



MEDICINES *Australia*

ANNUAL REPORT 2014-2015

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Medicines Australia vision, mission, strategic objectives

VISION

A longer and healthier life for Australians through availability and choice of world leading innovative medicines.

MISSION

In partnership with key stakeholders, drive the creation and development of a predictable environment for the continued sustainable growth of the innovative research-based prescription medicines industry so Australians continue to lead longer and healthier lives.

STRATEGIC OBJECTIVES

1. Full value of medicines is recognised by patients, payers and community as a whole.
2. Australians have early access to new medicines.
3. Development of new models to deliver multiple sources of funding for prescription medicines for Australians.
4. Australia to become a vibrant pharmaceutical investment worthy destination to increase investment, jobs and economic growth for Australians.

Chairman's report



2014-2015 was a year packed with small but important steps forward across many issues for members of Medicines Australia. Sadly, much of this hard work has been overshadowed by the financial impact and lack of predictability for our members as a result of the recent PBS Budget cuts and the lack of a five year Strategic Agreement.

This outcome will make for a challenging period ahead for all our member companies who need policy predictability and certainty when making product and investment decisions. Medicines Australia will continue to work constructively with government and advocate for a long term agreement to achieve this end. A strong, local industry is important for the millions of Australians whose lives are improved by our innovative, breakthrough medicines and also critical for the 14,000 employees of our members and the many thousands more who rely on our investment to support their businesses and careers. We also have a central role to play for Australia's future economy where medicines and advanced manufacturing have been recognised as two core priorities in the Government's Innovation and Competitive Agenda.

Ensuring that Australians continue to have timely access to the latest generation of cost effective medicines remains a top priority. We welcomed the Health Minister, Sussan Ley MP, accelerating the entry of a number of products which had been in hiatus for some time; however, speed of entry to the PBS remains a concern especially for life saving and transforming new products. The recent rapid entry of the new class of anti-cancer PD1 inhibitor under a managed access programme was

particularly encouraging. In March 2015, Medicines Australia released the first annual (Comparison of Access and Reimbursement Environments) COMPARE Report which revealed Australia ranks 18 out of 20 in the OECD for access to new chemical entities. The previous reforms of the PBS over the last eight years have already resulted in the PBS growing at less than CPI for the last five years. This has provided the headroom that could be made for timely PBS listing of new medicines. Unfortunately, this has not so far translated into access for Australian patients. If Australians are going to continue to benefit from timely access to cost effective medicines appropriately accelerating access needs to be addressed in partnership by both government and industry.

There have been many improvements made in 2014-2015 thanks to the strong advocacy of Medicines Australia and its members. The Government has recognised the importance of the medicines industry to Australia's future by promising to establish an Industry Growth Centre for medical technologies and pharmaceutical innovation. We helped to defeat proposed changes to the R&D tax credit, while the Clinical Trials Advisory Committee has now been established to help accelerate the much needed reforms to hopefully reverse the recent 30% decline in the numbers of clinical trials since the peak in 2008. The Access to Medicines Working Group has re-convened and already it has led to improvements in Managed Access and post-market reviews, while progress is being made on section 99ACB and towards improving transparency within the PBS process. Positively, parallel TGA-PBAC processing, the six month Cabinet timeframe along with no new therapeutic



groups have all continued to be honoured well after the expiry of the last Memorandum of Understanding (MOU) with the Commonwealth. Most importantly, the ACCC approved the 18th edition of the Medicines Australia Code of Conduct for five years including the industry leading transparency provisions.

The year concluded with some unresolved and new challenges for our industry. The Trans-Pacific Partnership (TPP) negotiations and efforts to include appropriate reward of innovation through extended data exclusivity are still possible but being hampered by scaremongering of vocal opponents of industry; while multinational taxation has erroneously become a hot issue as politicians search for ways to boost ailing Budget revenues. The solution to companies paying more tax in Australia is to encourage more R&D and manufacturing in Australia and more value generation beyond selling and distribution.

It has been a lot to juggle for Medicines Australia but I am pleased to say that our new CEO Tim James, who started in October last year, has worked hard to meet every member and has made a smooth transition into his role. Tim provides a new energy and insight for the organisation. Under the strategic direction of the new Board of Directors, Tim will drive and manage the implementation of the updated 2015 to 2020 Strategic Blueprint and operational plan.

I would like to thank all our outgoing Board members for the hard work, professionalism and passion that they have brought to their roles. Especially for the many hours they all contributed along with the Secretariat and

members with the government negotiations. It has been a difficult time for the industry and many lessons have been learned which will ultimately help to strengthen Medicines Australia.

The year ahead will be challenging but there remain enormous opportunities for Medicines Australia and the membership. This will involve an improved engagement with politicians, patient groups and other stakeholders about the broader values that our industry brings to Australia. Whether it's the investment and support to our nation's best research centres, the jobs we help create, or the economic, health and social benefits which our medicines provide, we have a wonderful story to tell in this country. Our members are an integral part of a smarter, stronger and healthier Australia today and for our future.



Dr Martin Cross
CHAIRMAN, MEDICINES AUSTRALIA

CEO's report



I'm delighted to present this my first report as CEO of Medicines Australia. Having joined in late October 2014, I want to commence by recognising the extraordinary efforts and contributions of my predecessor Dr Brendan Shaw over many years, including this past year. I'm relishing this role and it's a great privilege to serve the sector in this leadership position.

It certainly has been a year of great significance and intensity of activity for Medicines Australia. That was always going to be so given the need to seek both a further agreement for stability with the Commonwealth as well as a revised authorised Code of Conduct.

As you have read in the Chairman's report, the outcome of discussions with government around the Budget was disappointing and difficult. The PBS is more sustainable than ever and continues to deliver substantial savings to government consolidated revenues. It has been markedly and constantly reformed in the last decade. It has an effective consumer co-pay, which appears

elusive in other areas of health. This industry has shown leadership on the PBS in these and other respects. In these circumstances, the gravity and timing of the further reforms were, to be candid, difficult to deal with, and particularly in the absence of an agreement towards reasonable stability.

We nonetheless recognise the pressures upon government and fiscal constraints at this time. The further reforms will ensure that for many years the PBS will be the most sustainable program within Health. We will work constructively to ensure the best possible implementation and impact of the reforms and to ensure the PBS remains sustainable, universal and equitable.

On a more positive note, the 18th edition of our Code of Conduct is now in place. This was also a very considerable point of focus this year with very many stakeholder meetings and discussions with the ACCC towards authorisation. This ultimately brought about a balanced and effective Code. It's a Code of which we can



and must be proud in terms of transparency, trust and leadership. It's an example to other sectors and should be followed.

I believe that to be successful in the broader health eco-system we need to be more well understood. To be understood, we need to be more transparent, more proactive and more engaged. You will have seen these themes in a range of respects in the journey of change I am bringing to Medicines Australia and the industry. Whether it's in terms of being part of the conversation on social media, being more engaged in the Parliament, having a new improved website, or strengthening relations with patient organisations, I am seeking to ensure we are more well understood. We've made good progress this year and there remains a great deal to do.

I record my thanks to the Board, Secretariat, and Committees and Working Groups for making me so welcome, for constantly striving towards stability and success for this sector, and for tirelessly serving the

enduring cause of human health through science and innovation. I particularly thank the team of terrific people I work with at Medicines Australia – it has been a big year for all of us.

