees conducted workshops on roles, objectives, conduct, and administration of committees and working groups
- 4 The Secretariat reviewed existing governance guidelines to ensure currency and consistency with the Board Charter and other relevant documentation.

At its meeting on 25 October 2011 the Board endorsed the revised Medicines Australia Strategic Committee Governance Guidelines. After this time, nominations were received for the new committee term 2012-2013 and subsequently appointed in December 2011. In February 2012, Dr Shaw conducted a webinar for incoming committee and working group members to ensure all representatives are aware of the revised Strategic Committee Guidelines, including governance arrangements and meeting protocols.

Communication with our Members

Medicines Australia has conducted a number of member briefings and webinars with our members to update them on a range of topics:

- July – Managing Director briefing on current industry issues at separate events in Melbourne and Sydney
- October – Managing Director webinar on progress against key priorities and issues related to biologics and biosimilars
- November – Health Economics Working Group and Regulatory Affairs Working Group conducted a joint member briefing in Sydney on each group's role in providing strategic advice and support to the Medicines Australia Access Committee on medicine registration and reimbursement
- February – Webinar for strategic committee and working group members to brief them on the purpose, governance guidelines and priorities for the committees and working groups in the coming year

Numerous communications were also distributed throughout the year, including the daily Medicines Australia Media Report, MA Weekly, MA News and memos to members. A range of reports and papers were also provided to members, including *Quality Use of Medicines: What it means for industry*.

These documents are available on the [Medicines Australia Members Only Website](#).

MEDICINES AUSTRALIA PUBLICATIONS

PUBLICATIONS AND REPORTS

- [Medicines Australia Facts Book: Second Edition – Update](#) (December 2011)
- [Occasional Paper 3 – Keeping Clinical Trials in Australia: Why action is needed now](#) (November 2011)
- [Quality Use of Medicines and the medicines industry](#) (May 2012)
- *Medicines Advocate* newsletter for Members of Parliament (September 2011 and June 2012)
- *Medicines Matter: an information service for Health Consumer Organisations* (September 2011; December 2011; March 2012; June 2012)
- [Code of Conduct Educational Event Reports](#) (1 April – 30 September 2011; 1 October 2011 – 31 March 2012)
- *Code of Conduct Quarterly Reports* (July – September 2011; October – December 2011; January – March 2012; April – June 2012)
- *Reports of Code of Conduct complaints relating to activities directed at the general public* (1 July – 30 September 2011; February 2012; March – April 2012)
- *Code of Conduct Annual Report – 2011* (August 2011)
- *Report on the Outcomes of the Code of Conduct Monitoring Committee Review 2011* (August 2011)

Code of Conduct reports are available on the [Medicines Australia website](#).

SUBMISSIONS

Submissions are available on the [Medicines Australia website](#).

- July 2011 – PIC/Medicines Australia submission to the National Health & Medical Research Council on a Draft List of Clinical Trial Networks in Australia
- July 2011 – PIC/Medicines Australia submission to the National Health & Medical Research Council on Monitoring Arrangements for Multi-Centre Human Research
- August 2011 – Medicines Australia Submission in response to Department of Innovation, Industry, Science and Research R&D Tax Credit Exposure Draft Regulations and Decision Making Principles
- October 2011 – Medicines Australia Submission in response to the Exposure Draft PCEHR Bill 2011
- November 2011 – Medicines Australia Submission to the Federal Opposition's Industries for Australia's Future review
- January 2012 – Medicines Australia Submission to the 2012-13 Federal Budget
- February 2012 – Medicines Australia Submission in response to 'Activity based funding for Australian public hospitals: Towards a Pricing Framework'
- March 2012 – Medicines Australia Submission to The Australia in the Asian Century Taskforce
- March 2012 – Medicines Australia Submission to the Strategic Review of Health and Medical Research in Australia

INDEX OF ACRONYMS AND ABBREVIATIONS

ACCC	Australian Competition and Consumer Commission	MoU	Memorandum of Understanding
ACSQHC	Australian Commission on Safety and Quality in Healthcare	MTAA	Medical Technology Association of Australia
AMA	Australian Medical Association	NIP	National Immunisation Program
AMWG	Access to Medicines Working Group	NHMRC	National Health and Medical Research Council
ASMI	Australian Self-Medication Industry	NPS	National Prescribing Service
AUSFTA	Australia-US Free Trade Agreement	OECD	Organisation for Economic Co-operation and Development
AusPAR	Australian Public Assessment Report	OTC	Over The Counter (medicines)
CEP	Continuing Education Program	PBAC	Pharmaceutical Benefits Advisory Committee
CHF	Consumers Health Forum of Australia	PBPA	Pharmaceutical Benefits Pricing Authority
CHPNG	Collaboration for Health in Papua New Guinea	PBS	Pharmaceutical Benefits Scheme
CTAG	Clinical Trials Action Group	PhRMA	Pharmaceutical Research and Manufacturers of America
DoHA	Department of Health and Ageing	PIC	Pharmaceuticals Industry Council
DUSC	Drug Utilisation Sub-Committee	PIDG	Pharmaceutical Industry Discussion Group
EFPIA	European Federation of Pharmaceutical Industries and Associations	PIWG	Pharmaceuticals Industry Working Group
ESC	Economic Sub-Committee	PRAG	PBS Reform Access Group
GMiA	Generic Medicines Industry Association	QUM	Quality Use of Medicines
GWG	Government Working Group	QUMWG	Quality Use of Medicines Working Group
HCO	Health Consumer Organisation	RAWG	Regulatory Affairs Working Group
HCOWG	Health Consumer Organisation Working Group	TGA	Therapeutic Goods Administration
HEWG	Health Economics Working Group	TICC	TGA Industry Consultative Committee
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations	TRIPS	Trade-Related Aspects of Intellectual Property
IP	Intellectual Property	WDNWPT	Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation
IPSWG	International Policy Scanning Working Group	WIPO	World Intellectual Property Organization
MAVIG	Medicines Australia Vaccines Industry Group	WTO	World Trade Organization
MWG	Media Working Group		