

MEDICINES AUSTRALIA

ANNUAL REPORT 2013-14

MEDICINES
Australia



Contents

Medicines Australia Vision + Mission Statement	1	Key Issues	8
Vision	1	Stability, Predictability, Access	8
Mission	1	Code of Conduct performance: a snapshot	10
Strategic directions	1	Continuing Education Program (CEP)	11
Chairman's Report	2	Key Events Diary	12
Chief Executive's Report	3	Conferences and Events	15
Medicines Australia Membership 2013-2014	4	Awards	17
Medicines Australia Board Members 2013-2014	5	Working with the Community	20
Directors 2013-2014	5	Working with our Members	22
Medicines Australia Secretariat 2013-2014	6	Medicines Australia Issues Groups	23
Corporate	6	Inside Medicines Australia	25
Policy & Advocacy	6	Governance	25
Compliance	7	Risk Management	26
Staff who departed in 2013-2014	7	Secretariat	27
		Publications and Submissions	27

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

STRATEGIC DIRECTIONS

Leadership: To contribute to medicines policy development for the benefit of all Australians.

Policy: Policy development and collaboration to stimulate R&D, protect intellectual property, achieve optimal regulation, enhance access and reimbursement outcomes, and ensure long term funding sustainability.

Advocacy: Engage with key stakeholders to ensure effective operating environment.

Chairman's Report

There is no doubt, looking back over the last twelve months, there have been some significant challenges faced by the innovative pharmaceutical industry as well as significant achievements realised by our members.

The focus for Medicines Australia during the 2013-14 year has continued to be on Access to Medicines. This was the final year of the Memorandum of Understanding (MOU), agreed in 2010 with the former Government in order to provide a four year period of a stable and predictable operating environment. Whilst the MOU certainly did deliver elements of predictability for our industry in some areas – shared with the community through the remarkable success of pricing reforms – there remains elements of instability.

These elements of instability include policies such as post-market reviews aimed at prematurely cutting the prices of medicines and the announcement of new simplified price disclosure, made without consultation.

The industry values stability, certainty and predictability particularly when it comes to new products. We need to be confident when we're listing – especially from a global basis because we're in a global market – that the price remains stable, at least during the period of intellectual property protection. The Prime Minister's speech at the World Economic Congress in Davos summed up our sentiments precisely: "What investors really need is greater confidence that governments won't change the rules after the investments have been made."

Australia would be a tremendous place to invest, but business confidence in Australia as a destination for new and innovative medicines has been challenging. If we are to be truly 'open for business' then we must ensure that stability, certainty and predictability are maintained. It is my goal to continue working with the Government to actively raise awareness of the impact of changing policies – including unintended consequences of pricing reforms – that would reduce access to new medicines for Australian patients.

Notwithstanding, there have been some encouraging signs from Government early on. We welcome commitments made by the incoming Government including a commitment to provide predictability of PBS processes, to restore confidence in the PBAC, and to accelerate reform in clinical trials. The Board and the industry more broadly were encouraged to see many of the election commitments met early on in the term of the new Government, including the increase of the cost threshold for cabinet approval of PBS medicines to \$20 million, in effect catching up with inflation since the introduction of the original \$10 million threshold in 2001.

There were 50 products that were in the backlog waiting to go on the Pharmaceutical Benefits Scheme and I was very encouraged that Health Minister Peter Dutton listed these products without delay; and I'm encouraged for every patient that's now benefitting from those products.

Over the past year the Board has continued to drive collaborative engagement at a political and bureaucratic level to enable a stable policy framework. We will continue to work closely with government to ensure we continue to have an active voice for our members and the industry. The Board's commitment and the Minister's agreement for the reinvigoration of the Access to Medicines Working Group early in 2014 demonstrate a renewed willingness to work together.

In closing, I would like to acknowledge Chief Executive, Dr Brendan Shaw. It has been a pleasure working with Brendan since taking up my appointment as the Chair of Medicines Australia in November 2013. Brendan has been appointed to a new role – we wish him all the very best with his new endeavour.

I also acknowledge the work of the Medicines Australia Secretariat staff who put in substantial time, effort and hard work on behalf of all members of Medicines Australia. I thank them for their commitment and enthusiasm throughout 2013-14.

Finally, I would like to thank my fellow Board members, both those outgoing and the newly appointed. Their contribution and support has ensured a positive strategic direction for Medicines Australia.

A stylized, handwritten signature in black ink, appearing to read 'Martin Cross'.

Dr Martin Cross

CHAIRMAN OF MEDICINES AUSTRALIA

Chief Executive's Report

2013-14 has proved to be an engaging and challenging year for Medicines Australia and its members.

Early on the focus was on the 2013 Federal Election which delivered a change of Government on 7 September with the election of the Abbott Government. Medicines Australia achieved some success as a number of the issues the industry has been pursuing featured before and during the election campaign. Issues such as Australians' access to medicines, particularly cancer medicines; regulatory reform of clinical trials; a stable and predictable Pharmaceutical Benefits Scheme (PBS); and the importance of building innovative industries for Australia all featured in the election campaign.

The new Government came to office having made a number of important pre-election commitments including an impartial Pharmaceutical Benefits Advisory Committee (PBAC); a reduction in red tape; and further building innovative industries, such as ours, in Australia. Medicines Australia welcomed these commitments – and more – and throughout the year we worked with the new Government on the implementation of these commitments.

Medicines Australia and its members were active in briefing the incoming Government on key issues including the application of post-market reviews and parts of the National Health Act, the introduction of new simplified price disclosure, the sustainability of the PBS, the continuation of the Memorandum of Understanding and its reforms, and the benefits arising from a reinvigoration of the Access to Medicines Working Group (AMWG).

Medicines Australia also participated vigorously in the public debate about the future of the PBS. An important part of the Association's job is to help redress the inaccuracies and myths surrounding the PBS. The bottom line is that in 2013-14 the reforms the industry has worked on over a number of years with successive governments were realised: the savings reforms have made the PBS sustainable for the foreseeable future.

Moreover, Medicines Australia members should be proud of our part in achieving this goal for all Australians, despite not receiving the credit we deserve from the Government through to our staunchest critics.

Medicines Australia continues to lead the Australian health sector in relation to ethical conduct. This year we commenced the periodic review of our Code of Conduct, particularly looking at the issue of transparency and transfers of value between pharmaceutical companies and healthcare professionals. The review process, which included member and stakeholder consultations, culminated in the 18th Edition of the Code being adopted by members in June 2014; the Code is currently under consideration for authorisation by the Australian Competition and Consumer Commission.

The year has hailed in changes within the Secretariat. Our Chairman, Dr Martin Cross, commenced his term in November 2013. Dr Cross embraced his new role with energy and enthusiasm and I thank him for his stewardship and support. I would like to take this opportunity, also, to acknowledge our interim Chairman, Mr Mark Fladrich, for his contribution during a time of organisational restructure within the Association.

This is my last Chief Executive's report for Medicines Australia. I would like to thank the Chairman, the Board and our members not only for your support during 2013-14, but through my years of service and particularly those as Chief Executive.

In closing, I would like to thank the Secretariat staff for their energy and commitment throughout the year; it is their hard work and determination that underpins our achievements and progress.

The pharmaceutical industry is one of Australia's great industries, both in terms of the health benefits it provides to society and the economic benefits it provides to the country. It has achieved a lot for Australia already and has the promise to deliver more in the future.

I wish you well.



Dr Brendan Shaw

CHIEF EXECUTIVE OF MEDICINES AUSTRALIA

Medicines Australia Membership 2013-2014

CLASS ONE		
A. Menarini Australia Pty Ltd	Bristol-Myers Squibb Australia Pty Ltd	Mundipharma Pty Ltd
AbbVie Pty Ltd	Celgene Pty Limited	Novartis Pharmaceuticals
Actelion Pharmaceuticals Australia Pty Ltd	Eli Lilly Australia Pty Ltd	Novo Nordisk Pharmaceuticals Pty Ltd-Australia
Allergan Australia Pty Ltd	Gilead Sciences Pty Ltd	Pfizer Australia Pty Ltd
Amgen Australia Pty Ltd	GlaxoSmithKline Australia Pty Ltd	Roche Products Pty Limited
Astellas Pharma Australia Pty Ltd	Ipsen Pty Ltd	sanofi
AstraZeneca Pty Ltd	Janssen Pty Ltd	Servier Laboratories (Aust) Pty Ltd
Bayer Australia Limited	Leo Pharma	Shire Australia Pty Limited
bioCSL	Lundbeck Australia Pty Ltd	Takeda Pharmaceuticals Australia Pty Ltd
Biogen Idec Australia Pty Ltd	Merck Serono Australia Pty Ltd	UCB Australia Pty Ltd
Boehringer Ingelheim Pty Ltd	Merck Sharp & Dohme (Australia) Pty Ltd	

CLASS TWO		
Abbott Australasia Pty Ltd	Fresenius Kabi Australia Pty Ltd	Norgine Pty Ltd
Genzyme Australasia Pty Ltd	iNova Pharmaceuticals Pty Ltd	

CLASS THREE		
FIT-BioCeuticals Ltd	Medlab Pty Ltd	
IDT Australia Limited	Vifor Pharma Pty Ltd	

