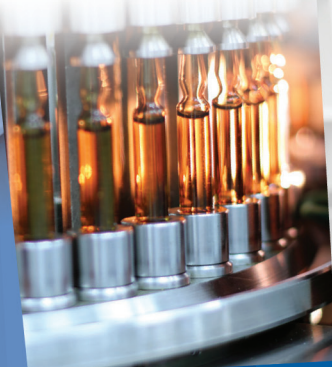


# MEDICINES *Australia*



ANNUAL REPORT 2015-2016



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# Medicines Australia vision, mission, leadership, & 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 and research based prescription medicines industry so Australians continue to lead longer and healthier lives.

## LEADERSHIP

Lead and maintain industry consensus and unity to contribute to medicines policy development for the benefit of all Australians.

## 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. Ensure sustainability 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

It gives me great pleasure to present my first annual report as Chairman of Medicines Australia. It has been an honour to work with and on behalf of members. I am delighted to be continuing in this role following my re-election as Chairman of the Board for the remainder of the 2015-2017 Board term.

I begin by acknowledging the hard work of the Board, staff and numerous committees who have all played an important role in supporting the innovative medicines industry over the last twelve months.

Medicines Australia has a long and proud record of positioning the discovery and research-based medicines industry as central to improving the healthcare outcomes of all Australians. Ensuring timely and universal access to medicines continues to be our main objective. But as Australia continues to transition away from traditional manufacturing, the focus on growing more sustainable, high-tech industries is progressively becoming more important in the current economic climate.

### Australia in 2015-2016

Several years of substantial changes to the Pharmaceutical Benefits Scheme (PBS) has impacted on our industry. Following the most recent reforms made by the Australian Government in 2015, our industry has needed time to adjust.

Despite these challenges Medicines Australia has worked constructively with the Parliament, the Government and relevant portfolio agencies on a number of key reforms. Medicines Australia has advocated strongly for the establishment of the Medical Research Future Fund, given it will transform Australia's research capabilities over the long-term. The fund finally became a reality following the passage of enabling legislation through the Parliament in 2015.

Soon after Malcolm Turnbull became Prime Minister, the Government placed a significant emphasis on refocussing innovation policies. As part of the Prime Minister's *National Science and Innovation Agenda* the medicines industry was identified as one of the industries of the

future with enormous growth potential – central to the nation's productivity, jobs and to our ongoing prosperity.

Australia became a signatory to the Trans-Pacific Partnership (TPP) treaty between twelve nations which includes other nations such as Japan, Singapore, and the United States. As part of the agreement, the Australian Government included provisions by which regulatory data protection can be extended to eight years for biologics. At the time of writing this message, uncertainty still exists on the detail of the agreement as it is not yet clear how this will operate in practice without changes to the current legislation.

### Highlights of our engagement in 2015-2016

The beginning of the 2015-16 financial year was a challenging time in the relationship between Medicines Australia and the Government following the inability to strike an agreement. A significant achievement during the year has been the successful rebuilding of those relationships. This has been demonstrated through the development and successful delivery of the Bennelong Forum where the Health Minister was the special guest at a packed auditorium of members and stakeholders. It showcased industry partnerships that deliver on innovation and improve the health and wealth of Australia.

Medicines Australia was also able to engage with the Health Minister, the Government and critical Departments on the research of Prof. Frank Lichtenberg whose data on the impact of innovative medicines on reduced mortality and hospitalisation is still being raised in conversations with policymakers today. I want to thank MSD whose sponsorship made this important research possible.

Our refreshed relationship was further reinforced by the Government's recognition of Medicines Australia as an important and valuable advisor on industry perspectives. Medicines Australia received invitations to participate in the Pharmaceutical Benefits Advisory (PBAC) Guidelines Review Steering Committee and every newly announced post market review as well as the Biosimilar Education and Awareness Initiative.

Significantly, Medicines Australia successfully partnered with several key groups including: the Pharmacy Guild of Australia; NPS MedicineWise; Consumers Health Forum; Royal Australasian College of Physicians; Council of Australian Therapeutic Advisory Groups; and the Society of Hospital Pharmacists of Australia for a multi-stakeholder forum. Entitled *Biologic and Biosimilar Medicines 2020: Making the most of the opportunities*, the forum provided opportunities to explore the successful introduction, uptake and use of biosimilars and enhance other work being undertaken by the Department of Health. The Department of Health, TGA, the Chair of the PBAC and other important stakeholders made valuable contributions to the success of the forum with further work earmarked for the coming years.

In 2016, an early double dissolution was announced after the Federal Budget in May. Funding was set aside ahead of the Government's planned policy response to the Sansom-led Medicines and Medical Devices Review (MMDR) of the Therapeutic Goods Administration (TGA). This significant development has followed years of work by Medicines Australia, close collaboration with our members and constructive engagement with Government. If implemented, the reforms have the potential to bring medicines to the Australian people faster as a result of streamlining approval and registration processes, creating efficiencies, reducing red tape and eliminating unnecessary duplication in medicines regulation.

The federal election campaign also delivered an important outcome for Medicines Australia members with the announcement of a new Clinical Trials policy. The Government has promised to reduce red tape barriers and make it more attractive to undertake Clinical Trials. Our advocacy in this priority area will continue to be a key focus next year.

## Changes for Medicines Australia

The coming Annual General Meeting marks the halfway point for our strategic blueprint, which runs from June 2014-2019.

This follows a time of significant change at Medicines Australia following an extensive and thorough review of our organisation and governance. I would like to take the opportunity to acknowledge the outstanding contribution of Interim Chief Executive Officer Lee Hill. He has done an incredible job working with the Board, the secretariat and our members to restructure and revitalise Medicines Australia. The Board believe the evolution of Medicines Australia that has taken place this year has built on the strengths of the organisation while preparing for the future.

I also welcome incoming Chief Executive Officer Milton Catelin after an extensive search led by our Board Nominations Committee. I look forward to working with Milton and the Board on a number of very significant projects as we continue to advance our strategic objectives in 2017.