I'm looking forward to the coming year and beyond with determination and optimism.



Tim James

Tim James

MEDICINES AUSTRALIA CEO

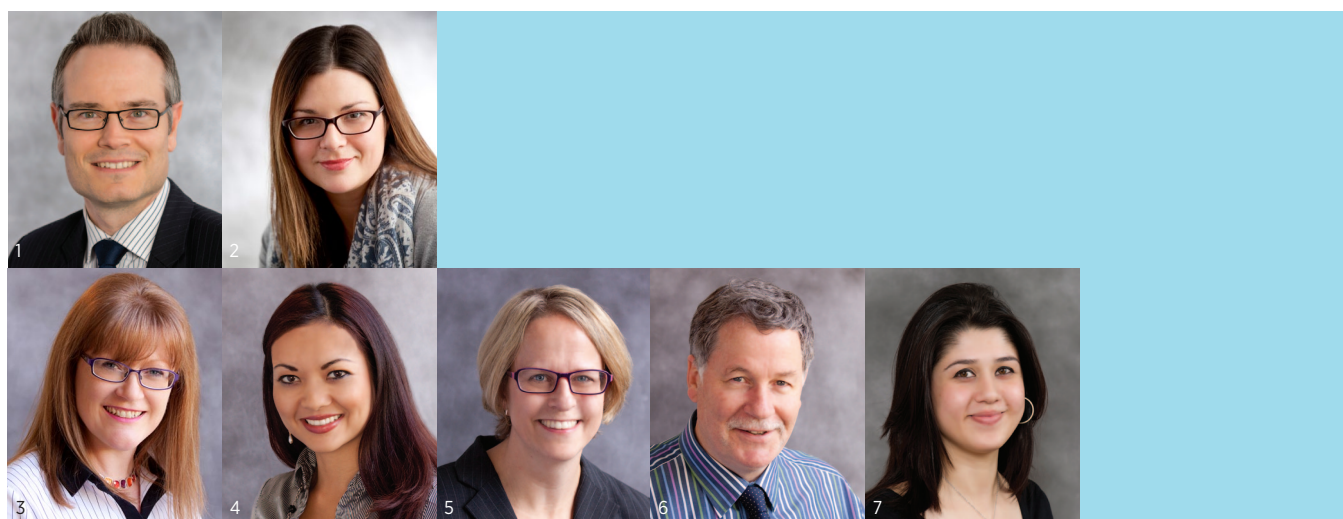
Medicines Australia Board Members 2014-2015



DIRECTORS

1	Dr Martin Cross	Chairman	
2	Mr Wesley Cook	Managing Director, Boehringer Ingelheim Pty Ltd	
3	Dr Susanne Fiedler	Vice President & Managing Director Australia & New Zealand, MSD Pty Ltd	
4	Mr Mark Fladrich	Managing Director, AstraZeneca Pty Ltd	
5	Mr David Gallagher	Chairman, Pfizer Australia	Appointed 02-09-2014
6	Mr Chris Hourigan	Managing Director, Janssen Pty Ltd	
7	Mr James Jones	Managing Director, Takeda Pharmaceuticals Australia Pty Ltd	
8	Mr Laurie McAllister	Managing Director, Sanofi	
9	Mr Geoff McDonald	Vice President/General Manager, GlaxoSmithKline	
10	Mr Anthony Mancini	Managing Director, Bristol-Myers Squibb Australia Pty Ltd	
11	Ms Kirsten O'Doherty	General Manager, Abbvie Pty Ltd	
12	Mr James Priour	Managing Director, Amgen Australia Pty Ltd	
13	Mr Jason Smith	Managing Director, Novartis Pharmaceuticals	
14	Mr George Varkanis	Vice President & General Manager Celgene Pty Ltd	Appointed 01-08-2014
15	Mr Shaju Backer	Managing Director, Merck Serono Australia Pty Ltd	Appointed 20-03-2013. Ceased 31-7-2014

Medicines Australia Secretariat 2014-2015



CORPORATE

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



POLICY & ADVOCACY

1	Elizabeth de Somer	Director, Policy & Advocacy	5	Zoe Croker	Access to Medicines Policy Officer
2	Samuel Develin	Reimbursement Manager		Vacant	Industry Policy Manager
3	Martin Snoke	Policy & Research Manager		Vacant	Regulatory Manager
4	Soelily Consen-Lynch	Research & Policy Officer			



2



COMMUNICATIONS

1 James Boyce

Director, Communications & Government Relations

2 Alexia Vlahos

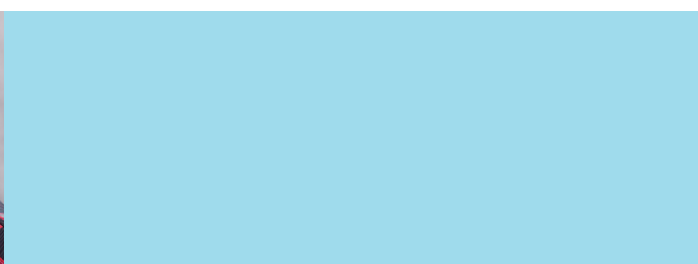
Public Affairs Officer



2



3



COMPLIANCE

1 Deborah Monk

Director, Compliance

3 Karen Patten

Code of Conduct Officer

2 Sophie Hibburt

Code of Conduct Manager



2



3



4



STAFF WHO DEPARTED IN 2014-2015

1 Brendan Shaw

Chief Executive

3 Omar Ali Khan

Industry Policy Manager

2 Michael Cook

Policy & Research Manager

4 Alice George

Regulatory Manager

Medicines Australia Membership 2014-2015

CLASS 1

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

CLASS 2

Besins Healthcare Australia Pty Ltd	iNova Pharmaceuticals Pty Ltd	Norgine Pty Ltd
Genzyme Australasia Pty Ltd	Mylan EPD	

CLASS 3

FIT-BioCeuticals Ltd	Medlab Pty Ltd	
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CLASS 4

Andrews Refrigerated Transport	IMS Health Australia Pty Ltd	PriceWaterhouseCoopers
Commercial Eyes Pty Ltd	IQnovate Ltd	Princeton Publishing Pty Ltd
Covance Pty Ltd	KMC Health Care	Quintiles Pty Ltd
Farmaforce Pty Ltd	Pretium 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	

A Snapshot of 2014-2015

THE POLITICAL ENVIRONMENT

The 2014-2015 political year was dominated by ongoing fiscal concerns and a Government that was under pressure for several unpopular measures within its first Federal Budget.

It was also a politically turbulent time for the health sector. There were significant changes to personnel, including a new Health Minister, the Hon. Sussan Ley MP, and a new Department Secretary, Martin Bowles PSM. There were also several key personnel changes within the Department and the Minister's office.

The new Minister was tasked with ending the dispute with the Australian Medical Association (AMA) over the controversial GP co-payment, signing the 6th Community Pharmacy Agreement (6CPA) and delivering the Medical Research Future Fund (MRFF).

The fate of these measures was set to put enormous strain on the Health Budget at a time when the Treasurer had directed all Ministers to find a dollar in savings for every dollar of new spending within their respective portfolios.