CLASS FOUR		
Andrews Refrigerated Transport	IMS Health Australia Pty Ltd	Pretium Pty Ltd
Commercial Eyes Pty Ltd	INCRResearch Australia Pty Limited	PricewaterhouseCoopers
Covance Pty Ltd	IQnovate Ltd	Princeton Publishing Pty Ltd
Farmaforce Pty Ltd	KMC Health Care	Quintiles Pty Ltd

HONORARY LIFE MEMBERS		
There are seven Honorary Life Members of Medicines Australia who are remembered for their meritorious service to the industry.		
Dr G Blackman OAM	Mr A Ferguson	Mr Al Stahel
Mr R Davies	Mr JA Purches	
Mr P Bell	Mr J Robertson	

Medicines Australia Board Members 2013-2014



DIRECTORS 2013-2014

			APPOINTED TO BOARD
1	Dr Martin Cross	Chairman	1 November 2013
2	Mr Shaju Backer	Managing Director, Merck Serono Australia Pty Ltd	20 March 2013
3	Mr Wesley Cook	Managing Director, Boehringer Ingelheim Pty Ltd	11 September 2012
4	Dr Susanne Fiedler	Vice President & Managing Director Australia & New Zealand, MSD Pty Ltd	26 June 2012
5	Mr Mark Fladrich	Managing Director, AstraZeneca Pty Ltd	1 January 2012
6	Mr Chris Hourigan	Managing Director, Janssen Pty Ltd	5 December 2012
7	Mr James Jones	Managing Director, Takeda Pharmaceuticals Australia Pty Ltd	11 September 2012
8	Mr Laurie McAllister	Managing Director, sanofi	1 January 2014
9	Mr Geoff McDonald	Vice President/General Manager, GlaxoSmithKline	15 June 2012
10	Mr Anthony Mancini	Managing Director, Bristol-Myers Squibb Australia Pty Ltd	1 January 2014
11	Ms Kirsten O'Doherty	General Manager, Abbvie Pty Ltd	24 May 2012
12	Mr James Priour	Managing Director, Amgen Australia Pty Ltd	1 January 2014
13	Mr Jason Smith	Managing Director, Novartis Pharmaceuticals	11 September 2012

		APPOINTED	RESIGNED
14	Dr Dominic Barnes	VP & General Manager, Shire Australia Pty Ltd	31 December 2013
15	Dr Graeme Blackman	Chairman, Institute of Drug Technology Australia Ltd	30 September 2013

Medicines Australia Secretariat 2013-2014



CORPORATE

1	Brendan Shaw	Chief Executive	5	David Newman	ICT Manager
2	Clair Petrie	Executive Assistant to the Chief Executive & Chairman	6	Rochelle Pelaez	Executive Officer
3	Katie Whitehead	Director, Corporate Services	7	Amna Khanzada	Office Administrator
4	Caroline Wood	Finance Manager			



POLICY & ADVOCACY

1	Elizabeth de Somer	Director, Policy & Advocacy	6	Zoe Croker	Access to Medicines Policy Officer
2	Alice George	Regulatory Manager	7	Soelily Consen-Lynch	Research & Policy Officer
3	Samuel Develin	Reimbursement Manager		Vacant	Government Relations & Communications Manager
4	Michael Cook	Policy and Research Manager			
5	Omar Ali Khan	Industry Policy Manager			



COMPLIANCE

1	Deborah Monk	Director, Compliance	3	Karen Patten	Code of Conduct Officer
2	Sophie Hibburd	Code of Conduct Manager			



STAFF WHO DEPARTED IN 2013-2014

1	Ms Kristin Trace MacLaren	Policy Manager	2	Mr Andrew Simpson	Government Relations Manager
---	---------------------------	----------------	---	-------------------	------------------------------

Key Issues

STABILITY, PREDICTABILITY, ACCESS

1 STABILITY

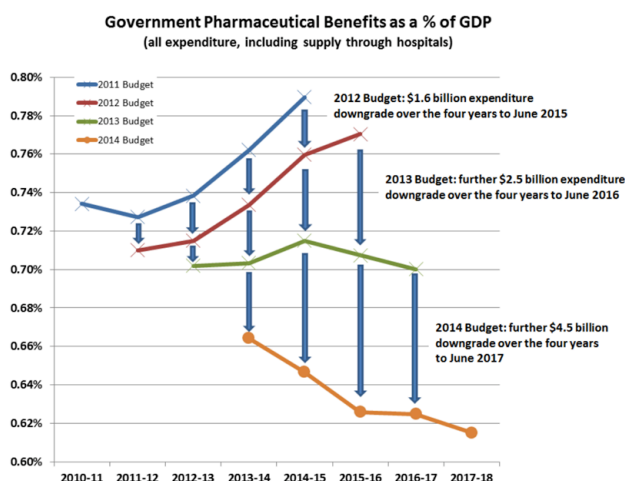
Industry has delivered a sustainable Pharmaceutical Benefits Scheme

During 2013-14, PBS reforms developed and implemented in the preceding years, delivered a sustainable and stable PBS for the foreseeable future. Nevertheless, government processes for access to new medicines have remained challenging, with the combined rate of PBAC rejections, deferrals, and recommendations containing difficult pricing conditions, continuing to rise during the year.

Government data confirms that PBS reforms, including expanded and accelerated price disclosure (EAPD), are delivering ongoing savings far in excess of those originally expected. This was dramatically demonstrated by the difference in the Government's forecast PBS costs between the 2013 and 2014 Budgets, which lowered total expenditure by \$4.5 billion over the forward estimates. This was reinforced by the Government's own updated Budget figures, released in late 2013, showing that PBS total expenditure fell by 3.5% or \$356 million during the 2012-13 year. It is anticipated the 2013-2014 year will be further written down, as it has been on successive occasions since 2011.

Delivering these reforms and the subsequent price cuts has come at a price for industry, with a number of restructures and job losses. In the face of continuing unpredictability of access, there is still much work to do.

FIGURE 1 Downward revisions of PBS expenditure



Source: 2014 Budget PBS Scorecard, Medicines Partnership of Australia, 2 June 2014.
<http://medicinespartnership.com.au/category/pbs-scorecards/>

2 PREDICTABILITY

More work to be done

Even during the term of the MOU from 2010, the government under Labor was able to introduce major policy measures not covered by the conditions within the agreement. Measures such as post market reviews and reinterpretation of section 99ACB of the National Health Act created significant uncertainty for the industry.

Additionally, changes to price disclosure through the introduction of Simplified Price Disclosure (SPD) were announced by the Labor Government in August 2013 without any consultation with industry, and were subsequently implemented by the new Coalition Government. This change brings price disclosure cuts earlier and more often and delivers close to \$1 billion in additional savings across the forward estimates.

However, in the lead up to the Federal election in September 2013 the Liberal party made significant promises to re-establish predictability, speed up access to medicines, and restore integrity to the process. The Liberal Health Minister indicated that there was no need to renew a formal agreement in order for the industry to have a stable and predictable business environment.

The Minister's assurances were reinforced when the 2014 Budget was the fifth consecutive Budget that did not introduce major harmful new policies or enact significant pricing or wholesale structural measures. Nevertheless, industry was acutely aware that the expiry of the MOU in June 2014 removed restrictions on government to introduce new price related savings measures. It also freed the government from maintaining a range of mutually productive policy reforms, such as the 6-month timeframe for Government consideration of new listings, the use of parallel TGA/PBAC processing and the joint monitoring of trends and drivers of PBS expenditure, amongst others.

The new Coalition Government initiated a National Commission of Audit (NCOA) of all Government programmes. The release of the NCOA report on 1 May 2014 proposed sweeping reforms of the PBS. The proposals included introduction of a fixed PBS funding envelope, establishing an "independent authority" to oversee management of pharmaceuticals, and creating a medicines tendering model. Many of the NCOA proposals were unsupported by modelling, ignored overseas experience and demonstrated a lack of understanding of Australia's pharmaceutical structure.

Following the release of the NCOA report, the Minister for Health expressed concern about uncertain PBS expenditure and unmanageable future growth and indicated a willingness to consider a new agreement with the sector. The industry's goals for any future agreement with Government remain focussed on ensuring a stable and predictable business environment, and timely access to new and innovative treatment options for Australian patients.

Industry has experienced a difficult year with many examples of delayed or difficult conditions for gaining access to new listings. However, there remains optimism for the future.

3 ACCESS Improving the PBS listing process

Medicines Australia was pleased with the Abbott Government's rapid implementation of election commitments; such as increasing the Cabinet consideration threshold of new medicine listings. Since 2001, any medicine that cost more than \$10 million in any one of the next four years had to go to Cabinet for approval. The incoming Coalition's early move to raise this threshold to \$20 million has meant a range of new medicines are made available to patients without unnecessary delays.

Medicines Australia was also encouraged by the reinvigoration of the Access to Medicines Working Group (AMWG). The AMWG has been a key vehicle to progress PBS listing and pricing reforms since the introduction of PBS reforms under the Howard Government in 2007. Announced in April 2014 and re-convened in June 2014, the group was proposed by the Minister for Health as a way to quickly and efficiently deal with long-standing issues. The first issues to be dealt with by the renewed group are resolving the Department's interpretation of Section 99ACB of the *National Health Act*, improving the Managed Entry Scheme, restructuring post market reviews, and improving transparency of the PBS process.

However, despite early enthusiasm, 2013-14 also saw a continuation of poor recommendation rates through the PBAC. Despite an increase in formal positive recommendations, following three years of falls, many recommendations contained conditions that had not been sought by the sponsors or were not able to be met, leading to unnecessary delays in listings.