## Thanks

I would like to thank Dr Martin Cross for his service as Chairman until October 2015. I also acknowledge the contribution of outgoing Board Directors Dr Susanne Fiedler, Mr Chris Hourigan, Mr Laurie McAllister, Mr Anthony Mancini, Mr Jason Smith and Mr George Varkanis.

The year has been one of significant renewal for the Board. The achievements and progress made this year could not have been done without my fellow Board colleagues and I thank them for their support. I would also like to thank the staff at Medicines Australia for their tireless work in what has been a busier than usual time.



**Wes Cook**

CHAIRMAN  
Medicines Australia



## Interim Chief Executive Officer's report

2016 has been a watershed year for Medicines Australia. It's been an opportunity to reform and modernise the organisation so that it better serves its members and can achieve its primary aim of ensuring Australians have the best possible access to innovative medicines and vaccines. While there have been many changes over the last year, our purpose of driving a predictable environment for the innovative medicines industry for the benefit of all Australians has remained unchanged.

After a difficult and challenging operating environment for the industry in 2015, significant progress has been made to refocus Medicines Australia. Our journey to a new organisational and governance structure will help ensure we remain agile in a rapidly changing environment.

### Industry leadership

We have continued to deliver on our strategic objectives through leadership, advocacy, policy development and our strong industry code. This is all made possible by collaborating with our members, who offer so much time, expertise and commitment in making Medicines Australia what it is.

The year saw Medicines Australia almost continuously working on a range of submissions into various inquiries and reform proposals. As the voice for the innovative medicines industry, our effort to ensure the full value of our industry in Australia is better understood has remained critical.

Improvements to our Code of Conduct for the advertising and promotion of prescription medicines mean we remain internationally recognised for our effectiveness in self-regulation and transparency of these activities.

### Changes to Medicines Australia in 2016

A review of our organisational structure and governance arrangements was commissioned following my appointment as Interim CEO in early 2016. Independent, expert advice ensured a robust and thorough review process. As a result we are making adjustments to the board composition and operation, establishing a new advisory council to assist the Board in shaping long-term strategy and implementing new arrangements to strengthen our member engagement and alignment. The changes to governance will further increase our effectiveness and allow us to be more nimble and effective in our decision-making in 2017.

A carefully planned restructure of Medicines Australia commenced during the second half of the year. As the restructure and staff recruitment draws closer to concluding, we can anticipate that Medicines Australia's revised structure will significantly build on our existing capabilities and sharpen our strategic focus.

### New CEO

Following an extensive recruitment search, we welcome our incoming Chief Executive Officer, Milton Catelin, who commenced in October 2016. We will be working to ensure a smooth transition during our handover period.

## Consolidation and readiness

But in and of itself, a restructure means nothing unless we ensure that our organisation – the essence of who we really are – evolves with it. So 2016 was the year of setting in place the strategies to do that.

To provide a roadmap to bring our new structure to life, we have been focussed on working with all staff to bring positive and transformational change.

Change management workshops have helped staff to embrace change, introduce new systems and refine our existing processes. The support and training for staff has assisted in the transition to a culture of more effective collaboration at Medicines Australia.

As a result of the change management process, the organisation is much stronger and even better placed to represent the interests of the community and our members in this wonderful sector.

staff of Medicines Australia for their commitment, tireless effort, and enthusiasm for change. A bright future awaits this wonderful industry and Medicines Australia is better positioned than ever before to support its members and the community to ensure, not just a thriving local biopharmaceutical sector, but that access to innovative medicines and vaccines remains of the highest priority for policy makers.



**Lee Hill**

INTERIM CEO  
Medicines Australia

## Member focus

Medicines Australia's new structure will also deliver a stronger oversight and accountability to members. We've been focussing on broadening our efforts to genuinely enhance the ways in which we represent the interests of all members.

Changes to our existing committees and working group structures will be made, so we can be sure we draw on the full range of skills and expertise within the membership needed to deliver on our strategic objectives.

## Thank you

Finally, it has been an honour and a privilege to lead the secretariat and its dedicated staff over the last year. I extend my best wishes to Milton Catelin as he leads Medicines Australia into an exciting future. I would like to take this opportunity to thank the Board, with a special thank you to Wes Cook, our Chairman. I also thank the

## About Medicines Australia

### MEDICINES AUSTRALIA BOARD MEMBERS 2015-2016

Mr Wesley Cook	Boehringer Ingelheim Pty Limited	Chairman (as at 20-10-2015)
Mr Brad Edwards	Shire Australia Pty Limited	(appointed 20-10-2015)
Mr David Gallagher	Pfizer Australia Pty Ltd	
Mr Brian Gladsden	Novartis Australia Pty Ltd	(appointed 20-10-2015)
Mr James Jones	Takeda Pharmaceuticals Australia Pty Ltd	
Mr Geoff McDonald	GlaxoSmithKline Australia Pty Ltd	
Ms Kirsten O'Doherty	AbbVie Pty Ltd	
Mr Svend Petersen	Roche Products Pty Limited	(appointed 20-10-2015)
Mr James Priour	Amgen Australia Pty Ltd	
Mr Paul Spittle	AstraZeneca Pty Ltd	(appointed 20-10-2015)

### Departed

Dr Martin Cross	Appointed Chairman (ceased 20-10-2015)
Dr Susanne Fiedler	(ceased 22-01-2016)
Mr Chris Hourigan	(ceased 01-01-2016)
Mr Laurie McAllister	(ceased 20-10-2015)
Mr Anthony Mancini	(ceased 12-10-2015)
Mr Jason Smith	(ceased 31-07-2015)
Mr George Varkanis	(ceased 20-10-2015)



## MEDICINES AUSTRALIA MEMBERSHIP 2015-2016

### CLASS 1

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

### CLASS 2

Besins Healthcare Australia Pty Ltd	Mylan EPD	Pfizer Australia Pty Ltd
iNova Pharmaceuticals Pty Ltd	Norgine Pty Ltd	