It has been a difficult political environment for the pharmaceutical industry, which has been under pressure for some time following several years of PBS reforms and is now suffering the consequences of a Government unwilling to sustain a political battle with powerful and popular sectional interests within the health sector.

It was within this context that the Government cut more than \$6 billion from Pharmaceutical Benefits Scheme expenditure at the same time that they finalised a \$3.5 billion increase in spending for the 6CPA.

Both the Government and the Opposition are now putting much of their focus toward the delivery of primary care services as they each search for further savings to help fund upcoming election promises.

STRATEGIC AGREEMENT

Medicines Australia entered the 2014-2015 year with a significant amount of work to do. It proved to be one of the most challenging years for the industry and for the membership of Medicines Australia in the last decade.

After a long period of relative stability under the Memorandum of Understanding (MOU) and action and progress through the Access to Medicines Working Group (AMWG) during 2014, the first six months of 2015 were dominated by budget discussions. Despite years of preparation in anticipation of a new agreement to replace the MOU, Medicines Australia was drawn into a process led by the Government's negotiation for the sixth community pharmacy agreement (6CPA).

In 2014, Medicines Australia approached the Government to open a dialogue on the development of a new strategic agreement with industry. The message was simple and clear, "Stability, Predictability and Access". At the time, the industry was advised that these asks could be met without the need for a formal agreement.

This position changed in early 2015 when the new Minister for Health, the Hon. Sussan Ley MP, announced a decision to hold multi-stakeholder negotiations across the PBS supply chain. Changes in Government coincided with changes at the highest levels of the bureaucracy with the appointment of Mr Martin Bowles PSM as Secretary of Health and the movement of Ms Jane Halton to lead the Finance Department. These personnel appointments occurred at a critical time for the industry.

Medicines Australia was also in a period of change with the exiting of long time employee and CEO, Dr Brendan Shaw, and the search and appointment of new CEO Mr Tim James.

The Government's failure to get the 2014 budget measure to increase patient co-payments passed through the Senate and consequent inability to count those savings amidst expanding health expenditure, shifted Government focus to the pharmaceutical industry, with the objective of finding savings within the PBS.

In early 2015 Medicines Australia commenced discussions with the Department of Health to reach an agreement that would deliver significant savings to the Government across the entire PBS supply chain. Medicines Australia entered these negotiations in good faith. The process was challenging and the environment was rapidly evolving. The lack of visibility of parallel negotiations with the Pharmacy Guild and the GMiA made the process all the more difficult.

After much effort and goodwill Medicines Australia was unable to secure an agreement that would be in the best interests of our members. The outstanding concerns related to the stability of the pricing environment for F1 medicines, the scope of the policy to remove an originator medicine from price disclosure calculations after three years and the application of biosimilars reimbursement policy including substitution ("a" flagging). This was a disappointing outcome and has left considerable uncertainty in its wake.

The PBS Access and Sustainability Package (PASP), introduced in June 2015, will have far reaching impact on the sustainability and viability of the industry in the coming years. Medicines Australia and the membership will need to remain strong with a unity of purpose to face these challenges ahead.

Despite the disappointment of being left without an agreement, Medicines Australia remains committed to working with Government to ensure the ongoing sustainability of the PBS and timely access to innovative medicines, stability of the policy environment with a focus on growth and investment in the industry. The greatest challenge will be to reestablish a culture of trust and partnership with the Department of Health and the relevant Members of Parliament.

THE POLICY ENVIRONMENT – VALUE, ACCESS, FUNDING, INVESTMENT

Over the last twelve months the Medicines Australia policy team, committee and working groups have focussed on the strategic objectives as agreed by the Board and the members on Value, Access, Funding and Investment.

Access to Medicines Working Group

The AMWG provided a significant policy vehicle to discuss and develop good policy solutions in partnership with the Department of Health on timely reimbursement and access to medicines.

Resolution was reached on the process for the initiation and conduct of *post market reviews* with the agreement and publication of a new framework. The revised post market review framework was published by Minister of Health, the Hon. Sussan Ley on 18 March 2015. Post market reviews into diabetes, the lifesaving drugs program (LSDP), antibiotics, opioids and the application of Authorities on PBS medicines continued over this period. The post market review into asthma medications for children was completed and the report was released on in July 2015. No new reviews were announced.

Significant progress was also made on improving the framework for introducing and listing medicines under a *Managed Access Program* (MAP) formerly the Managed Entry Scheme (MES). The revised MAP framework was provided to the PBAC for consideration at their March meeting and there have been several new listings announced to follow a Managed Access approach.

Medicines Australia and the Department of Health continued to develop solutions to the application of *Section 99ACB of the National Health Act* to ensure that innovations and product improvements could be promptly listed without jeopardising existing exclusivity arrangements, or incurring unnecessary price cuts. However, there remains fundamental disagreement between the Department of Health and Medicines Australia on the intent of this legislation and there is still much work required. In the meantime many patients continue to miss out on new presentations whilst this issue remains unresolved.

Significant mapping of the HTA process and opportunities to improve *transparency* and timeliness were also explored. Medicines Australia successfully facilitated the piloting of a new format and approach to the development of Public Summary Documents (PSD) to streamline and improve transparent reporting to the public on the PBS decision making processes. Whilst there remain some implementation issues, the collaboration between member companies and the Department of Health demonstrated the strong ability to work well together to achieve common goals. There are a number of transparency topics; including reviewing and improving consumer input and streamlining the process to accommodate varying submission complexity, that we remain keen to progress.

Whilst the AMWG was held in abeyance for the first half of 2015, during the budget discussions, the Minister has confirmed re-engagement of the AMWG. The first meeting of the AMWG for 2015 will take place in the coming September and work will progress on the existing topics before new policy priorities are agreed.

Medicines Australia is confident that the AMWG will continue to be an effective foundation for the development of strong policy solutions in the interests of the industry and to generate some stability and predictability in the absence of an agreement. This platform will assist Medicines Australia to reset the relationship with government going forward.

COMPARE: Comparison of Access and Reimbursement Environments

At the Medicines Australia National Press Club address in March 2015, the *COMPARE* report – *Comparison of Access and Reimbursement Environments* – which benchmarks Australia's access to new medicines to 20 OECD countries, was publicly released by Dr Martin Cross, Chairman. This independent analysis of 247 new and innovative pharmaceutical medicines that were first registered between 2009 and 2014 shows that out of 20 comparable countries, Australia ranks 3rd last. This report was an important step in highlighting how Australia is positioned internationally for access and reimbursement for new pharmaceuticals, and resulted in continuing discussions with the Department of Health.

The Liberal Government has generated a substantial review program across the health, industry and economic portfolios with which Medicines Australia has been compelled to engage.

Biosimilars

Biosimilars evaluation and reimbursement policy has created much concern across a wide range of stakeholders including patients, clinicians and the industry, both locally and globally. During the negotiations for multiple agreements, the GMiA and the Government reached agreement that substitutability of biosimilars would be a default position going forward ("a" flagging). This was subsequently clarified to explain that "a" flagging would be assessed by the PBAC on a case by case basis. Medicines Australia will continue efforts to ensure that the introduction and uptake of biosimilars is appropriate and in accordance with international best practice, built on principles of safety and evidence. Meanwhile the TGA is reviewing the existing guidelines for the evaluation of biosimilars.