Additionally, Medicines Australia was disappointed that the Pharmaceutical Benefits Pricing Authority (PBPA) was disbanded without consultation. The PBPA was an integral part of the PBS listing process and provided necessary and independent oversight and industry input into the listing of new medicines.

Throughout 2013-14, the industry has continued to work, and offer to work, in good faith with the government. This includes collaborative projects with the medicines regulator, the Therapeutic Goods Administration, on a range of important improvements to the evaluation process for prescription medicines; including a project to introduce electronic submission capability. These measures 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 efficiencies in the registration process.

In May 2014 Medicines Australia responded to the Governments "Open for Business" assertion and made a wide ranging proposal to Federal Industry Minister Ian Macfarlane on steps the Government could take to build a stronger biopharmaceutical industry in Australia. Broadly, the proposal called on Government to ensure a stable, predictable and efficient business operating environment; strengthen Australia's intellectual property system; enable growth in the Australian biotechnology sector, and enact globally competitive incentives to encourage investment in research and development (R&D), high-tech manufacturing and public-private partnerships.

Implementation of clinical trial reform was reinvigorated, which saw the new Coalition Government establish the Clinical Trials Advisory Committee to oversee the implementation of key reforms. This new group, co-chaired by senior officials from the Department of Health and the Department of Industry, is comprised of senior leaders from Government, industry (including Medicines Australia), health consumer organisations and the broader medical research community.

Additionally, as part of the 2014-15 Budget, the Government committed \$9.9 million over 5 years for projects designed to ensure Australia remains a leading destination for global clinical trial investment. Speaking just before the Budget, the Federal Health Minister Peter Dutton said, "It should be our goal to make Australia the number one destination in the world for clinical trials". Given the level of commitment at all levels of government in Australia to improve this country's competitiveness as a destination for clinical trial investment, Medicines Australia is hopeful that we will see significant progress in the next 12 months.

Throughout 2013-14, Medicines Australia continued to call for an extension of the term of data exclusivity, a critical element of Australia's IP system. Currently, the term of data exclusivity in Australia is just five years, compared to between eight and 12 years in most other OECD countries. The importance of data exclusivity has risen considerably in light of Australia's participation in ongoing negotiations on the Trans Pacific Partnership Agreement, where data exclusivity is one issue being discussed.

Furthermore, Medicines Australia has called on the Australian Government to restore the R&D Tax Incentive to its pre 2014-15 Budget form. The programme, as it was originally implemented in 2011, provided a globally competitive incentive for both home-grown and foreign-owned companies to conduct research and development activities in Australia.

In summary, Medicines Australia and the research pharmaceutical industry have continued to operate within an unstable and unpredictable business and policy environment and to deal with a slowing down of medicines listings. Having delivered a range of measures to ensure a sustainable PBS into the future, and with promising pipelines of breakthrough therapies, the Australian pharmaceutical industry focus will remain on strengthening the processes and systems in Australia to ensure Australian patients have access to new and innovative treatment options as early as possible and that Australia becomes a globally competitive destination for Australian pharmaceutical industry investment into the 21st century.

CODE OF CONDUCT PERFORMANCE: A SNAPSHOT

Code of Conduct Review

Edition 17 of the Code of Conduct came into effect in January 2013. In authorising the Code for two years, until December 2014, the Australian Competition and Consumer Commission (ACCC) urged the industry to consider further transparency measures about how companies interact with doctors, pharmacists and other healthcare professionals. Medicines Australia had already established the Transparency Working Group to develop a model that could provide greater transparency about payments and transfers of value between companies and healthcare professionals. The Transparency Model Consultation and Discussion Paper was released on 21 June 2013. This initiated the Code Review to produce Edition 18 of the Code.

The primary purpose for each Code 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. The focus of the Code Review in 2013-2014 was primarily to consider the transparency model for public reporting of payments and transfers of value to healthcare professionals. However, the Review also considered other amendments to the Code.

During 2013-2014 Medicines Australia consulted widely with stakeholders about the transparency model. Stakeholder forums were held in Sydney, Canberra and Melbourne in September 2013 and again in Sydney and Melbourne in April 2014. Medicines Australia also convened independently facilitated consultation workshops with consumers in Sydney, Perth and Melbourne in October 2014. In addition, of course, Medicines Australia consulted extensively with member companies. Over 80 submissions to the Code Review were received from member companies and other stakeholders.

On 24 June 2013, immediately following publication of the Transparency Working Group's Consultation Paper, the European Federation of Pharmaceutical Industries and Associations (EFPIA) published its *Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations*. This Code adopted an activity-based model under which transfers of value are recorded by activity, rather than by amount spent (which is the approach in the US). Following consideration of the submissions to the Code Review and consultations with members and stakeholders, the Code Review Panel recommended that Medicines Australia include a transparency model closely similar to the EFPIA model in the Code Edition 18.

Medicines Australia particularly wishes to acknowledge the hard work and persistence of the Code Review Panel, which included representatives of the Australian Medical Association and Consumers Health Forum, in analysing all submissions and developing the updated Code of Conduct, Edition 18.

Edition 18 of the Code of Conduct was unanimously adopted by members on 17 June 2014. The new Code has since been submitted to the ACCC for consideration for authorisation.

Edition 18 of the Code represents a further step up in delivering transparency about the interactions between companies and healthcare professionals. The transparency model requires member companies to report on individual healthcare professionals, who have given consent to publish the information, all payments relating to flights, accommodation, registration fees for educational meetings and any sitting or consulting fees. If authorised by the ACCC, Code Edition 18 will come into effect in January 2015, with the transparency model requirements commencing from 1 October 2015.

Transparency Reporting under Edition 17

Member companies have continued to report all educational meetings and symposia that they organise or sponsor. Medicines Australia publishes these reports every six months on its website. Under the Code of Conduct Edition 17, new transparency reports were introduced in which member companies report on their consultancies involving healthcare professionals and meetings of their Advisory Boards. The Advisory Board reports are published every six months, coinciding with the educational event reports. The healthcare professional consultancies report is an annual report covering a calendar year, published in June each year.

In December 2013 and June 2014 Medicines Australia published educational event reports for the periods April to September 2013 and October 2013 to March 2014. These were the thirteenth and fourteenth six monthly reports published since reporting commenced in 2007. There were 16,891 events reported for the period April to September 2013 and just over 13,000 events reported for October 2013 to March 2014. The number of events reported for each period in 2013-2014 is consistent with previous years and reflects that fewer events are held during the Christmas and New Year period.

In addition, in December 2013 and June 2014 Medicines Australia published member companies' Advisory Board reports. These reports covered the periods April to September 2013 and October 2013 to March 2014. There were 247 Advisory Board meetings held by 32 member companies during the 12 month period.

The first member companies' healthcare professional consultancies reports were published in June 2014. These reports covered consultancies commenced during the 2013 calendar year. Thirty-three of our member companies engaged 1017 healthcare professional consultants across 728 projects during the year.

In June 2014 Medicines Australia also published the first reports of member companies' financial support for Health Consumer Organisations (HCO), a new requirement under Edition 17. Previously member companies published these reports on their websites and did not include the financial information. Member companies supported 130 different HCOs across Australia in calendar year 2013, ranging from national consumer organisations to small local groups, relating to 356 different projects or events.

In 2013-2014 member companies consistently demonstrated a high level of compliance with the Code and their ongoing commitment to improved transparency of interactions with

CONTINUING EDUCATION PROGRAM (CEP)

healthcare professionals, to deliver and support valuable education about the treatments available to Australians, and to support health consumer organisations in their important services to Australian consumers.

How we performed

In 2013-2014, Medicines Australia received 10 new complaints. This is a decrease over each of the previous two years, where 18 and 12 complaints were received. Half of these new complaints were submitted by Member Companies (five complaints) with the balance submitted by healthcare professionals (two complaints), a company employee (one complaint) and the Monitoring Committee (two complaints).

Of the seven complaints received but not finalised in 2012-2013 and 10 new complaints received in 2013-2014, 16 complaints were considered and finalised by the end of this financial year. One complaint from a member company was against a non-member company which declined to have the complaint heard under the Code of Conduct. The member company decided to continue to seek resolution with the non-member company rather than refer the complaint to the TGA.

Of the 16 finalised complaints, ten were found not in breach of the Code and six complaints were found to be in breach of some or all aspects of the alleged breaches. There were four appeals against the Code of Conduct Committee's decisions during the year. One appeal was upheld and three appeals were not upheld. Details of the complaints considered and finalised in 2013-2014 and the outcomes are reported in the [Code of Conduct Annual Report](#), published on the Medicines Australia website.

The Monitoring Committee continued its busy schedule of monitoring reviews during 2013-2014. The Committee undertook six reviews of materials associated with particular therapeutic areas:

- advertisements in audio-visual media in the cardiovascular therapeutic area
- printed promotional material in the alimentary therapeutic area
- patient educational materials in the eye therapeutic class
- electronic detail aids in the central nervous system therapeutic class
- printed advertisements in the musculoskeletal therapeutic class
- printed promotional material in the neoplastic therapeutic area

The Committee also undertook a review of the new Health Consumer Organisation support reports that now include funding amounts. These reviews of HCO support reports company materials and are in addition to the regular annual review of one quarter of all educational event reports submitted by Member Companies, for support of health consumer organisations covering activities commenced on or after 1 January 2013 to December 2013. The Monitoring Committee reviewed reports from 34 companies for 130 Health Consumer Organisations supporting 356 projects to the total value of \$9,093,111.