### CLASS 3

FIT-BioCeuticals Ltd	Medlab Pty Ltd
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### CLASS 4

Clinical Research Corporation (CRC)	IQnovate Ltd	Princeton Health
Commercial Eyes Pty Ltd	KMC Health Care	Prospection Pty Ltd
Covance Pty Ltd	Pretium Pty Ltd	Quintiles Pty Ltd
Farmaforce Pty Ltd	PriceWaterhouseCoopers	Symbion Pty Ltd
IMS Health Australia 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	

1 Abbott EPD was acquired by Mylan on 27 February 2015

# Highlights in 2015-2016

## WORKING WITH THE PARLIAMENT

A change of Prime Minister and the first Double Dissolution federal election in almost three decades made for a turbulent period for the decision makers in Canberra. The Prime Minister's enthusiasm for innovation put the innovative medicines industry firmly in the Government's sights as a future growth industry for Australia. However, identifying savings within the Budget remained a consistent theme for the Turnbull Government; it faced many challenges to deliver on this ambition. The Health portfolio was a high profile focus for Budget savings with reviews, including into the Medicare Benefits Schedule (MBS), ensuring health took centre stage in the election campaign.

Despite this turbulence Medicines Australia was able to work constructively with the Parliament, the Government, the Health Minister and the Department of Health on a number of key areas. The Sansom-led review of Medicines and Medical Devices Regulation (MMDR) of the Therapeutic Goods Administration (TGA) delivered many positive recommendations including significant support for many of the outcomes sought by Medicines Australia and the membership. The Federal Government set aside resources in the Federal Budget in May ahead of its planned policy response to the Sansom Review with early details revealing a promising outcome for the industry.

The Federal election campaign also delivered an important outcome for Medicines Australia members with the announcement of a new Clinical Trials policy. The package aimed to reduce red tape barriers and make it more attractive to undertake Clinical Trials in Australia. It promised to improve harmonisation of rules and regulations across the states and deliver a one stop shop for sponsor companies who undertake clinical trials in multiple sites and states.

The year also had its challenges including the implementation of the difficult reforms delivered in the PBS Access and Sustainability Package (PASP) changes from last year. Medicines Australia was able to bring the industry back to the table on policy development for Biosimilars as the Government looks at how it can take advantage of these cheaper medicines without compromising patient safety.

The Prime Minister's enthusiasm for innovation led to a greater focus on industry policies culminating in the National Innovation and Science Agenda (NISA). This included the creation of Innovation and Science Australia (ISA). To be chaired by Bill Ferris AC (who had also been named Chair of Innovation Australia), with the new Chief Scientist Prof. Alan Finkel AO as Deputy Chair, the group's first task has been to review



1 Senator the Hon Kim Carr, Shadow Minister for Higher Education, Research, Innovation and Industry speaking at the 2016 Parliamentary Dinner



2 John Alexander OAM MP, Federal Member for Bennelong; Brian Gladson, Country President, Managing Director Novartis Australia and New Zealand; with the Hon Sussan Ley MP, Minister for Health and Sport, opening Novartis

## WORKING WITH THE PARLIAMENT

Australia's R&D tax incentive; it will also play a key role in delivering policies which encourage more collaboration and commercialisation between researchers, universities and industry.

The NISA also contained plans to boost government funding and corporate investment in early stage research through its Biomedical Translation Fund (BTF). The Australian Government has flagged that future NISA measures will encourage more commercialisation opportunities in Australia.

Industry growth centres for Australia's most promising sectors were established in late 2015, with medical technologies and pharmaceuticals included as a key priority area, with the establishment of MTPConnect.

Another significant outcome for the Government was the signing of the Trans-Pacific Partnership Agreement (TPP) by the Trade Minister Andrew Robb in October 2015. The TPP is a 12 member nation economic and trade treaty aimed at reducing barriers among member countries, including Japan, Korea, the USA, New Zealand and Chile. As part of the TPP the Australian Government included provisions by which regulatory data protection can be extended to eight years for biologics. It is yet to be clarified how this will operate in practice without changes to the current legislation.

### Parliamentary Friends of Medicines

#### No Work No Pay: Why adult immunisations are important to keep seniors fit, healthy and productive

In August 2015 Sanofi and Pfizer hosted the Parliamentary Friends of Medicines "No work No Pay" event. The lunch discussion speakers included Professor Raina MacIntyre, Head, School of Population Health, UNSW, Head, NHMRC Centre of Research Excellence in Population Health Research, and Dr Mark Simmerman, Regional Director of Epidemiology and Medical Affairs, Sanofi Pasteur Asia Pacific.

#### An Introduction to the Pharmaceutical Benefits Scheme

Medicines Australia hosted an event "An Introduction to the Pharmaceutical Benefits Scheme" at Parliament House in March 2016 through the Parliamentary Friends of Medicines group. The event provided the opportunity for parliamentarians and their staff to be briefed on some of the most common questions that constituents ask about the Pharmaceutical Benefits Scheme.

Medicines Australia extends our thanks to Dr Greg Cook, Associate Director of Market Access at BMS who delivered a short presentation and Christian Sellars, Director of Market Access, Public Affairs and Customer Centricity for MSD who assisted with the presentation and answered all the questions of participants.

#### Professor Frank Lichtenberg Address

A highlight of the calendar was the presentation by Professor Frank Lichtenberg of Columbia University of his study into the impact of innovative medicines on reduced mortality and hospitalisation in Australia. The event of November 2015 was one of the most popular Parliamentary Friends of Medicines lunches for the year and was well attended by politicians and other stakeholders in health. The event was co-sponsored by Medicines Australia and MSD.

## THE POLICY ENVIRONMENT

### Value

#### ► OBJECTIVE 1:

**Full value of the industry and innovative medicines are recognised and accepted by patients, payers and the community**

Medicines Australia represents the innovative medicines industry by engaging with government and government departments, consumer groups and health professionals to develop health, medicines and industry policy.