Cancer inquiry

Medicines Australia appeared before a Senate Committee hearing into access to cancer medicines. The key messages, aligned with multiple stakeholders, was that the time for Australians to gain access to new, innovative and even breakthrough cancer medicines is too long. The key outcomes from the inquiry highlighted the importance of ensuring that the processes for evaluation and listing medicines is not a barrier to timely access for patients.

TGA Review

During the year, the Government undertook an expert review of Medicines and Medical Devices. Medicines Australia as a key stakeholder of this review has actively engaged with the Department of Health through multiple submissions and participation in stakeholder forums. The release of the review report was strongly anticipated, with ongoing engagement with the Department of Health and the Therapeutic Goods Administration to assist with implementation of the 32 recommendations. Follow up stakeholder forums highlight the need for ongoing consultation, which will be a focus in the coming year.

PBAC Guidelines

In April 2015 the Minister for Health announced the long-awaited review and update of the PBAC Guidelines. After a global search, the University of Adelaide was selected to run the review. Medicines Australia is appointed to the steering committee and members are keenly engaged in the project, aiming to deliver world's best practice for the evaluation and reimbursement decision on medicines.

Tax review

Medicines Australia also had the opportunity to engage with the Government on taxation issues during the year through a submission to the Treasury's discussion paper on Re:Think Tax in June. This submission raised questions from the innovative pharmaceutical industry around the competitiveness of the corporate tax rate, the GST system and how to strike the right balance on tax incentives to encourage innovation, research and development.

Multinational Tax Avoidance

Also in June, Medicines Australia made two submissions to the Senate Inquiry into Multinational Corporate Tax Avoidance. These submissions called on the Parliament and Government to ensure that Australia continues to have a transparent and robust tax system that is also supportive of innovation and investment in a global business environment. Subsequent to the first submission, the Senate Committee requested a number of Medicines Australia member companies to appear at a public hearing where they answered a number of questions around transfer pricing and engagement with the Australian Taxation Office through advanced pricing agreements. Following the public hearing and submissions, Medicines Australia has also engaged with the Australian Taxation Office to educate and better understand changes in the Government's policy position on tax issues for the innovative pharmaceutical industry in Australia.

Industry Policy

In December 2014 the Pharmaceutical Industry Working Group (PIWG), presided jointly by the Ministers for Industry and Health was disestablished by the Government. Subsequently, in November 2014 the Pharmaceutical Industry Council (PIC) comprised of Medicines Australia, GMIA and AusBiotech, also disbanded after the withdrawal of the GMIA. The PIC's Research and Development Task Force (RDTF) was consequently re-established as an independent working group, comprised of members from Medicines Australia and MTAA to ensure that the RDTF can continue to advocate on behalf of the industry for implementation of agreed clinical trial reforms. Dr Cross continued to represent Medicines Australia at the Clinical Trials Advisory Council (CTAC) during 2014-2015 monitoring progress against the government's clinical trial reform implementation program.

Research

Medicines Australia has commissioned a research project into labour force participation and the value of medicines to be led by Chair and Professor of Health Economics, Deborah Schofield at the University of Sydney. This project is expected to be completed in early 2016. This will form part of our seminal work to understand and advocate for improved value systems. Medicines Australia is also exploring opportunities to broaden funding for pharmaceuticals. This work continues and will form part of the comprehensive advocacy around sustainability of access to innovative, breakthrough medicines with a growing population, ageing demographic and increasing fiscal constraints.

Intellectual Property

Medicines Australia continues to develop policies to strengthen intellectual property and has persevered in calling for extensions to Data Exclusivity in the context of the Trans Pacific Partnership Agreement (TPPA).

CODE OF CONDUCT PERFORMANCE

Code of Conduct Edition 18 Authorisation

On 24 April 2015, the Australian Competition and Consumer Commission (ACCC) published its final determination, granting 5 years' authorisation for Code of Conduct Edition 18. This was the culmination of almost 10 months' discussion and negotiation between Medicines Australia, the ACCC and interested stakeholders. Although the authorisation included several conditions relating to the details of the transparency model in Code Edition 18, we are very pleased to have achieved this important, positive outcome for Medicines Australia's Members.

Through implementing Code Edition 18 and the new transparency model, the innovative Australian medicines industry is putting patients first by demonstrating the value of industry partnerships and taking the lead to boost transparency. The new Code builds on 55 years of successful, responsible, ethical industry self-regulation.

The new Code transparency model requires member companies to report for individual healthcare professionals, initially with the healthcare professional's consent to publish the information, all payments relating to flights, accommodation, registration fees for educational meetings and any sitting or consulting fees.

In its media release announcing the authorisation, ACCC Commissioner Dr Jill Walker commended Medicines Australia for introducing transparency about payments provided to individual doctors. The ACCC agreed that the new transparency regime is a significant and important change to the Code.

Following authorisation, Code Edition 18 came into effect on 16 May 2015 and the new transparency requirements will commence on 1 October 2015.

Medicines Australia moved swiftly following authorisation of the Code to implement the required changes to the transparency model flowing from the authorisation conditions. At a General Meeting of Members on 11 June 2015, Members agreed to adopt the amended Code.

Having achieved the Code's authorisation, Medicines Australia has initiated a broad healthcare professional communications campaign. The campaign reinforces that a strong working relationship and ongoing knowledge exchange between the companies that make medicines and healthcare professionals are critical to better patient outcomes. Our communications through a range of media seek to ensure that all relevant Australian healthcare professionals are aware of the new Code and the transparency requirements for Member companies and are confident that the transparency requirements will be implemented professionally and in accordance with Australia's privacy laws.

Medicines Australia particularly wishes to acknowledge the extensive contributions by many Member companies during the ACCC's Code authorisation review, through submissions and participating in discussions with the ACCC. In particular, we appreciate the work by the Members of the Code Guidelines Working Group, which extensively revised, updated and expanded the Guidelines for Code Edition 18 in readiness for the Code's implementation, and of the Central Database Working Group, which has been investigating the feasibility and desirability of establishing a centralised database for reporting payments and transfers of value to healthcare professionals.

Transparency Reporting under Code Edition 17

In 2014-2015 member companies consistently demonstrated a high level of compliance with the Code and their ongoing commitment to improved transparency of interactions with 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.

Whilst transitioning between Code Edition 17 and 18, member companies have continued to report all educational meetings and symposia that they organise or sponsor, as required by Code Edition 17.

In December 2014 and June 2015 Medicines Australia published educational event reports for the periods April to September 2014 and October 2014 to March 2015. These were the fifteenth and sixteenth six monthly reports published since reporting commenced in 2007. There were 15,962 events reported for the period April to September 2014 and 12,278 events reported for October 2014 to March 2015. The number of events reported for each period in 2014-2015 is consistent with previous years and reflects that fewer events are held during the Christmas and New Year period.

In addition, in December 2014 and June 2015, Medicines Australia published member companies' Advisory Board reports. These reports covered the periods April to September 2014 and October 2014 to March 2015. There were 211 Advisory Board meetings held by 35 member companies during the 12 month period.

The second member companies' healthcare professional consultancies reports were published in June 2015. These reports covered consultancies commenced during the 2014 calendar year. Thirty-four of our member companies engaged 973 healthcare professional consultants across 741 projects during the year.