The Monitoring Committee reviewed 7920 educational events from 38 companies for events held between 1 April 2013 and 31 March 2014.

The Medicines Australia Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. It also educates other company personnel about the Medicines Australia Code of Conduct. Medicines Australia acknowledges the committed team at the University of Tasmania who delivered the CEP in 2013-2014 for our members led by Professor Greg Peterson.

Key Events Diary

July 2013

- Minister for Health and Medical Research, the Hon Tanya Plibersek MP announced new and amended listings to the Pharmaceutical Benefits Scheme.
- Medicines Australia lodged its submission to stage three of the Post-Market Review of Products Used in the Management of Diabetes. The submission is available on the [Medicines Australia Website](#).
- The Pharmaceutical Benefits Advisory Committee (PBAC) met for its July meeting.
- The Pharmaceuticals Industry Council (PIC), which comprises of Medicines Australia, AusBiotech and GMiA, hosted its third annual Industry-Government Luncheon in Canberra.

August 2013

- The Medical Oncology Group of Australia (MOGA) held its annual scientific meeting in Melbourne. Medicines Australia Oncology Industry Taskforce (OIT) launched its discussion paper on access to cancer medicines in Australia at this meeting. The report and its key findings can be found [here](#).
- Managing Directors met with Medicines Australia secretariat and Board members to discuss PBS Policy.
- Medicines Australia hosted a Managing Directors Dinner with guest speaker Martin O'Shannessy, CEO of Newspoll.
- The Code Review Panel held their first meeting in Sydney to commence the review of Code Edition 17.
- Medicines Australia and PWC launched a report into the Australian Pharmaceutical Industry. A copy for the report is available [here](#).
- In the election campaign, the Greens announced commitments to restore the integrity of the PBAC and focussing PBS post-market reviews on achieving better health outcomes rather than cost-cutting.
- The Hon Kim Carr, Minister for Innovation, Industry, Science and Research announced commitment to establish a Biopharmaceutical Innovation Partnership, committing up to \$6 million investment to be matched with co-investment from partner organisations.
- During the election campaign the Coalition announced their commitment to restoring predictability and confidence into the PBS as well as changes in the Health Minister's authority to list medicines, increasing cabinet threshold from \$10 million to \$20 million. The Coalition also announced their Manufacturing and Exports policy which looks to boost manufacturing in Australia and attract exports by increasing competitiveness with other nations.
- The 2013 Health Policy debate took place at the National Press Club between the Hon Tanya Plibersek and Shadow Health Minister the Hon Peter Dutton.

September 2013

- Stakeholder Consultation Forums were held in Melbourne, Sydney and Canberra to discuss the Code of Conduct Review.
- Member Company Janssen hosted an industry pre-election networking breakfast meeting with Former Federal Health Minister, the Hon Dr Michael Wooldridge as guest speaker.
- The Coalition formed the Abbott Government after the 2013 Federal Election. Medicines Australia welcomed the return of all the Parliamentary friends of Medicines Co-chairs, John Alexander, Member for Bennelong, Richard de Natalie, Senator for Greens, Victoria and Shayne Neumann, Member for Blair.
- A Managing Directors webinar was held to provide a brief on the election outcomes and Medicines Australia's plans to work with Government post-election.
- The Medicines Partnership Australia met in Canberra. Agenda items included changes to PBS price disclosure arrangements and joint initiatives to educate Members of Parliament on the PBS.
- The Department of Health and Ageing held a stakeholder forum to discuss the progress of the Post-Market Review of Products Used in the Management of Diabetes. The Medicines Australia submission to the review is available [here](#).
- The Prime Minister the Hon Tony Abbott announced his Ministry for the newly formed Government. Key appointments confirmed were the Hon Peter Dutton, Minister for Health and Sport and the Hon Ian Macfarlane, Minister for Industry.
- Member briefings were held in Sydney and Melbourne to discuss a review of the Strategic Committee Framework.

October 2013

- Medicines Australia submitted its paper in response to the latest consultation paper on patentable subject matter from IP Australia. The submission is available [here](#).
- Medicines Australia held the first of three Consumer Workshops on the Code of Conduct Review and Transparency Model. Led by Ms Ann Porcino, health consumers actively engaged in discussion of the transparency model.
- The Medicines Australia Annual General Meeting was held in Sydney. The Chairman presented the [2012-2013 Annual Report](#). The audited [Financial Statements of Medicines Australia](#) and the [Code of Conduct Annual Report](#) were also presented. The Chairman announced the recipient of the 2013 Pat Clear award, Sara Pantzer of Amgen for her ongoing commitment to shaping the policy landscape in the Australian Pharmaceutical industry. Graeme Blackman was presented with Honorary Life Membership to Medicines Australia for his outstanding contribution to the industry and 18 years of service to the Medicines Australia Board.

November 2013

- Martin Cross assumed the role of Chairman for Medicines Australia.
- Brendan Shaw attended the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Head of Association meeting and Council Meeting in Geneva.
- Communiqués from the Code Review Panel's first two formal meetings were made available on the Code Review Panel.
- Medicines New Zealand representatives visited Australia for key meetings with Medicines Australia, the TGA, and Government representatives.
- Managing Director Dinners were held in Sydney and Melbourne. The dinners gave MDs the opportunity to meet with new Chairman Martin Cross and discuss key priorities for industry going forward.
- The Oncology Industry Taskforce (OIT) held a Luncheon under the 'Parliamentarians supporting cancer causes' group focussing on the report, 'Access to cancer Medicines in Australia'.

December 2013

- The World Diabetes Congress took place in Melbourne. Martin Cross participated in the Symposium 'Affordability of Diabetes Drugs'.
- Medicines Partnership of Australia (MPA) issued letters to key MPs and Government departments to express concern over recent public calls for further cuts to the PBS. Access the MPA website [here](#).
- Member briefings were held in Melbourne and Sydney. Members were updated on current industry issues including the PBS, post-election environment, Code of Conduct and transparency.
- The Annual MA-PBAC meeting was held at the Department of Health in Canberra. Agenda items included a review of the year, Transparency, Data Requirements for PBAC submissions & Key Activity Indicators (KAIs).

January 2014

- The 2014-2015 Medicines Australia Board met for the first time to appoint the Chairman (under the terms of the Constitution) and Board committee members. The Board confirmed Martin Cross as Appointed Chairman and appointed members for the Board committees.
- Three Consumer Workshops were held as part of the Code Review: The Consumer Workshop Report is available on the Code Review page of the Medicines Australia [website](#).
- Medicines Australia made a submission to the Senate Economics Committee on the *Tax Laws Amendment (Research and Development) Bill 2013*.

February 2013

- Medicines Australia lodged a Budget submission with Treasury, which sets out six measures that will protect the PBS for future generations.
- Medicines Australia lodged a submission to the Securing Australia's Manufacturing Future review, which calls for Australia to match overseas pharmaceutical incentives. View the submission [here](#).
- Medicines Australia lodged a submission to Senate Standing Committees on Economics on the *Tax Laws Amendment (Research and Development) Bill 2013*. View the submission [here](#).
- Martin Cross presented at the NPS MedicineWise Board meeting, focussing on the Medicines Australia strategic priorities for the coming year.
- The Medicines Partnership of Australia (MPA) hosted a Parliamentary Friends of Medicine event to launch the MPA publication, "An introduction to the Pharmaceutical Benefits Scheme". A copy can be found [here](#).

March 2013

- Medicines Australia had its annual bilateral meeting with TGA representatives to discuss changes to the TGA fees and charges for the coming financial year.
- Martin Cross presented at the State of the Industry Symposium at the Australian Professional Pharmacy (APP) conference, hosted by the Pharmacy Guild of Australia.
- Member consultation briefings were held in Sydney and Melbourne to present the draft proposed transparency model and updated Code Edition 18.
- Martin Cross took centre stage at Medicines Australia National Press Club address. The theme for the speech was 'Timely access to affordable medicines for all Australians – Certainty the key to the future'. Click [here](#) to view.
- Medicines Australia hosted its Annual Parliamentary Dinner in the Great Hall at Parliament House in Canberra. Minister for Health, the Hon Peter Dutton MP, was guest of honour for the evening and Professor John Shine AO FAA, Chairman of CSL and prominent scientist and genetic engineer, provided a key note speech. Click [here](#) for event overview and videos of the speeches.
- Representatives from the Pharmaceuticals Industry Council, met with Industry Minister Ian Macfarlane, the Shadow Industry Minister Senator Kim Carr and senior representatives from the Treasury and the departments of Industry and Prime Minister and Cabinet to discuss issues affecting the biopharmaceutical industry in Australia.
- Martin Cross, Brendan Shaw and other Medicines Australia and industry representatives participated in the Cancer Drugs Alliance Stakeholder Forum in Canberra.
- The Medicines Australia Members Only Policy Conference was held in Sydney.
- Medicines Australia hosted the Continuing Education Program (CEP) Awards in Sydney. Martin Cross provided the welcoming address.
- The Medicines Australia Code of Conduct Award, for highest marks in the Code of Conduct Program, was presented to Philip Berry (Pfizer). Eilise D'Arcy (Alphapharm) received the UTAS Prize for Excellence.