We work with other health professional and consumer organisations on issues of mutual concern and educate the community about the industry and our activities.

#### **Working Together Guide launch**

In August 2015, Medicines Australia and the Consumers Health Forum jointly launched the web-based edition of the *Working Together Guide* at a breakfast in Sydney. The guide is a useful tool for pharmaceutical companies and health consumer organisations to build positive, constructive, lasting relationships.

The Consumers Health Forum of Australia is the national peak body representing the interests of Australian healthcare consumers.

The event was attended by representatives from health consumer organisations, Medicines Australia member companies, as well as representatives from the Consumers Health Forum and Medicines Australia. Attendees learned more about some of the experiences of consumer organisations and pharmaceutical companies working together to achieve better health outcomes for health consumers, carers and families.

The *Working Together Guide* was developed by the Consumers Health Forum of Australia and Medicines Australia in 2005 and was first updated in 2008.

The guide includes advice about how to manage collaborations between health consumer organisations and pharmaceutical companies, especially when complexities arise. It also highlights how successful collaborations require significant effort, openness, trust and respect.

Successful collaborations improve the health and quality of life of consumers and their carers. They can raise awareness of health conditions and related issues, and health consumer organisations and pharmaceutical companies can share skills with each other.

The *Working Together Guide* highlights the role collaboration plays in contributing to knowledge, mutual problem solving as well as contributing to the national goal of improved health care outcomes for patients.

We would like to acknowledge the dedication of the *Working Together Guide* steering committee to ensure the success of the launch of the new web-based edition:

- Ms Clare Stuart, Tuberous Sclerosis Australia
- Mr Paul Murdoch, Australian Pain Management Association
- Ms Zarli French, MSD
- Mr Peter Murphy, Novartis.

The Committee was supported by Ms Jo Root, Consumers Health Forum, and Ms Katie Whitehead, Medicines Australia.

We would also like to particularly acknowledge The *International Alliance of Patients Organisations* (IAPO) who have allowed the use of the *Working with partners and stakeholders toolkit* in the online *Working Together Guide*.



1 *Working Together Guide* committee officials, from left to right: Peter Murphy, Novartis; Leanne Wells, CHF; Andrew Thirlwell, Pfizer; Zarli French, MSD; Elizabeth Carrigan, Australian Pain Management Association; Tony Lawson, CHF; Wes Cook, Medicines Australia; Paul Murdoch, Australian Pain Management Association; Clare Stuart, Tuberous Sclerosis Australia.



## THE POLICY ENVIRONMENT

### The impact of pharmaceutical innovation on premature mortality, hospital separations, and cancer survival in Australia

Medicines Australia continues to play an active role through research activities. In terms of informing the research agenda, Medicines Australia jointly hosted Professor Frank Lichtenberg from Columbia University with Medicines Australia member MSD. MSD commissioned Professor Lichtenberg to research the impact of pharmaceutical innovation in Australia. The report titled: *The impact of pharmaceutical innovation on premature mortality, hospital separations, and cancer survival in Australia* clearly shows that investing in new medicines pays for itself by reducing other public health expenditure.

The research estimated that innovative medicines saved taxpayers almost \$7 billion in hospital costs for people up to 80 years of age in 2011 – more than the cost of reimbursing these medicines through the PBS.

The report has also estimated how medicines listed on the PBS affected cancer survival. The five year survival rate for all cancers in Australia increased from 49% to 62% between 1986 and 2007. An estimated 40% of this improvement is the result of new medicines listed on the PBS. In the absence of new medicines, the five-year survival rate would have been 57% in 2007.

During Professor Lichtenberg's visit to Australia in November 2015, he delivered two keynote speeches and engaged in briefings with key policy makers. Over a hundred guests attended Professor Lichtenberg's address to the National Press Club.

Parliamentarians were briefed on key public health policy findings arising from the research. Senior officials at the

Departments of Health, Finance, Treasury, Prime Minister & Cabinet and the Parliamentary Budget Office were also engaged to discuss the findings and how these fit within the policy landscape.

Professor Lichtenberg also met with senior academics and economists from the Australian National University to share the research findings on the value of pharmaceuticals to our healthcare system.

Following a period of review and increased focus by governments on health expenditure, Medicines Australia continues to play a key role in promoting engagement between leading research experts and policy-makers.

Medicines Australia would like to acknowledge MSD for commissioning the research and for supporting Professor Lichtenberg's visit.

### University of Sydney productivity project

Medicines Australia has continued to progress a commissioned research project into labour force participation and the value of medicines led by Chair and Professor of Health Economics, Deborah Schofield at the University of Sydney. This project achieved major milestones throughout the year and forms part of our seminal work to understand and advocate for improved value measures. Medicines Australia is also exploring opportunities to ensure the ongoing sustainability of 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.



1 Professor Lichtenberg, Columbia University addressing the National Press Club, November 2015



## THE POLICY ENVIRONMENT

### Access

#### ► OBJECTIVE 2:

##### Australians have early access to new medicines

Medicines Australia has worked with member companies and the Australian Government in a range of ways to improve healthcare outcomes for Australians through timely and early access to medicines.

We build and maintain relationships with government for fair reimbursement of medicines (through the Pharmaceuticals Benefits Scheme) to ensure the continuation of a viable medicines industry.

Working with the Department of Health, Pharmaceutical Benefits Division and Therapeutic Goods Administration, substantial progress has been made to improve the regulation of medicines, the operation of the PBS and ensure Australia's decision-making frameworks for the listing of medicines keeps pace with international best practise.

#### Improving the regulation of therapeutic goods

An independent review of Medicines and Medical Devices Regulation was announced in 2014 with the aim of improving the regulation of therapeutic goods available in Australia.

The review was conducted by a panel of three experts, Mr Will Delaat AM, Professor John Horvath AO and chaired by Emeritus Professor Lloyd Sansom AO. The Panel reported in two stages, delivering the first report in May 2015 with a second report delivered in July 2015.