In June 2015 Medicines Australia also published the second annual 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 260 different HCOs across Australia in the calendar year of 2014, ranging from national consumer organisations to small local groups, relating to 376 different projects or events.

How we performed

In 2014-2015 Medicines Australia Member Companies continued to demonstrate their strong commitment to ethical conduct in their interactions with healthcare professionals and consumers.

In 2014-2015, Medicines Australia received 15 new complaints. This is an increase over 2013-2014, when 10 new complaints were received, but a decrease when compared with 2012-2013, when 18 new complaints were received.

A third of the new complaints received this year were submitted by Member Companies (five complaints), another third submitted by the Monitoring Committee (five complaints), with the balance submitted by healthcare professionals (four complaints) and a member of the general public (one complaint).

Of the 15 new complaints received and finalised in 2014-2015, six were found not in breach of the Code and nine 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 all complaints considered and finalised in 2014-2015 and the outcomes are reported in the Code of Conduct Annual Report, published on the Medicines Australia website.

The Monitoring Committee continued its rigorous monitoring reviews during 2014-2015. The Committee undertook five reviews of materials associated with particular therapeutic areas:

- Medical educational material for healthcare professionals supplied for electronic media across all therapeutic areas
- Product specific media statements directed to the general public media in any therapeutic class
- Disease Education Activities in any media in the respiratory system therapeutic class
- Printed advertisements directed at healthcare professionals in the Immunology therapeutic class
- Printed and electronic material directed at healthcare professionals in the Skin therapeutic class.

The Monitoring Committee also undertook a review of Member companies' Health Consumer Organisation support reports. This was the second review of these reports the Committee has conducted. Thirty-three Member companies supported 260 different HCOs across Australia in the calendar year of 2014, ranging from national consumer organisations to small local groups, relating to 376 different projects or events to the total value of \$10,025,160.

The Committee also reviewed Members' Healthcare Professional Consultants reports. This was the first review the Committee has undertaken of these aggregate reports. Thirty-four Member companies contracted 973 healthcare professionals in 741 separate consulting projects during calendar year 2014, with the total value of consultancies of \$2,577,525.

The reviews of Members' HCO support reports, Healthcare Professional Consultants Consultant Reports and company materials as noted above are in addition to the Monitoring Committee's annual review of one quarter of all educational events reported by Member Companies during the preceding 12 months. The Committee reviewed 7969 educational events held between 1 April 2013 and 31 March 2014 reported by 39 companies. Of these events, two were referred to the Code of Conduct Committee for its consideration of whether the events had breached the Code. One event was found to have breached the Code; the other did not breach the Code.

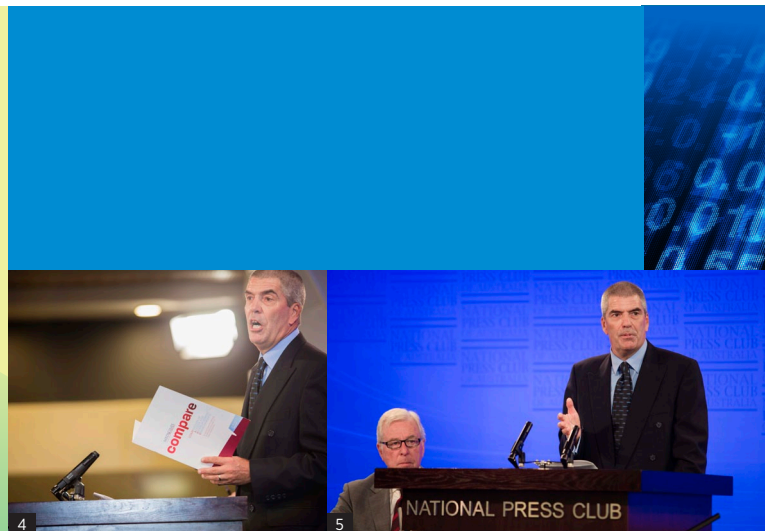
Continuing Education Program (CEP)

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



1 Medicines Australia Annual General Meeting, October 2014
 2 Dr Martin Cross addressing members at the AGM, October 2014



3-5 Dr Martin Cross addressing the National Press Club, March 2015

ANNUAL GENERAL MEETING

October 2014

The Medicines Australia Annual General Meeting was held in Sydney. The Chairman presented the 2013-2014 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 2014 Pat Clear award, Andrew Carter of Commercial Eyes for his ongoing commitment and support to deliver on strategic priorities that focus on the health and growth of the innovative biopharmaceutical sector in Australia.

MANAGING DIRECTORS' DINNERS

November 2014, February 2015 and April 2015

During 2014-15 Medicines Australia hosted three Managing Directors' dinners. Managing Directors' dinners provide a unique opportunity for the leaders of our member companies to come together to discuss issues of mutual interest and to meet and hear from influential opinion leaders and key stakeholders on matters of direct interest to the operating environment of the industry.

Two Dinners were held with guest speaker Paul Cross, Editor of PharmaDispatch. Paul provided a timely update to the membership on his insights into recent published PBS figures as well as other issues facing the industry at present. The dinners were held in Melbourne (November 2014) and Sydney (February 2015).

The third Managing Directors' dinner was held in Sydney in April. The primary purpose of this event was to update Managing Directors on the outcomes of the Board Retreat which took place on 21-22 April. The event also presented as an opportune time to follow up on issues raised at the Member's only conference.

These events provided an opportunity for Tim James as incoming CEO to discuss in more detail progress made against the Medicines Australia work plan and to outline his vision for Medicines Australia in the future.

THE CHAIRMAN'S NATIONAL PRESS CLUB ADDRESS

March 2015

Medicines Australia Chairman, Dr Martin Cross, took centre stage at the National Press Club in Canberra, launching the *Comparison of Access and Reimbursement Environments* (COMPARE) report which benchmarks Australia's access to new medicines.

Dr Cross' address emphasised the importance making the right changes to modernise the way Australians access medicines, including shifting from the cost of medicines to the value they provide in keeping the Australian population healthy, participating and productive.

The theme for the address was *The Value of Medicines: Longevity, Quality of Life, Productivity and Independence*.

The COMPARE report is available on the Medicines Australia website.



- 1 Professor John Zalcberg from the Peter MacCallum Cancer Centre was a keynote speaker at the Medicines Australia Parliamentary Dinner, March 2015
- 2 Professor John Zalcberg, Dr Martin Cross, the Hon. Sussan Ley MP and Tony Lawson, Chair, Consumers' Health Forum of Australia
- 3 Dr Laura Fitzgerald, Medicines Australia Special Purpose Fund Shalom Gamarada College graduate, speaking at the Medicines Australia Parliamentary Dinner in March 2015

- 4 Dr Martin Cross addressing guests attending the Members' Only Conference in Sydney, March 2015
- 5 Tim James CEO, Medicines Australia, Members' Only Conference
- 6 Health Minister the Hon. Sussan Ley MP addressing the Members' Only Conference in Sydney, March 2015

MEDICINES AUSTRALIA PARLIAMENTARY DINNER

March 2015

Medicines Australia hosted its annual Parliamentary Dinner on 18 March 2015 at Parliament House with guests of honour, Health Minister, the Hon. Sussan Ley MP, and Head, Cancer Research Program, Professor John Zalcberg. More than 300 guests from industry, parliament, government and the broader healthcare sector attended. The event provided an insight into the role and value of medicines in Australia and the importance of collaboration between government and industry.