April 2014

- Martin Cross, Brendan Shaw and senior representatives of Medicines Australia delivered member briefings in Melbourne and Sydney.
- Martin Cross was appointed to the Government's newly-formed Clinical Trials Advisory Committee, which will provide advice to Government on the implementation of clinical trial reforms in Australia.
- Minister Dutton announced the re-establishment of the Access to Medicines Working Group (AMWG).
- Brendan Shaw met with the Ambassador and Head of Delegation of the European Union, H.E. Mr. Sem Fabrizi. The meeting was the first introduction the Ambassador had with Medicines Australia.

May 2014

- Martin Cross met with Assistant Minister for Health, the Hon Fiona Nash to discuss Indigenous Health Projects in which Medicines Australia have played an active role, such as the Purple Truck. Dr Cross also updated the Assistant Minister on the Code Review and proposed Transparency Model as well as ANZTP negotiations.
- Stakeholder consultation meetings were held in Melbourne and Sydney about the transparency model and the Code of Conduct.
- Medicines Australia and AusBiotech submitted a joint proposal to Industry Minister Ian Macfarlane on steps the Australian Government should take to build a stronger biopharmaceutical industry in Australia.
- Medicines Australia held further consultation meetings with Member companies in Melbourne and Sydney to discuss the final draft of Edition 18 of the Code of Conduct and seek member feedback before the formal member vote in June.
- Brendan Shaw presented at the National Medicines Symposium in Brisbane on PBS sustainability and access to medicines and took part in a panel discussion on how to transform the health system for the future.
- Martin Cross attended the first meeting of the new Clinical Trials Advisory Committee.
- Medicines Australia participated in a Diabetes stakeholder roundtable in Sydney.
- Medicines Australia announced the departure of Chief Executive Brendan Shaw in September.
- The Assistant Minister for Health, Senator the Hon Fiona Nash, launched the Medicine Shortages Information Initiative at Parliament House. Brendan Shaw spoke at that event.
- The Health Journalism Awards and Minister for Health's National televised Address were held at the National Press Club, Canberra, click [here](#) to view details.

June 2014

- Medicines Australia's Industry Policy Manager, Omar Ali Khan, received the 2014 ARCS Australia's Clinical Research Advocate Award.
- Brendan Shaw attended the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Heads of Associations meeting and Council Meeting in Geneva.
- Medicines Australia and senior industry representatives met with senior representatives of the Department of Health for the first renewed Access to Medicines Working Group meeting.
- Members unanimously adopted Edition 18 of the Code of Conduct at a General Meeting of the Association.

Conferences and Events



1. Steve Lewis from the National Press Club congratulates Dr Martin Cross after his address
2. Medicines Australia Chairman, Dr Martin Cross, addresses the National Press Club
3. Dr Martin Cross with Minister Peter Dutton at the Medicines Australia Parliamentary Dinner

4. Professor John Shine delivers his speech as keynote speaker
5. Guest of Honour, Minister the Hon Peter Dutton, addresses the gathering
6. Dr Brendan Shaw with Professor Jane Halton and Dr Martin Cross

The Chairman's National Press Club Address

In his address to the country on 19 March 2014 at the National Press Club in Canberra, Chairman of Medicines Australia, Dr Martin Cross, emphasised the sustainability of the Pharmaceutical Benefits Scheme and the importance of working closely with government.

Dr Cross' address emphasised the importance of a stable policy framework between government and the industry to ensure the future viability of the PBS, despite the challenges industry has faced in the past.

He also said pragmatic solutions are now required to ensure Australians continue to have universal, timely access to the latest medicines and the industry remains a strong contributor to the wealth as well as the health of the nation.

The transcript, live streaming and media release of the address are available on the [Medicines Australia website](http://medicinesaustralia.com.au).

Medicines Australia Parliamentary Dinner

Medicines Australia hosted its annual Parliamentary Dinner on 19 March 2014 at Parliament House with guest of honour, Health Minister, the Hon Peter Dutton, and keynote speaker, Professor John Shine AO, Chairman of CSL.

Mr Dutton told the gathering of about 300 guests from industry, Parliament, government and the broader healthcare sector, that the Parliamentary Dinner was a good opportunity for industry to showcase their work, so government can get a better understanding of how it can provide support, including support for the growth of what is an important sector.

Professor Shine also reiterated the importance of industry, explaining that with greater certainty around PBS assessment and reimbursement, industry can turn its mind to growing its business interests in Australia as a key partner in the future vision for Australia as a world-class centre of innovative drug development, manufacturing and healthcare delivery.

Transcripts of the speeches, including videos of the night are available at <http://medicinesaustralia.com.au/media-events/latest-events/>.



Managing Directors discuss the strategic priorities with the Board and Secretariat at the Members' Only Policy Conference in March

Parliamentary Friends of Medicines

The Parliamentary Friends of Medicines Group is a non-partisan forum through which members of the medicines industry can interact with parliamentarians to discuss issues affecting industry and patients. The Group is chaired by John Alexander MP, Senator Richard Di Natale and Senator Claire Moore.

In 2013-14, Medicines Australia and individual member companies hosted four luncheon briefings for the Group. Topics covered included:

- Partners in Targeting Diabetes – Sponsored by Novartis & Eli Lilly
- Introduction to the PBS – In association with the Medicines Partnership of Australia

Managing Directors Dinners

Medicines Australia held four Managing Directors dinners during the year.

AUGUST

Medicines Australia hosted a Managing Director Dinner in Sydney. The primary focus of this dinner was to hear from guest speaker, Mr Martin O'Shannessy. Martin is CEO of Newspoll, one of Australia's leading polling companies. Martin's presentation provided insight into the upcoming outcomes of the Federal Election based on political polling figures.

NOVEMBER

Medicines Australia ran two Managing Director Dinners in November, the first in Sydney and another in Melbourne. Both dinners were hosted by newly appointed Chairman, Dr Martin Cross. Martin presented to the membership on key issues and strategies of the association going forward.

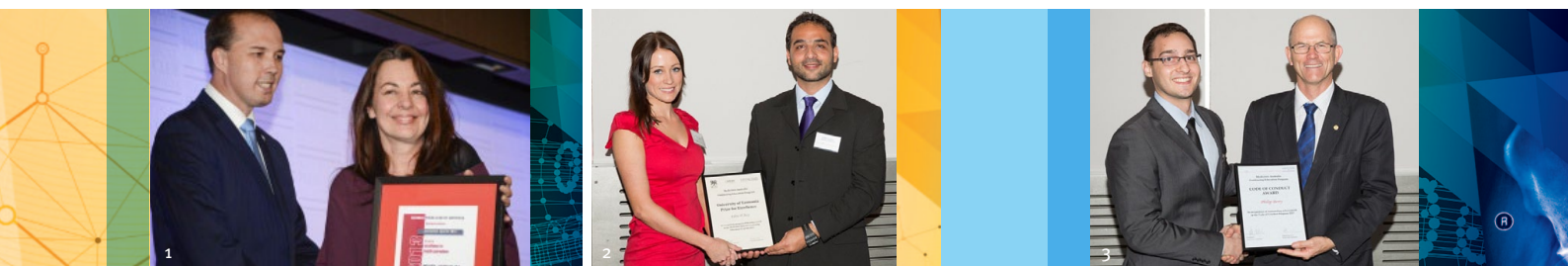
JUNE

A Managing Director Dinner was held in June in Sydney to discuss and update the membership on Strategic Priorities for 2014/2015. Dr Brendan Shaw, Medicines Australia Chief Executive presented the Membership with the draft Strategic Priorities for the coming year.

Medicines Australia Members' Only Conference

Managing Directors were invited to workshop the key priorities of the organisation on 25 March. It allowed members to engage with the Board on the future directions for the industry and to provide views on the strategies required. Twenty-eight member representatives attended the one-day workshop-style conference. The outcomes of the conference assisted the Board in its deliberations at its Strategic Retreat in April 2014.

Awards



1. Sonya Pemberton, Winner of the 2013 Excellence in Health Journalism Award, receives her award from Minister for Health, Peter Dutton
2. Ms Elise D'Arcy from Alphapharm receiving her award from Dr Nikolas Dietis, Program 4 Coordinator, University of Tasmania

3. Mr Philip Berry from Pfizer receiving the award from former AMA President, Dr Steve Hambleton

Excellence in Health Journalism Awards

The annual Excellence in Health Journalism Awards were presented by Medicines Australia Chief Executive, Dr Brendan Shaw, at the National Press Club on 28 May 2014.

Medicines Australia is the principal sponsor of the annual awards, which honour journalists who have contributed the best work on health and health science. The prize for category winners is \$1000 in cash. The prize for Health Journalist of the Year is \$10,000 in cash and an international study tour.

SBS journalist, Sonya Pemberton, was named the 2013 Health Journalist of the Year for her feature documentary 'Jabbed: Love, Fear and Vaccines' which looks at the public health issues and debate around vaccinations.

Other Award winners included:

- Best News Feature, Article or Presentation; Health, Health Sciences or Innovation: Amy Corderoy, The Sydney Morning Herald – 'A pox on both your parents'
- Best Documentary or Documentary Series; Health, Health Science or Innovation: Sonya Pemberton, SBS – 'Jabbed: Love, Fear and Vaccines'
- Best Feature, Article or Presentation; Health Policy, Health Economics and Health Business: Amanda Sheppard, Australian Doctor – 'Far from home'
- Best News Feature, Article or Presentation: Health, Health Science or Innovation directed to medical professionals: Paul Smith, Australian Doctor – 'Corporate Culture'

Special Commendations went to:

- Tim Elliott, The Sydney Morning Herald – 'Shock Value'
- Sarah Dingle, ABC – 'An ill wind'
- Paddy Wood, Australian Doctor – 'Money to be had'
- Peter Waterman, Australia Pharmacist – 'Prescription addiction: The creeping menace'

For more information about the Awards, visit the Medicines Australia website.