Medicines Australia made multiple submissions into the review process and participated in consultation processes together with other key stakeholders in the health sector.

The Australian Government responded to the review and committed funding in the 2016-2017 budget to bring medicines onto the Australian market faster, by up to two years, through streamlining of regulations and processes.

We are pleased to see a number of our key recommendations aimed at accelerating TGA medicines approval times have been addressed in the Australian Government's response to the review. These include:

- Optimising work sharing activities with comparable overseas regulatory agencies
- Creating multiple approval pathways and eliminating administrative duplication
- Utilise improved technological capabilities.

Implementing these changes will reduce or remove the time lag that can occur between Australia receiving new medicines and vaccines compared to other regions like the United States, Europe and the United Kingdom. The changes will also drive significant efficiency gains by reducing unnecessary red tape, delivering real savings to the benefit of government, patients and industry.

Building on these significant developments, Medicines Australia will continue to focus on working with the Government as reforms are implemented over the coming years.



## THE POLICY ENVIRONMENT

### Continuing to enhance the operation of the PBS

The Access to Medicines Working Group (AMWG) continued to provide a forum for improved coordination of activities involving the Department of Health and Medicines Australia. The AMWG is currently co-chaired by the Deputy Secretary of the Department of Health and the Medicines Australia Chairman.

Representatives met in September 2015 and April 2016 to consider ongoing issues regarding timely and appropriate access to new medicines for the PBS. The AMWG reviewed progress on:

1. Managed Access Programme (formerly Managed Entry Scheme)
2. Section 99ACB of the *National Health Act 1953*
3. Transparency and efficiency of PBS processes

Improving the co-ordination of activities relating to these areas between the Department and Medicines Australia are contributing to tangible improvements and efficiencies in the operation of the PBS.

The Managed Access Programme (MAP) is a mechanism that enables the PBS listing of products, under special circumstances of high unmet clinical need. Significant progress had been made on developing a framework for an effective Managed Access Programme (MAP).

Current interpretations of the *National Health Act 1953* (the Act) have led to instances of Australian patients being unable to access improvements in the delivery of medicines. While both the Department and Medicines Australia have exchanged proposed frameworks a resolution has not yet been reached, however we are continuing to engage on a pathway forward.

AMWG is continuing to explore efficiencies that might free up capacity for more complex initiatives such as MAP and support greater transparency of processes and avenues for improved interaction for the community.

### Pharmaceutical benefits decision-making framework

During the year, a comprehensive review of the Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines for making a submission to list a new medicine on the Pharmaceutical Benefits Scheme was undertaken.

The PBAC Guidelines provide detailed instructions for sponsor companies on what information is required by the PBAC and its subcommittees to assist them in making a recommendation to the Government to list a medicine on the PBS. Medicines Australia welcomed the commencement of the PBAC Guidelines Review. The aim of the review was to ensure the PBAC Guidelines meet the world's best practices, incorporate new and updated methodological approaches and more generally incorporate improvements to PBAC assessment processes.

The volume and depth of information provided by pharmaceutical companies to the PBAC is large and complex. As new technologies are developed and drug discovery and research becomes more intricate and more able to be targeted to specific genetic variations, it is vital to regularly review the Guidelines that govern the system.

Updating, streamlining and incorporating the latest Health Technology Assessment methodological advances into the Guidelines will ensure they are fit for purpose.

There has been positive ongoing consultation between Medicines Australia and the Department of Health during the PBAC Guidelines Review process. Industry, through Medicines Australia, was represented on the PBAC Guidelines Review Steering Committee (GRSC). The industry representative was Dr Greg Cook (BMS) and Industry Co-Chair of the Health Economics Working Group.

A hallmark of the process has been the commitment by all parties to open, ongoing communication and engagement which will continue as the Guidelines are to be implemented.

## THE POLICY ENVIRONMENT

### Funding

#### ► OBJECTIVE 3:

**Ensure sustainability of funding for prescription medicines**

Medicines Australia continues to contribute to policy development for the benefit of all Australians. Through our engagement and advocacy with key stakeholders we seek to collaborate to ensure the sustainability of funding for prescription medicines.

#### **PBS Access and Sustainability Package**

Medicines Australia acknowledges that offset savings measures are taken within the health portfolio to allow for expenditure on new PBS listings. This was first introduced around the time of the global financial crisis by the Government given the structural state of the budget and the objective of achieving a 'surplus'. Medicines Australia is continuing to advocate for minimising the requirement of finding spending offsets within the health budget to fund new medicines which may create delays to the availability of new and innovative medicines that are of benefit to Australians.

The ongoing impacts resulting from the 2015 PBS changes through the PBS Access and Sustainability Package (PASP) are yet to be completely realised. Medicines Australia has continued to work with the Australian Government to manage the impact that these reforms are having on members and other stakeholders.

#### **Submission to the Federal Budget**

Medicines Australia member companies contribute to maintaining a sustainable PBS through rebates and risk sharing agreements with the Government for high cost drugs. These agreements, whilst not taken into account in the Government's reporting of expenditure on PBS medicines, are an important part of ensuring that the PBS remains sustainable into the future. During the year, Medicines Australia continued to advocate for public recognition of the contributions that members make to a sustainable funding system for prescription medicines.

### Investment

#### ► OBJECTIVE 4:

**Australia as an attractive destination for innovation and investment**

Medicines Australia has engaged on a range of issues related to innovation and investment. We seek to advance policies that encourage investment and drive economic prosperity in Australia. This year we have contributed to a number of public policy discussions, including R&D and intellectual property.

#### **Intellectual Property**

Medicines Australia continues to develop policies to strengthen intellectual property and has persevered in calling for extensions to regulatory data protection in the context of the Trans Pacific Partnership Agreement (TPP). With Australia becoming signatory to the agreement in late 2015, Medicines Australia has continued to advocate for Australia's regulatory data protection to be aligned with the agreement.