Transcripts of the speeches, including videos of the night are available at the Medicines Australia website.

MEMBERS' ONLY CONFERENCE

March 2015

The Medicines Australia Members' Only Conference was held in Sydney which focused on reviewing the Medicines Australia key strategic priorities. The event provided Managing Directors and senior representatives with an opportunity to discuss the Medicines Australia strategic plan, consider key strategic issues impacting Australia's pharmaceutical industry, and have input into Medicines Australia's key priorities for the

next 12 month period. Minister for Health, Sussan Ley, also attended and addressed members.

The Conference informed the Medicines Australia Board on its deliberations at the Medicines Australia Board Strategic Retreat in April 2015.

PARLIAMENTARY FRIENDS OF MEDICINE

November 2014 and June 2015

Parliamentary Friends of Medicines held an event at Parliament House in Canberra on 26 November. The event, which focused on intellectual property, and investment in pharmaceuticals R&D and manufacturing, included guest speakers Dr John Anderson, Senior Vice President & General Manager, bioCSL, and Ms Julie Philips, Chief Executive Officer, BioDiem.

Chairman and CEO of Merck Inc (MSD) and Chair of Pharmaceutical Research and Manufacturers of America, Ken Frazier, presented at the Parliamentary Friends of Medicine event in Canberra, on 17 June. The event focused on advancing Australia's role in healthcare innovation, attracting investment, building employment, saving and improving lives. Many stakeholders attended the event including Ron Walker AC CBE, Senator Deb O'Neill, Stephen Jones MP, John Alexander MP, Dr David Gillespie MP, including Medicines Australia staff and members.

Awards



- 1 Pat Clear Award recipient 2014, Mr Andrew Carter of Commercial Eyes with Mr Martin Bowles PSM, Secretary of the Department of Health
- 2 Pat Clear Award

- 3-4 UTAS Prize for Excellence recipients, Jacqui Bardellini, Sanofi, and Olivia De Sisto, iNova, with Professor Greg Peterson, University of Tasmania

PAT CLEAR AWARD 2014

Andrew Carter has been part of the Australian biopharma industry for over two decades, commencing his career in 1990. In 2001, he saw an opportunity to use his experience in the healthcare sector to establish a business that provides commercialisation services to pharmaceutical and medical device companies. Andrew has actively participated in industry policy development through Medicines Australia committee membership, where he has provided ongoing support to deliver on strategic priorities that focus on the health and growth of the innovative biopharmaceutical sector in Australia. The unwavering commitment to the local biopharma industry is central to his achievement.

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.

CONTINUING EDUCATION PROGRAM AWARDS

Twelve sales representatives were honoured at the Continuing Education Program Awards ceremony in Sydney in March 2015 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 each semester for 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 Jacqui Bardellini from Sanofi (Semester 1), and Ms Olivia Di Sisto from iNova Pharmaceuticals (Semester 2).



1 Code of Conduct Award winner Sean Newman, AstraZeneca, with Dr Brian Morton AM Australian Medical Association

2 Dr Martin Cross, Chairman, and Mr Tim James, CEO, with the Medicines Australia Code of Conduct Award winners

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 Sean Newman from AstraZeneca.

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 2014 were:

- Eilise D'Arcy – Alcon
- Irma Brink – Bristol-Myers Squibb
- Sean Newman – AstraZeneca
- Catherine Solomonson – AstraZeneca
- Ben Warner – Pfizer
- Louise Thomas – iNova Pharmaceuticals
- Alex Roytman – Mundipharma
- Edward Punshon – Alphapharm
- Lawrence Curron – Novartis
- Catriona Truscott – Independent Student

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.

Working with the Community



1 Shalom Gamarada sponsored graduate of Medicine, Dr Laura Fitzgerald, with Medicines Australia Chairman, Dr Martin Cross

2 Patrick Tjungerryi's story, *Beyond Borders*

MEDICINES AUSTRALIA SPECIAL PURPOSE FUND

Medicines Australia continues to support two organisations – Shalom Gamarada and The Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation – through the Medicines Australia Special Purpose Fund. Established in 2008, the Fund supports not-for-profit organisations committed to improving indigenous health outcomes.

Shalom Gamarada Ngiyani Yana Residential Scholarship Programme

In December 2014 *Dr Laura Fitzgerald* – a student sponsored by Medicines Australia through the Shalom Gamarada Ngiyani Yana Residential Scholarship Programme – graduated from Medicine.

The Shalom Gamarada scholarship was set up in 2005 to support the enrolment and retention of Aboriginal and Torres Strait Islanders studying medicine and allied health disciplines. It gave Laura the opportunity to enrich her studies – including a placement at the Purple House in Alice Springs, an opportunity that presented itself through Medicines Australia's support for the **Purple Truck**. This experience further cemented her passion to help close the gap for her community and other communities around Australia.

As part of her degree, Laura's Individual Learning Project looked at current follow-up practices for trauma patients and their outcomes with the aim of setting up a follow-up clinic for trauma patients at St George Hospital, in

Sydney. During her studies, she was the recipient of a number of awards, including:

- the Nura Gili Excellence in Medicine Award 2013, and
- in 2014, the Nura Gili Burbuga Birrung (Rising Star) Award for her involvement with Nura Gili, academic progress and encouragement of other students.

For this latter award, she was nominated by her peers – the UNSW Indigenous students – an acknowledgement she was honoured to receive.

Medicines Australia is proud to have assisted Laura and her achievement was acknowledged at our Parliamentary Dinner in March 2015.

Medicines Australia has been supporting the scholarship programme since 2011; Dr Laura Fitzgerald is the first student sponsored by Medicines Australia to graduate.

The Purple Truck

The Western Desert Corporation is better known as the Purple House, a dialysis clinic based in Alice Springs offering services to patients with end state renal disease. Medicines Australia provided funds for a mobile renal dialysis unit – the Purple Truck – which was launched in Alice Springs on 12 December 2011. Medicines Australia continues to support the Purple Truck with maintenance and running costs.



1 The Purple Truck is adorned with the work of Patrick Tjungarrayi, Purple House dialysis patient, resident of Kiwirrkurra

Launch of the Purple House Fund

In April 2015, Medicines Australia and members attended the launch of the Purple House Fund. The Purple House Fund is the result of a valuable collaboration with the Business Council of Australia and Australian Unity, who have been working in partnership with the Purple House since 2012. A special edition book, Patrick Tjungarrayi's story, *Beyond Borders*, was launched about artist Patrick Tjungarrayi, one of Australia's most collectable artists and a dialysis patient who is living at home in Kiwirrkurra with the support of the Purple House. Patrick's artwork adorns the Purple Truck.

SBS Foundation Partners for 2015-2016

The SBS Foundation was launched in 2009 and has since partnered with over 100 charities and non-profit organisations, spanning the arts, health, sport, environment, multicultural and regional sectors to increase awareness of its activities and work within the community. The Purple House is one of twelve organisations appointed as SBS Foundation Partners for 2015 to 2016.