Continuing Education Program Awards

Twelve sales representatives were honoured at the Continuing Education Program Awards ceremony in Sydney on 25 March 2014 where they received the industry's top accolades for ethical sales and marketing.

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

UNIVERSITY OF TASMANIA PRIZE FOR EXCELLENCE

CEP Course Facilitators at the University of Tasmania select one finalist from their program who has scored the highest marks in each CEP Program. If there is more than one student with the highest mark, the winner is determined through review of the optional reflective assignment and online and discussion forum participation. The winner is selected by a panel from the University.

UTAS Prize for Excellence was presented to Ms Elise D'Arcy from Alphapharm.

CODE OF CONDUCT AWARD

Finalists for the Code of Conduct Award include all students who achieve the highest final mark for Program 1.

- Excludes anyone who has achieved 100% final mark via resubmission or supplementary assessment.
- Among the finalists, the winner is determined through review of an optional reflective assignment and online participation by a UTAS panel; Medicines Australia will make the final decision if it is difficult to identify a clear winner.

The Code of Conduct Award was presented to Mr Philip Berry from Pfizer.



1. Mark Fladrich, Medicines Australia Chairman, presents Sara Pantzer with the Pat Clear Award 2013

CEP ACHIEVEMENT AWARDS

CEP Achievement Award winners are the 10 students who achieve the highest aggregate marks for the five core programs (out of a possible total aggregate of 500).

Program 3 Human Anatomy and physiology is not included in the aggregate calculation as not all students are required to undertake this program.

The award evaluation excludes anyone who has achieved their marks via resubmission or supplementary assessment.

CEP Achievement Award recipients in 2013 were:

- Amgad Luka – Novartis
- Christine Yeo – Boehringer Ingelheim
- Craig Trevethan – Bayer
- Sarah Frankland – Mundipharma
- Emma Stowe – Mundipharma
- Hannah Carthew – Servier
- Jeffrey Chu – Mundipharma
- Mei Vien – Bayer
- Michaela Blasina – iNova Pharmaceuticals
- Teal Bubb – AstraZeneca

*Award recipients' companies were correct at time of completion of 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.

Pat Clear Award 2013

The 2013 Pat Clear Award recipient was Sara Pantzer, Head of Government Affairs and Policy, Amgen Australia. Sara has been a key contributor to shaping the policy landscape for the Australian pharmaceutical industry since joining the industry in 1995, with the ultimate goal of ensuring access to medicines for Australian patients. She was a key contributor to the industry's work on PBS reform policy, approach to the Australia United States Free Trade Agreement, Memorandum of Understanding, and Oncology Industry Taskforce.

The Pat Clear Award was established in 2002 to commemorate the substantial contribution Pat Clear, former Chairman and Chief Executive of Medicines Australia, made to the medicines industry during his career, spanning 40 years. Pat Clear's association with Medicines Australia was characterised by his determination, commitment and dedication.

The Award is presented annually to recognise an outstanding performance and contribution by an individual, group or team who work in the industry.

In these modern times, it is a rare privilege to be able to acknowledge one person's long standing commitment to an organisation.



1. Medicines Australia Chief Executive, Brendan Shaw, and Mark Fladrich, Interim Chairman, congratulate Dr Graeme Blackman OAM on his Honorary Life Membership

Honorary Life Membership awarded to Dr Graeme Blackman OAM

In the presence of the Hon John Alexander, Member for Bennelong, and industry representatives past and present, Dr Graeme Blackman was awarded Honorary Life Membership to Medicines Australia for 18 years of service on the Medicines Australia Board and in recognition of his outstanding contribution to the pharmaceutical industry in Australia.

With over 25 years' experience in the international pharmaceutical industry including the research and development sector, Dr Blackman has been a member of key government and pharmaceutical industry policy committees, including former Chairman of the Pharmaceutical Industry Action Agenda for three years from its inception in 2003 through to 2006, when the Pharmaceutical Industry Council was established.

In 2005 he received the Pat Clear Award, the industry's highest recognition, for his contribution to the Pharmaceutical Industry Action Agenda policy setting.

Dr Blackman joined the Board in 1995, when the organisation was known as the Australian Pharmaceutical Manufacturers Association. Within this period he held the positions of Deputy Chairman, twice, and Honorary Treasurer. He was also the Chair of the Nominations Committee of the Medicines Australia Board and a Board sponsor on the Innovation Strategic Committee.

Additionally, over a number of years Dr Blackman has offered his time and provided skills and expertise to the broader community, including directorships of Benatas Aged Care, the Australian Youth Orchestra and the National Trust of Australia. It is his work across the not for profit community sectors of education, welfare, aged care and heritage, as well as his commitment to the pharmaceutical industry, that earned him the honour of the Medal of the Order of Australia in 2009.

His contribution to the industry has been significant and is greatly appreciated.

Dr Graeme Blackman OAM was awarded Honorary Life Membership of Medicines Australia on 22 October 2013.

Working with the Community



1. Shalom Gamarada Scholarship students, Trent Boyle and Laura Fitzgerald, present to Medicines Australia members on 22 October 2014

2-3. Alice Springs Town Camp residents participating in the Baker IDI Health Project

Medicines Australia Special Purpose Fund

Medicines Australia's Special Purpose Fund was established in 2008, to support notforprofit organisations committed to improving indigenous health outcomes.

The inaugural projects supported through the fund are the Jimmy Little Foundation *Thumbs Up!* healthy eating program and the Western Desert Mobile Renal Dialysis unit – the Purple Truck.

Since then, Medicines Australia has supported indigenous students of medicine through the Shalom Gamarada Residential Scholarship Program and Baker IDI Heart & Diabetes Institute, Central Australia.

Shalom Gamarada Ngayami Yana Residential Scholarship Program

In 2010, Medicines Australia contributed \$150,000 over five years towards the education of two indigenous medical students, adding another two students to the commitment in 2012. Throughout this period, a number of students have benefited from our support – Laura Fitzgerald, Brendan Phillips, Brylie Frost, Maiysha Craig, Trent Boyle, Luke Walker, Sean Westbury and India Kinsey.

Dr Hilton Immerman OAM, Chief Executive Officer, of The Shalom Institute and Shalom College presented at the Member Briefing immediately following the Annual General Meeting on

22 October 2013. He explained the importance of providing a safe and supportive environment to encourage scholarly pursuits. This was followed by two students who told of their personal stories and what the scholarship has meant to them in pursuit of a medical career.

With the first five year commitment drawing to a close, Medicines Australia continues to support three indigenous students: Laura Fitzgerald, Luke Walker and Sean Westbury.

Baker IDI Heart & Diabetes Institute, Central Australia

In 2013, Medicines Australia supported Baker IDI to undertake the Alice Springs Town Camp Health Project. Baker IDI employed a full time health care worker over a 15 month period to work in the Town Camps around Alice Springs, in partnership with Tangentyere Council and other local stakeholders. The project has enabled key health service providers to focus specifically upon the role of local organisations in relation to the lives of Town Camp residents and has provided valuable information on how health care is provided, as well as how residents of the Town Camps access available services.



1. Sarah Brown, CEO of WDNWPT (Purple House), presents to Medicines Australia members on 22 October 2014

2-4 The Purple Truck in communities

The Purple Truck

The Purple Truck was launched in Alice Springs on 12 December 2011. Since then, the Purple Truck has provided more than 140 dialysis treatments for over 30 people in remote locations. The Truck has visited communities in South Australia, the Northern Territory and Western Australia.

The fundamental purpose of the Purple Truck project was always to help Aboriginal people from remote communities to return home to visit country and family. The Purple Truck helps communities to experience dialysis at home and has become a symbol of community determination to have permanent services provided in country.

In 2013 the Purple Truck was fitted with a second dialysis machine with the support of a Commonwealth Government grant of \$15,000 and the donation of the machine from Fresenius Medical. There is now the capacity to dialyse eight people in country.

Medicines Australia continues to support the Purple Truck with maintenance and running costs, having announced ongoing funding for a further two year period in 2012.

In November, The Purple Truck was awarded the Excellence in Accessible Communities at the National Disability Awards ceremony held in Canberra. Assistant Minister for Social Services, Mitch Fifield, presented the Purple House with the award for its outstanding work to improve the lives of people with kidney disease living in remote communities.

Engagement with Health Consumer Organisations – the Working Together Guide

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 *Working Together Guide 2008*, a collaboration between Medicines Australia and the Consumers' Health Forum, 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 a respect for independence, openness and transparency and accountability. In 2013, a committee representative of industry and consumer groups began a review of the *Working Together Guide*. The work of the committee continues.

Working with our Members

Following on from the Medicines Australia Board's review of the Strategic Plan and the restructure of the Secretariat, the Board reviewed and restructured the Strategic Committee Framework, which took effect in June 2014.

The new structure includes one overarching Strategic Committee and five standing working groups, namely: Industry Policy Working Group; Regulatory Affairs Working Group; Health Economics Working Group; Government Working Group; and Future Issues Planning Working Group.