In November 2015, the Productivity Commission released an issues paper on the review of intellectual property arrangements in Australia. Medicines Australia, supported by a member working group, made two submissions and appeared at a specially convened pharmaceutical roundtable with the Commission along with members from AusBiotech, GBMA, academics and legal advisors. Medicines Australia was also joined by colleagues from the IFPMA (Mr Andrew Jenner) and the JPMA (Ms Yoko Makino) at a public hearing before the Commission. Medicines Australia continues to advocate for a strong and stable intellectual property system in Australia.

#### **Multinational Tax Avoidance**

In July 2015, 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 that a number of Medicines Australia member companies appear at a public hearing where they elaborated on a number of issues such as transfer pricing and engagement with the

## THE POLICY ENVIRONMENT

Australian Taxation Office through advanced pricing agreements. The Committee found that although there were differences in how transfer pricing models have been used internationally, the pharmaceutical sector had been actively engaging with the Australian Taxation Office to ensure compliance.

Following the public hearing and submissions, Medicines Australia has also engaged with the Australian Taxation Office to discuss and better understand changes in the Government's policy position on tax issues for the innovative pharmaceutical industry in Australia.

### Establishment of the Medical Research Future Fund

Medicines Australia continues to advocate strongly for the Medical Research Future Fund (MRFF). We have highlighted the need for continued and further investment in medical research in the innovative medicines industry.

Increasing funding for health and medical research will help Australia to develop ground breaking discoveries. These discoveries can help to fight diseases and provide patients with access to new innovative medicines that can improve their quality of life.

Medicines Australia supported the passing of legislation through the Parliament on August 2015 which provided a dedicated financial asset supporting medical research and innovation. A substantive submission was made to the [Senate Community Affairs Legislation inquiry](#) advocating for involvement of relevant partners including industry to ensure alignment between the MRFF and the Government's Industry Innovation and Competitiveness Agenda.

In December 2015, the Australian Government announced a Biomedical Translation Fund. The scheme includes \$250 million from the Australian Government matched by funds from the private sector. In recognition of the need to improve the commercialisation of research, Medicines Australia supports continued investment in the fund.

Medicines Australia continued to contribute to the public policy debate around how Australia can better commercialise our research. This includes through making a submission the Australian Medical Research Advisory Board who are developing priorities and strategies for the MRFF.

Medicines Australia will continue to play an active role in advocating for the development of coherent strategies for the MRFF that encourage research in the areas of the national health priorities.

### Medical Technologies and Pharmaceuticals Growth Centre

The Medical Technologies and Pharmaceuticals Growth Centre (MTPConnect) was established in November 2015 as part of the Australian Government's \$248 million Industry Growth Centers Initiative.

Medicines Australia has welcomed the Australian Government's commitment to growing the medical technologies and pharmaceuticals sectors in Australia. Growth Centres are intended to unlock commercial opportunities and drive innovation by building links between businesses and industry organisations and the science and research sector.

Since MTPConnect's establishment in late 2015, Medicines Australia have remained in ongoing dialogue as various initiatives and activities have progressed.

### Research & Development (R&D) Tax Incentive

The members of Medicines Australia discover, research and develop the latest medicines and vaccines and are some of the largest investors in R&D around the world.

Locally, our members invest around \$1 billion a year in Australian R&D and are at the forefront of collaboration and commercialisation with Australian research centres, universities and biotechnology companies.

Medicines Australia joined AusBiotech, MTAA, Research Australia, BioMelbourne Network and BioSA in making a submission to the R&D tax incentive review led by Innovation and Science Australia. This submission called for continuing the tax incentive and for the review to consider how this incentive is important in driving investment in the innovative pharmaceutical and biotechnology sector.

With global demand for new medicines expected to double over the next decade, Australia stands at the cusp of exciting opportunities in medical research and development. Over the coming year we will continue to engage with the Government and key stakeholders on how Australia might best improve the R&D incentive to deliver more high-skilled STEM jobs and provide Australians with improved access to medicines.

## CODE OF CONDUCT PERFORMANCE

### Code of Conduct Edition 18 Implementation

Following the authorisation of Code of Conduct Edition 18 in April 2015 by the Australian Competition and Consumer Commission (ACCC) Medicines Australia's Ethical Conduct activities in 2015-2016 have been focussed on ensuring effective implementation of the revised Code.

Code Edition 18 and the new transparency model demonstrate the strong leadership of the Australian innovative medicines industry in delivering even greater transparency to the Australian community about the support that is provided to healthcare professionals. This support enables them to engage in educational activities and compensates them for the valuable expertise and advisory services provided to member companies. The new Code builds on 56 years of successful, responsible, ethical industry self-regulation.

In 2015-2016, in alignment with global standards for the innovative medicines industry, member companies consistently demonstrated a high level of compliance with the Code and an 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.

Through implementing the new transparency model in Code of Conduct Edition 18, the Australian innovative medicines industry continues to put patients first by demonstrating the value of industry partnerships and continuing to lead the sector in delivering transparency.

### Transparency Reporting

#### Educational Event Reports

In June 2016 Medicines Australia published member companies' educational event reports for the period April to September 2015. This was the seventeenth and final six monthly report published since reporting commenced in 2007. There were 14,872 events reported for the period April to September 2015. This is consistent with the same period in previous years.

#### Advisory Board Reports

In December 2015, Medicines Australia published member companies' Advisory Board meeting reports. These reports covered meetings held between April and September 2015. There were 108 Advisory Board meetings held by 29 member companies during the six month period.

#### Healthcare Professional Consultants Reports

The third member companies' Healthcare Professional Consultancies reports were published in March 2016. These reports covered consultancies contracted during the 2015 calendar year. A review of these reports showed that 33 of our member companies engaged 689 healthcare professional consultants across 578 projects during the year, with the total value of consultancies of \$1,820,992.

The information published in the educational events, Advisory Board meetings and Healthcare Professional Consultancies reports will now be reported under the new transparency reports for individual healthcare professionals.