ENGAGEMENT WITH HEALTH CONSUMER ORGANISATIONS

The Working Together Guide

During the year, Medicines Australia worked closely with Consumers' Health Forum of Australia, representatives from health consumer organisations and its members to continue the review of the *Working Together Guide* (Edition 2008). *The Working Together Guide* is a collaboration between Medicines Australia and the Consumers' Health Forum, containing a basic framework to guide industry and consumer group engagement. 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. *The Working Together Guide* Committee has been developing a web-based version to provide ready access to a number of practical tools and online resources, to be launched in August 2015.

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.

Working with our Members

Medicines Australia has worked productively with our members through the well established committee and working group structure.

The Strategic Committee continues to provide advice to the CEO and the Secretariat on the full work plan and makes a valued contribution to the strategic objectives of the organisation. The Strategic Committee has shown immense commitment, flexibility and value over the past twelve months with a demanding workload.

The standing working groups have also shown their ability to respond rapidly and cohesively to the range of challenges this year. Additionally, a number of Issues Groups have been maintained this year to continue to work towards specific goals on behalf of the industry and to supplement the resources to deliver on a broad range of policy matters.

Members at 30 June 2015:

Strategic Committee

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

Industry Policy Working Group

REPRESENTATIVE	COMPANY
Duncan Purvis	Janssen (co-chair)
Claire Willmott	Roche
Julia Jenkins	Novartis
Kristin MacLaren	GlaxoSmithKline
Lee McKerracher	Abbvie
Luke Cornish	MSD
Paul Lindsay	Merck Serono
Ric Degaris	Commercial Eyes

DEPARTED REPRESENTATIVES

Stuart Englund, Eli Lilly, April 2015

Omar Khan, Medicines Australia (co-chair), April 2015

Regulatory Affairs Working Group

REPRESENTATIVE	COMPANY
Susan Alexander	Roche (co-chair)
Alice George	Medicines Australia (co-chair)
Helen Critchley	Sanofi
Brain Hewitt	Pfizer
Carolyn Tucek-Szabo	GlaxoSmithKline
Elizabeth Joshi	Bayer
Emma Williams	BioCSL
George Lillis	Novartis
Kirpal Kaur	Bristol-Myers Squibb
Mark Rowland	Amgen
Michael Parker	AstraZeneca

Health Economics Working Group

REPRESENTATIVE	COMPANY
Greg Cook	Bristol-Myers Squibb (co-chair)
Sam Develin	Medicines Australia (co-chair)
Ben Kluge	Bayer
Carlene Todd	Roche
Geoffrey Chin	Novartis
Kate Webb	Takeda
Louise Graham	Amgen / Pfizer
Peter Germanos	Boehringer Ingelheim
Susan Phillips	Commercial Eyes
Natalia Price	AbbVie

DEPARTED REPRESENTATIVES

Mirella Daja, Novo Nordisk, June 2015

Alison Wright, Janssen, January 2015

Government Working Group

REPRESENTATIVE	COMPANY
Sara Pantzer	Amgen (co-chair)
Elizabeth de Somer	Medicines Australia (interim co-chair)
James Boyce	Medicines Australia (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
Todd Stephenson	Janssen

DEPARTED REPRESENTATIVES

Michael Cook, Medicines Australia, February 2015
Stuart Englund, Eli Lilly, April 2015

Future Issues Planning Working Group

REPRESENTATIVE	COMPANY
Mendel Grobler	Pfizer (co-chair)
Elizabeth de Somer	Medicines Australia (co-chair)
Alice George	Medicines Australia (co-chair)
Alissa Brown	Sanofi
Brendan Price	MSD
Cheryl Maley	Novartis
Delia Schaffer	Takeda
Kaylene O'Shea	Celgene
Kelly Kirchmann	KMC Health Care
Kristin MacLaren	GlaxoSmithKline
Nathan Walters	Janssen
Terese Cole	Eli Lilly
Annette Kerr	Roche

MEDICINES AUSTRALIA ISSUES GROUPS

Members at 30 June 2015:

Biosimilars Issues Group

Sara Pantzer	Amgen (co-chair)
Zoe Croker	Medicines Australia (co-chair)
Alissa Brown	Sanofi
Amy Gye	Takeda
Annette Kerr	Roche
Bronwyn Underwood	AbbVie
Bronwyn West	Merck Serono
Christine Black	Novartis
Daniel Thut	Novo Nordisk
Greg Cook	BMS
Jim Crompton	Janssen

Kate Webb	Takeda
Kristin MacLaren	GSK
Marius van den Berg	Mylan
Mark Schulz	Novartis
Matthew Little	Abbvie
Paul Lindsay	Merck Serono
Peter Vermeer	Eli Lilly
Rachael Anderson	Pfizer
Todd Stephenson	Janssen

Diabetes Review Issues Group

Christian Sellars	MSD (co-chair)
Sam Develin	Medicines Australia (co-chair)
Alena Strizek	Janssen
Christine Black	Novartis
Geoffrey Chin	Novartis
Nicola Richards	MSD
Peter Germanos	Boehringer
Alissa Brown	Sanofi
Christian Sellars	MSD
Mike Smith	AstraZeneca
Charles Harvey	MSD
Charles Waterfield	AstraZeneca
Mirella Daja	NovoNordisk
Amy Gye	Takeda
Kate Webb	Takeda

Oncology Industry Taskforce

Sara Pantzer	Amgen (co-chair)
Ian Black	Roche (co-chair)
Kristina Turner	Abbvie
Todd Stephenson	Janssen
Kathryn Glase	Janssen
Sean Lybrand	Amgen
Carmel Spiteri	MSD
Nicola Richards	MSD
Mike Smith	Astrazeneca
Kieran Schneemann	Astrazeneca
Peter Murphy	Novartis
Jodie Thomas	Novartis
Adrian Dolahenty	Bayer
Louise Graham	Pfizer
Phillippa Delahoy	Pfizer
Greg Cook	BMS
Carlene Todd	Roche
David Grainger	Eli Lilly
Delia Schaffer	Takeda
Kate Webb	Takeda
Alissa Brown	Sanofi
Jane Kerr	Boehringer Ingelheim
Wes Cook	Boehringer Ingelheim
Paul Lindsay	Merck Serono

Inside Medicines Australia

MEDICINES AUSTRALIA BOARD

It has been a year of intense activity for the Medicines Australia Board, with a particular emphasis on the strategic agreement negotiations with the Government. During the period April – June 2015, the Board met on 50 occasions to specifically progress the negotiations with the Government: 8 April, 14 April, 23 April, 24 April (two meetings held), 27 April, 28 April, 29 April (two meetings held), 30 April, 1 May, 4 May, 5 May, 6 May, 7 May, 8 May (two meetings held), 13 May (two meetings held), 14 May, 15 May, 17 May, 20 May, 21 May (two meetings held), 22 May (two meetings held), 23 May, 25 May, 26 May, 27 May, 28 May, 1 June, 2 June, 4 June, 5 June, 6 June, 8 June, 11 June, 13 June, 15 June, 17 June (two meetings held), 18 June, 19 June (three meetings held), 22 June, 23 June (two meetings held).

The Board also attended seven Managing Director Briefings throughout the negotiation period in order to provide updates and seek feedback from the broader membership.