In addition, there are a number of issues groups formed to progress specific elements of the work plan against the strategic priorities. During the year there were five issues groups assisting in the development of industry policy positions.

The new structure will also include member communication networks to provide opportunities for members to engage on particular areas of interest. The network is not part of the formal committee framework, but is designed to be an alternative means of communication with our members. It is anticipated most communication will be via an internet forum and a pilot is currently being developed.

Strategic Committee

The Strategic Committee is principally responsible for assisting the Secretariat to deliver the strategic priorities as set by the Medicines Australia Board. The Strategic Committee also assists the Secretariat to finalise the Medicines Australia priority work plan and provide guidance and oversight of its implementation.

Members at 30 June 2014:

- Elizabeth de Somer Medicines Australia, co-Chair
- Michelle Burke Bristol-Myers Squibb, co-Chair
- Albert Spanos Celgene
- Alissa Brown Sanofi
- Andrew Carter Commercial Eyes
- Charles Waterfield AstraZeneca
- Christian Sellars MSD
- David Herd GSK
- Kathy Cargill Abbvie
- Mendel Grobler Pfizer
- Nicol Kurstjens Novartis
- Peter Germanos Boehringer Ingelheim
- Peter Vermeer Eli Lilly
- Sara Pantzer Amgen
- Steve Crowley Janssen
- Sue Alexander Roche

Industry Policy Working Group

Advises Medicines Australia on issues pertaining to Government policies to attract investment in pharmaceutical R&D and manufacturing.

Members at 30 June 2014:

- Omar Ali Khan Medicines Australia, co-Chair
- Duncan Purvis Janssen, co-Chair
- Luke Cornish MSD
- Ric Degaris Commercial Eyes
- Stuart Englund Eli Lilly

- Julia Jenkins Novartis
- Paul Lindsay Merck Serono
- Kristin MacLaren GSK
- Lee McKerracher Pfizer
- Clair Willmott Roche

Regulatory Affairs Working Group

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 2014:

- Alice George Medicines Australia, co-Chair
- Sue Alexander Roche, co-Chair
- Brian Hewitt Pfizer
- Carolyn Tucek-Szabo GlaxoSmithKline
- Elizabeth Joshi Bayer
- Emma Williams BioCSL
- George Lillis Novartis
- Helen Critchley sanofi
- Kirpal Kaur Bristol-Myers Squibb
- Mark Rowland Amgen
- Michael Parker AstraZeneca

Health Economics Working Group

Provides strategic policy advice and support on matters relating to the reimbursement, listing and pricing of medicines on the Pharmaceutical Benefits Scheme.

Members at 30 June 2014:

- Sam Develin Medicines Australia, co-Chair
- Greg Cook Bristol-Myers Squibb, co-Chair
- Alison Wright Janssen
- Ben Kluge Bayer
- Carlene Todd Roche
- Geoffrey Chin Novartis
- Kate Webb Takeda
- Louise Graham Amgen
- Mirella Daja Novo Nordisk
- Peter Germanos Boehringer Ingelheim
- Susan Phillips Commercial Eyes

Government Working Group

Develops and shares information between industry members to communicate a unified industry position to Government on relevant issues, policies, and legislation. It also provides advice on political and government relations issues as they arise.

Members at 30 June 2014:

- Michael Cook Medicines Australia, co-chair
- Sara Pantzer Amgen, co-chair
- Adrian Dolahenty Bayer
- Andrew Thirlwell Pfizer
- Cameron Milliner Shire
- Karen Barfoot Bristol-Myers Squibb
- Kieran Schneemann AstraZeneca
- Nicola Richards MSD
- Penny George Sanofi
- Stuart Englund Eli Lilly
- Todd Stephenson Janssen

Future Issues Planning Working Group

Assist in identifying long-term trends and risks affecting the pharmaceutical industry, and recommending possible actions and strategies.

Members at 30 June 2014:

- Elizabeth de Somer Medicines Australia, co-Chair
- Mendel Grobler Pfizer, co-Chair
- Alissa Brown Sanofi
- Brendan Price MSD
- Cheryl Maley Novartis
- Delia Schaffer Takeda
- Kaylene O'Shea Celgene
- Kelly Makarounas-Kirchmann KMC Health Care
- Kristin Trace-MacLaren GSK
- Nathan Walters Janssen
- Terese Cole Eli Lilly

MEDICINES AUSTRALIA ISSUES GROUPS

99ACB Issues Group

- Elizabeth de Somer Chair (Medicines Australia)
- Natalia Price Abbvie
- Steve Quinn Amgen
- Mike Smith AstraZeneca
- Mike Cloonan Biogen Idec
- Sean Lybrand Biogen Idec
- Georgie Broadbent Bristol-Myers Squibb
- Greg Blanch Janssen
- Matt Kirchmann KMC Healthcare
- Sam Develin Medicines Australia
- Paul Lindsay Merck Serono
- Cathy Harvey Mundipharma
- Jodie Thomas Novartis
- Mary-Anne Bonney Novartis
- Annette Kerr Roche

Biosimilars Issues Group

- Elizabeth de Somer Medicines Australia (Chair)
- Sara Pantzer Amgen (Chair)
- Marius van den Berg Abbott
- Kathy Cargill Abbvie
- Carolyn Cameron Allergan
- Michelle Frost Allergan
- Greg Cook BMS
- Kristin Maclaren GSK
- John Bower GSK
- Jim Crompton Janssen
- Cindy Warren Janssen
- Todd Stephenson Janssen
- Omar Ali Khan Medicines Australia
- Richard Slingsby MSD
- Paul Lindsay Merck Serono
- Christine Black Novartis
- Mark Schulz Novartis
- David Wanigesekera Novartis
- Mirella Daja NovoNordisk

- Hristina Piltz Pfizer
- Rachael Anderson Pfizer
- Annette Kerr Roche
- Alissa Brown Sanofi
- Amy Gye Takeda

Diabetes Pilot Group

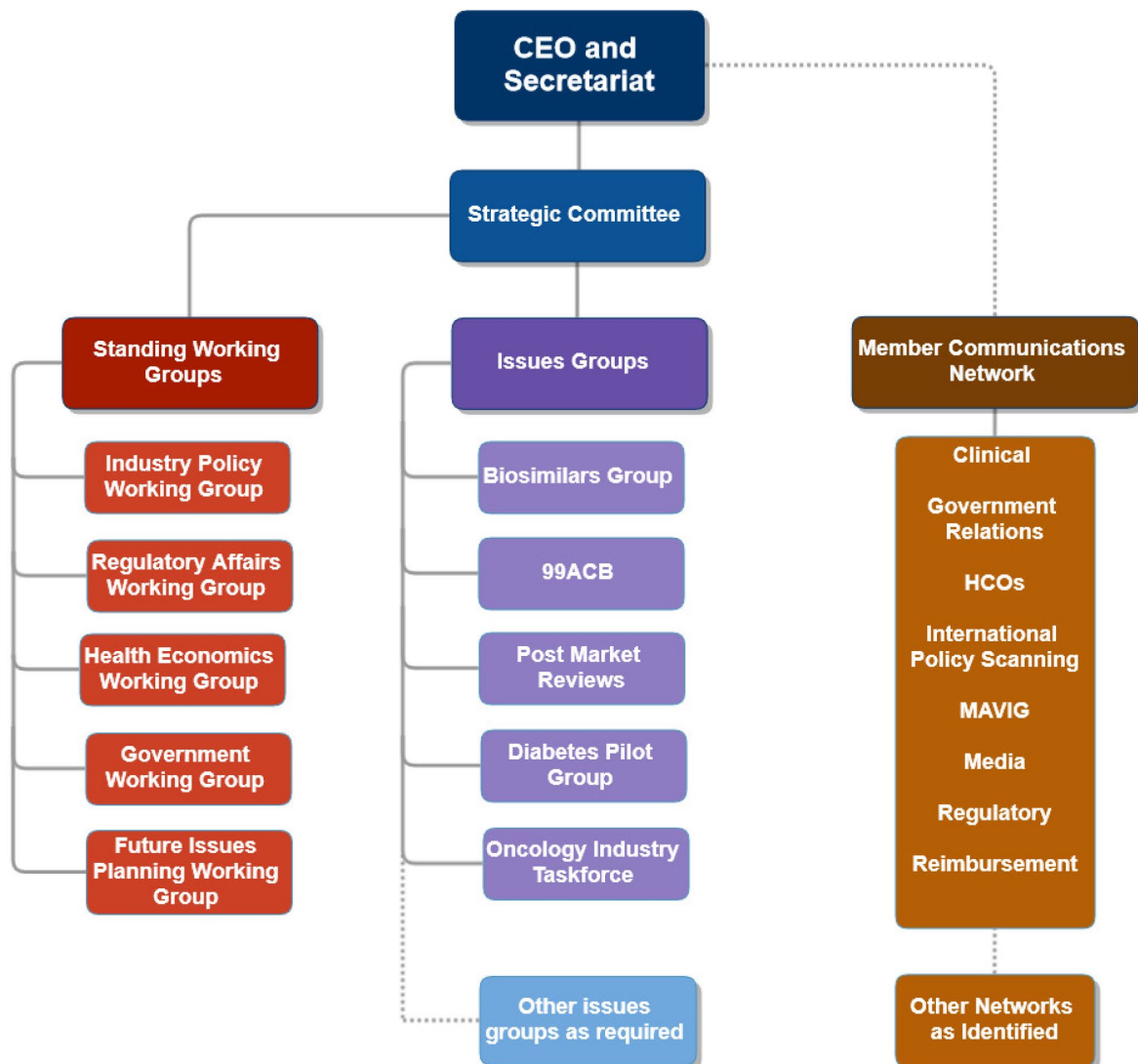
- Christian Sellars co-Chair (MSD)
- Mirella Daja co-Chair (Novo Nordisk)
- Alissa Brown co-Chair (Sanofi)
- Charles Waterfield AstraZeneca
- Peter Germanos Boehringer Ingelheim
- Stuart Englund Eli Lilly
- Alena Strizek Janssen
- Sam Develin Medicines Australia
- Mark Schulz Novartis