#### Reporting Payments and Transfers of Value to Healthcare Professionals

Edition 18 of the Code requires member companies to report the cost of all flights, accommodation and registration fees provided to an individual healthcare professional and any honoraria, sitting or consulting fees. Commencing on 1 October 2015, the first twelve months of reports will occur with each healthcare professional's consent to publish the information. From 1 October 2016 reporting will become mandatory for member companies. That is, companies may not make a payment or provide an airfare, accommodation or registration fee unless a healthcare professional is notified of the company's disclosure obligation and therefore expects the information to be disclosed.

The first publication of reports under this new transparency model covered the period 1 October 2015 to 30 April 2016. The reports were published on member company websites on 31 August 2016.

In the lead up to the commencement of the new transparency model on 1 October 2015, the Ethics & Compliance team focussed its efforts on communicating



## CODE OF CONDUCT PERFORMANCE

with healthcare professionals. Medicines Australia undertook a communication campaign which reinforced that a strong working relationship between companies and healthcare professionals and ongoing knowledge exchange are critical to better patient outcomes. Through a range of media, in collaboration with member companies, we sought to inform all relevant Australian healthcare professionals of the new Code and its requirements.

### Health Consumer Organisation Support Reports

In June 2016 Medicines Australia published the third annual reports of member companies' financial support for Health Consumer Organisations (HCO). Member companies supported 276 different HCOs across Australia in calendar year 2015, ranging from national consumer organisations to small local groups, relating to 412 different projects or events to the total value of \$9,156,063 of support.

## Complaints, Appeals and Monitoring

### Complaints handling

In 2015-2016, Medicines Australia received nine new complaints. This is a decrease from 2014-2015, when 15 new complaints were received.

Of the nine new complaints received and finalised in 2015-2016, three 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 three appeals against the Code of Conduct Committee's decisions during the year. None of the three appeals were upheld.

Details of the complaints considered and finalised in 2015-2016 and the outcomes are reported in this Code of Conduct Annual Report, published on the Medicines Australia website.

### Monitoring of Member company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2015-2016. The Committee undertook five reviews of materials associated with specific therapeutic areas:

- Company websites in the genitourinary system and contraceptive agents therapeutic areas
- Patient support materials in the endocrine & metabolic disorders therapeutic area
- Market research in all therapeutic classes (reviewed over two meetings)
- PFP consent forms
- Hospitality procedures.

The Monitoring Committee also undertook a review of member companies' HCO Support reports. These reviews are in addition to the Monitoring Committee's annual review of one quarter of all educational event reports submitted by member companies during the preceding 12 months.

The Monitoring Committee reviewed 7,947 educational events held between 1 April 2014 and 31 March 2015 reported by 36 companies. No events were referred to the Code of Conduct Committee.

The Monitoring Committee has commenced its review of educational event reports submitted between 1 April 2015 and 30 September 2015. The outcomes of this review will be reported in the 2016-2017 Code of Conduct Annual Report.

### Continuing Education Program

The Medicines Australia Continuing Education Program (CEP) provides education for company medical representatives to a recognised industry standard. It also educates other company personnel about the Medicines Australia Code of Conduct. In 2015-2016 1,258 individual students enrolled in one or more Programs offered under the CEP. This demonstrates the real value of the CEP to our members and others. In 2015-2016, 1,461 company personnel undertook the updated Refresher Module for Code Edition 18. This shows the high level of interest by members in ensuring that their personnel and the external agencies they engage are well informed about the new Code requirements.

We wish to thank Professor Peterson and his team at the University of Tasmania who delivered the CEP in 2015-2016 for our members.

# Engagement

## WORKING WITH THE AUSTRALIAN GOVERNMENT

Medicines Australia has ongoing dialogue with the Australian Government through expert advisory panels and submissions. We have representation on a number of policy-specific committees established by the Australian Government to better coordinate health and industry policy formulation and delivery.

### Clinical Trials Advisory Committee

Medicines Australia was represented on the Clinical Trials Advisory Committee (CTAC) by the Medicines Australia Chairman. The CTAC provides advice to the Department of Health and the Department of Industry and Science on various measures under the clinical trials reform initiative.

### Economics Sub Committee (ESC) and Drug Utilisation Sub Committee (DUSC)

Medicines Australia sat on the Economics Sub Committee (ESC) of the Pharmaceutical Benefits Advisory Committee (PBAC) and the Drug Utilisation Sub Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC), represented by Ms Elizabeth de Somer.

The DUSC assesses estimates on projected usage and financial costs for medicines. It also collects and analyses data on actual use (including in comparison with different countries), and provides advice to the PBAC.

The ESC assesses clinical and economic evaluations of medicines submitted to the PBAC for listing, and advises PBAC on the technical aspects of these evaluations.

## Access to Medicines Working Group (AMWG)

The Access to Medicines Working Group (AMWG) is currently co-chaired by the Deputy Secretary of the Department of Health and the Medicines Australia Chairman. This group provides a forum for improved coordination of activities, and development of appropriate policies, involving the Department of Health and the innovative pharmaceutical industry.

## Biologic and Biosimilar Medicines on the PBS

Medicines Australia engaged with the Australian Government on the development of the Biosimilars Awareness Initiative Implementation Framework, and through the Government's Biosimilar Education and Awareness Initiative Reference Group.

The Reference Group provides ongoing advice and guidance on the activities of the Biosimilar Education and Awareness Initiative and ensures messaging is clearly articulated and appropriately targeted.

To complement these engagements, Medicines Australia collaborated with a group of key stakeholders to convene a multi stakeholder forum. The forum, held in June, enabled a broader understanding of the impact of biosimilar's policy development to support the successful introduction, uptake and use of biologics and biosimilars.

## Post-Market Reviews

Medicines Australia further engaged with the Department of Health during the year to implement the revised post-market review framework as announced in early 2015. In accordance with the post-market review framework the industry, through Medicines Australia, continues to be represented on the respective active post-market reviews.