In addition to the special meetings to progress the strategic negotiations with the Government, the Board met on the following occasions:

25 July 2014 – via teleconference
 30 July 2014 – Sydney
 2 September 2014 – Melbourne
 21 October 2014 – Sydney
 2 December 2014 – Sydney
 30 September 2014 – via teleconference
 4 November 2014 – via teleconference
 18 November 2014 – via teleconference
 20 November 2014 – via teleconference
 16 December 2014 – via teleconference
 17 February 2015 – Sydney
 18 March 2015 – via email
 29 March – via email
 21 & 22 April 2015 (Board Retreat) - Canberra
 12 May 2015 – Canberra
 29 June – via teleconference

Finance and Audit Committee

MEMBERS

Mr Chris Hourigan, Chairman
 Mr Jason Smith
 Mr Shaju Backer (resigned 31 July 2014)
 Mr James Jones (appointed 2 September 2014)
 Mr David Gallagher (appointed 2 December 2014)

Performance Remuneration & Governance Committee

MEMBERS

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

Nominations Committee

MEMBERS

Mr Mark Fladrich, Chair
 Dr Susanne Fiedler
 Ms Kirsten O'Doherty

SECRETARIAT

Medicines Australia's website

Medicines Australia released its new website in March 2015 – a complete restructure – designed to utilise current and trending technologies and to be fully accessible on all mobile devices. Additional key features include the ability to sign-up for email notifications in order to be updated on important announcements, key policy developments and industry activities; as well as social media integration – Twitter and LinkedIn.

Staff

2014-2015 was a year of great change in Medicines Australia. The Secretariat has welcomed new staff to the team and fondly farewelled others.

NEW STAFF:

Mr Tim James (appointed 20 October 2014)
 Mr James Boyce (appointed 18 May 2015)
 Dr Martin Snoke (appointed 10 June 2015)

DEPARTING STAFF:

Dr Brendan Shaw (resigned 12 September 2014)
 Mr Michael Cook (resigned 3 February 2015)
 Mr Omar Khan (resigned 10 April 2015)
 Ms Alice George (resigned 30 June 2015)

Submissions, Publications and Reports

SUBMISSIONS

- **July 2014** Medicines Australia made a submission to the inquiry into the *National Health Amendment (Pharmaceutical Benefits) Bill 2014*, relating to the co-payment and safety net threshold changes. [Inquiry into the National Health Amendment \(Pharmaceutical Benefits\) Bill 2014](#)
- **July 2014** Medicines Australia made a submission to contribute to the Senate Economics References Committee's Inquiry into the Australian Innovation System. [Senate Economics References Committee's inquiry into the Australian Innovation System](#)
- **October 2014** Medicines Australia made a submission to the PBAC on the draft report of the post-market review of products used in the management of diabetes – Stage 3: Type 2 Diabetes Medicines. [Medicines Australia's submission to the PBAC on the draft report of the post-market review of products used in the management of diabetes – Stage 3: Type 2 Diabetes Medicines](#)
- **November 2014** Medicines Australia made a submission to provide comment on the review and evaluation of the Life Saving Drug Programme. [Submission to the Post-Market Review Of The Life Saving Drugs Programme](#)
- **January 2015** Medicines Australia provided its submission to the Expert Review of Medicines and Medical Devices Regulation. Medicines Australia believes that targeted reform is required to evolve the Australian regulatory system to better serve the Australian community and to reflect the contemporary global environment. [Submission to the Expert Review of Medicines and Medical Devices Regulation](#)
- **February 2015** Medicines Australia lodged a submission to the 2015-16 Federal Budget in which the Government was called to affirm a commitment to maintain a sustainable PBS, to recognise the importance of predictability for the industry and to provide certainty by ensuring no new unilateral PBS saving measures in the 2015-16 Budget. [The Medicines Australia 2015-16 Federal Budget submission](#)
- **February 2015** Medicines Australia made a submission to the Senate Inquiry into the availability of new, innovative and specialised cancer drugs. The submission consists of a detailed review of the burden of disease and the added value that new, innovative and specialised cancer medicines have provided for patients. [Submission to the Senate Inquiry into the availability of new, innovative and specialist cancer drugs in Australia](#)
- **February 2015** Medicines Australia made a submission to the Health Inquiry into Hepatitis C in Australia, highlighting the important contribution the industry plays in treating those diagnosed with Hepatitis C. [Submission to the Standing Committee on Health Inquiry into Hepatitis C in Australia](#)
- **March 2015** Medicines Australia made a submission to the inquiry into introduction of the *Regulator of Medicinal Cannabis Bill 2014* to establish a Regulator of Medicinal Cannabis and a system of regulating medicinal cannabis. [Submission to the Legal and Constitutional Affairs Legislation Committee Inquiry into the Regulator of Medicinal Cannabis Bill 2014](#)
- **March 2015** Medicines Australia co-wrote an open letter to the Australian Parliament regarding media commentary on the proposed Trans Pacific Partnership (trade) Agreement and concerns raised about the possibility of changes to Australia's intellectual property system. [Open Letter to Parliament on TPP & IP](#)
- **June 2015** Medicines Australia made a submission to the Department of Treasury's consultation on the Re:Think Tax Reform Discussion Paper. [Submission to the Department of Treasury Re:Think Tax Discussion Paper](#)
- **June 2015** Medicines Australia made a submission to the Therapeutic Goods Administration's Orphan Drugs Program review and looked forward to working with the TGA to support an appropriate policy environment to encourage members to continue to invest in orphan drug development. [Submission to the TGA's Review of the Orphan Drugs Program](#)
- **June 2015** Medicines Australia has made a submission to the Senate Economics References Committee Inquiry into Corporate Tax Avoidance. [Submission to the Senate Inquiry into Corporate Tax Avoidance](#)

- **June 2015** Medicines Australia made a submission into the inquiry of the provisions of the National Health Amendment (Pharmaceutical Benefits) Bill 2015. [Submission to the Senate Economics Legislation Committee Inquiry on National Health Amendment \(Pharmaceutical Benefits\) Bill 2015](#)
- **July 2015** Medicines Australia made a strong and high-level submission to the joint committee inquiry on business experience using Australia's Free Trade Agreements (FTAs). [Submission to the Joint Select Committee on Trade and Investment Inquiry into the Business Experience in Utilising Australia's Free Trade Agreements](#)
- **July 2015** Medicines Australia made a submission to the inquiry into the *Medical Research Future Fund Bill 2015* and the *Medical Research Future Fund (Consequential Amendments) Bill 2015* to highlight the need for continued and further investment in medical research in the innovative medicines industry. [Submission to the Inquiry into the Medical Research Future Fund Bill 2015 and the Medical Research Future Fund \(Consequential Amendments\) Bill 2015](#)
- **July 2015** Medicines Australia also made a supplementary submission to the Senate Economics References Committee Inquiry into Corporate Tax Avoidance to provide the committee further clarity on some technical aspects relating to the industry. [Supplementary Submission into Corporate Tax Avoidance](#)

PUBLICATIONS AND REPORTS

The COMPARE Report

- COMPARE (Comparison of Access and Reimbursement Environments): A report benchmarking Australia's access to new medicines – [Edition 1](#).

The Intergenerational Report

- [The 2015 Intergenerational Report](#) (IGR) will help guide Government policy and focus public debate on the sustainability of its major spending programs. A critical assessment of previous reports' projections for the Pharmaceutical Benefits Scheme (PBS), together with the most recently available independent data and projections will help to inform the community of the long term sustainability of the PBS.