Oncology Industry Taskforce

- Sara Pantzer co-Chair (Amgen)
- Ian Black co-Chair (Roche)
- Kathy Cargill Abbvie
- Kristina Turner Abbvie
- Louise Graham Amgen
- Mike Smith AstraZeneca
- Mike Thompson AstraZeneca
- Adrian Dolahenty Bayer
- Greg Cook BMS
- Jane Kerr Boehringer Ingelheim
- Wes Cook Boehringer Ingelheim
- Julie Anne Bridge Eli Lilly
- John Bower GlaxoSmithKline
- Kris Ashpole Janssen
- Todd Stephensen Jansen
- Paul Lindsay Merck Serono
- Elizabeth de Somer Medicines Australia
- Sam Develin Medicines Australia
- Carmel Spiteri MSD
- Nicola Richards MSD
- Bronwyn Underwood Novartis
- Peter Murphy Novartis
- Koray Koksak Pfizer
- Carlene Todd Roche
- Alissa Brown sanofi
- Delia Schaffer Takeda
- Kate Webb Takeda

Post Market Reviews Group

- Elizabeth de Somer Chair (Medicines Australia)
- Charles Waterfield AstraZeneca
- Peter Germanos Boehringer Ingelheim
- Greg Cook Bristol-Myers Squibb
- Sam Develin Medicines Australia
- Christian Sellars MSD
- Alissa Brown sanofi



Inside Medicines Australia



1 Gary Saliba, Director, Strategic Journeys and Visiting Fellow Crawford School of Economics and Government, ANU, facilitates the Medicines Australia Board Strategic Retreat

2-3 Medicines Australia Board Strategic Retreat

4-6 Medicines Australia General Meeting 17 June 2014

GOVERNANCE

Medicines Australia Strategic Retreat

The Medicines Australia Annual Strategic Retreat was held on 10-11 April 2014.

The Retreat focused on ensuring that Medicines Australia is adequately resourced and appropriately focused to serve the requirements of member companies. The Board reviewed the Medicines Australia Strategic Blueprint, particularly focusing on the Vision and Mission of Medicines Australia and the key priorities for the ensuing five year period.

The Retreat followed the Members' Only Conference held in March 2014, where Managing Directors of the members were invited to join with the Board to consider the key issues the industry is facing and to assist in prioritising projects and strategies for Medicines Australia. The Retreat was facilitated by Dr Gary Saliba, Director Strategic Journeys and Visiting Fellow Crawford School of Economics and Government, ANU.

Medicines Australia Board meetings

Eighteen meetings of the Medicines Australia Board were held in 2013-2014:

- 6 August 2013, via teleconference
- 13 August 2013, via teleconference
- 3 September 2013, Melbourne
- 18 September 2013, via teleconference
- 9 October 2013, via teleconference
- 22 October 2013, Sydney
- 13 November 2013, via teleconference
- 3 December 2013, Sydney
- 17 January, via teleconference
- 31 January, via email
- 5 February, via email
- 18 February 2014, Melbourne
- 12 March 2014, via teleconference
- 20 March 2014, Canberra
- 11 April 2014, Canberra (Board Retreat)
- 22 May 2014, via teleconference
- 27 May 2014, Canberra
- 17 June 2014, Sydney

Medicines Australia acknowledges and thanks the Directors for their tireless commitment to the industry.

Throughout 2013-2014 there were two Casual Vacancies arising on the Board. Medicines Australia also acknowledges the commitment and expertise of Board members who resigned throughout 2013-2014.

Finance & Audit Committee

Members:

Mr Chris Hourigan, Chairman
Mr Jason Smith
Mr Shaju Backer

Meetings:

20 August 2013
28 November 2013
18 March 2014
14 May 2014
10 June 2014

Nominations Committee

Members:

Mr Mark Fladrich, Chair
Dr Susi Fiedler (from January 2014)
Ms Kirsten O'Doherty
Dr Graeme Blackman, Chair (until September 2013)

Meetings:

16 May 2014
28 May 2014

Performance, Remuneration & Governance Committee

Members:

Mr Mark Fladrich, Chair
Mr Chris Hourigan, Chair Finance & Audit Committee
Mr Geoff McDonald

Meetings:

14 August 2013
27 August 2013
11 September 2013
24 June 2014

Medicines Australia Member meetings

There were two meetings of members in the 2013-14 financial year.

- The Annual General Meeting was held on 22 October 2013, AstraZeneca Conference Centre, North Ryde
 - Mr Mark Fladrich, Interim Chair, presented the Annual Report of Medicines Australia
 - Mr Jason Smith, member of the Finance and Auditor Committee presented the Financial Statements and Directors' Report to members
 - Moore Stephens was appointed as Company Auditor
 - Ms Deborah Monk, Director Compliance, presented the Code of Conduct Annual Report to members

- The Board 2014-2015 was announced
- Ms Sara Pantzer, Amgen Australia Pty Ltd, was awarded the Pat Clear Award 2013
- A General Meeting of Members was held on 17 June 2014, Stamford Plaza Sydney Airport, Mascot
 - Special Resolution – Amendments to the Constitution of Medicines Australia Limited (Code of Conduct)
 - Special Resolution – Amendments to the Constitution of Medicines Australia Limited (Company Board, Directors and Chairman)
 - Special Resolution – Amendments to the Constitution of Medicines Australia Limited (Miscellaneous)
 - Special Resolution – Medicines Australia Code of Conduct – Adoption of Edition 18

RISK MANAGEMENT

Anti-bribery and corruption

The Medicines Australia Board recognises and acknowledges that companies operating in or connected to foreign jurisdictions need to be aware of international laws regarding bribery and corruption. Failure to do so may result in serious financial and reputational risks for the Association, its members and employees. As a result, Medicines Australia devoted considerable time and resources during the year to develop compliance arrangements in response to anti-bribery laws and setting out procedures to ensure appropriate conduct in accordance with international laws, in particular in relation to the US *Foreign Corrupt Practices Act*, and the UK *Bribery Act*.

Australian privacy legislation

The Secretariat has undergone a privacy risk assessment to ensure it meets its obligations under the *Privacy Act 1988* and obligations arising from the amendments to the Privacy Act which came into effect in March 2014. The review focused on the collection and retention of data, particularly in relation to the Medicines Australia Contacts Database implemented during the year and the Medicines Australia Continuing Education Program (CEP) database.

Business continuity

The Medicines Australia Board is cognisant of its duties and obligations to ensure appropriate internal controls are in place, including minimising interruption to the conduct normal business operations. Several key personnel within Medicines Australia participated in a review of operations and potential issues that could impact on the business continuity for the organisation. Based on a business impact analysis a Business Continuity Plan is being developed. This will ensure the Secretariat is able to continue

working for its members with minimal interruption in the event of disruption. As part of this process, Medicines Australia:

- has installed new financial software to increase efficiency in work practices, particularly payroll, and to better support business continuity with limited staff resources.
- continues to maintain robust IT policies and practices to ensure that Business as Usual (BAU) operation can be consistently maintained despite the ever-growing security risks and threats within the IT landscape.
- introduced custom built records management and contacts databases to serve the specific needs of Medicines Australia. These databases enable the Secretariat to retain corporate knowledge and promote knowledge transfer into the future.

SECRETARIAT

Following on from the organisation restructure of Medicines Australia, the Secretariat has welcomed a number of new staff to the team.

New staff:

Ms Alice George (August 2013)
Ms Soelily Consen-Lynch (November 2013)
Mr Michael Cook (January 2014)
Ms Zoe Croker (January 2014)
Ms Alexia Vlahos (January 2014)

Departing staff:

Kristin Trace MacLaren (August 2013)
Andrew Simpson (September 2013)

Publications and Submissions

June 2014

[Submission to the Terms of Reference for the Post-market Review of Authority Required PBS Listings](#)

May 2014

Proposed removal of red tape affecting the Australian Medicines Industry.

Submission regarding the draft report of the Post-market Review of Pharmaceutical Benefits Scheme Medicines Used to Treat Asthma in Children .

February 2014

[Submission to the "Ensuring Australia's Manufacturing Future" review](#)  88k

[Submission to the 2014-15 Federal Government Budget](#)  543k

January 2014

[Submission to Senate Standing Committees on Economics on the Tax Laws Amendment \(Research and Development\) Bill 2013](#)  46k


November 2013

[Submission to the National Commission of Audit](#)  701k

September 2013

[Submission to IP Australia on Patentable Subject Matter \(Object Clause and Patent Exclusion Criteria\)](#)  54k

July 2013

[Submission to Stage Three of the Review for Medicines Used in the Treatment of Type 2 Diabetes](#)  1,018k