Post-market reviews fall under the quality use of medicines objective of the National Medicines Policy framework. This includes promoting the safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

## Submissions

The reporting period was characterised a high number of reviews and consultations, with Medicines Australia making more than the usual number of submissions:

- Submission to the Public Consultation on the draft chapter “Product Type 4 – Hybrid Technologies and Co-dependent Technologies” of the draft revised Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines (Draft Version 5.0)
- Submission to the Public Consultation on the draft revised Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines (Draft Version 5.0)
- Submission to the 2016-17 Federal Government Budget
- Submission to the Private Health Insurance Consultations 2015-16
- Submission to the Productivity Commission Review of Intellectual Property Arrangements
- Submission to the Medicare Benefits Schedule (MBS) Review Taskforce
- Submission to the Senate Inquiry of the Health Legislation Amendment (eHealth) Bill 2015
- Submission to the Public Consultation on the Advisory Council on Intellectual Property Recommendation on the Innovation Patent System
- Submission to the Review of Research Policy and Funding Arrangements for Higher Education
- Submission to the Public Consultation on the Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review
- Supplementary Submission into Senate Economics References Committee Inquiry into Corporate Tax Avoidance
- Submission to the Inquiry into the Medical Research Future Fund Bill 2015 and the Medical Research Future Fund (Consequential Amendments) Bill 2015
- Submission to the Joint Select Committee on Trade and Investment Inquiry into the Business Experience in Utilising Australia’s Free Trade Agreements



1 Inaugural ACTA Clinical Trial of the Year Awards, held in Melbourne May 2015. Award winner, Professor Jonathan Morris AM, The Kolling Institute for Medical Research (second from left), pictured with, from left to right: Parliamentary Secretary for Medical Research in Victoria, Frank McGuire; the Hon Sussan Ley, Minister for Health, Ageing and Sport; Professor John Zalcberg OAM, Chair of ACTA; and Wes Cook, Chairman of Medicines Australia

## THE AUSTRALIAN CLINICAL TRIALS ALLIANCE

The Australian Clinical Trials Alliance (ACTA) held an international symposium on clinical trials in Sydney from 7-10 October 2015.

Medicines Australia representatives presented to clinicians, academics and key government officials at this conference on how the industry engages with and is fundamental to clinical trials in Australia, calling for further partnering between industry, Government and researchers.

ACTA, together with Medicines Australia, AusBiotech and Research Australia hosted the *Clinical Trials 2016 Breakfast & Award Ceremony* in May 2016 in Melbourne. The event is held to mark International Clinical Trials Day and announce the inaugural ACTA Clinical Trial of the Year Award.

The inaugural ACTA Clinical Trial of the Year Award was presented to Professor Jonathan Morris from the Interdisciplinary Maternal Perinatal Australasian Collaborative Trials network and Sydney's Kolling Institute.

Special guests who took part in the ceremony included the Hon Sussan Ley MP, Minister for Health and Aged Care and Minister for Sport, who presented the awards, Mr Frank McGuire, Victorian Parliamentary Secretary for Medical Research, Professor Anne Kelso AO, CEO of the NHMRC and Mr Wes Cook, Chairman of Medicines Australia.

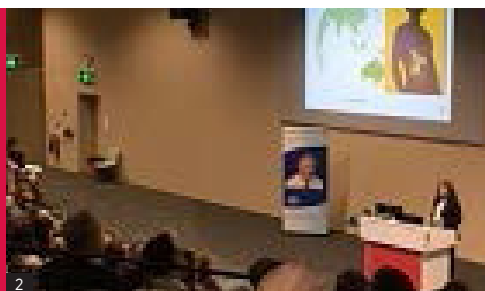
Close to 200 leading researchers, industry representatives, clinical trialists, and consumer representatives attended.

## SHOWCASING AUSTRALIA'S ROLE IN GLOBAL PHARMACEUTICAL DEVELOPMENT

The Bennelong Forum at Macquarie University was held in December 2015. The event, which showcased some of the innovation being undertaken in Australia by Medicines Australia member companies, was held as part of a visit to the seat of Bennelong by the Minister for Health and Aged Care and Minister for Sport the Hon Sussan Ley MP. Around 500 staff from Medicines Australia member companies attended the event and were able to ask the Minister a series of questions regarding her portfolio. These presentations showcased some of the work being done in Australia by the innovative medicines industry.

Presentations included:

- the transformation of the AstraZeneca manufacturing facility in Macquarie Park and its export growth;
- the Diabetes pilot App designed by Telstra and several Medicines Australia member companies;
- the commercialisation of the Pharmaxis anti-inflammatory treatment by Boehringer Ingelheim; and
- Monash University collaborations with Pfizer and Janssen.



1 Shalom scholarship students who are now doctors: Brendan Phillips and Laura Fitzgerald

2 The Bennelong Innovation Forum

## BIOLOGICS AND BIOSIMILARS STAKEHOLDER FORUM

The Medicines Australia Board agreed to support a jointly led biologics and biosimilars stakeholder forum held in June 2016. The forum, titled *Biologic and Biosimilar Medicines 2020: Making the most of the opportunities* aimed to enhance the current policy framework in relation to biosimilars in line with the objectives of the National Medicines Policy.

The forum drew together a broad range of healthcare professionals, consumers and consumer groups, industry as well as policy and decision makers. Participants shared different views and experiences, gained new insights and discussed the opportunities and challenges for the introduction, uptake and use of biologic and biosimilar medicines. The forum and associated report are intended to complement existing and new initiatives in this area.

Medicines Australia thanks stakeholders on the organising committee including: the Pharmacy Guild of Australia; NPS MedicineWise; Consumers Health Forum; Royal Australasian College of Physicians; Council of Australian Therapeutic Advisory Groups; and the Society of Hospital Pharmacists of Australia.

## MEDICINES AUSTRALIA SPECIAL PURPOSE FUND

Medicines Australia continues to support two students of medicine through its 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 Program

Medicines Australia has been supporting the Shalom Gamarada Ngiyani Yana Residential Scholarship Program since 2010. The program results from a collaboration between Shalom College, the Muru Marri Indigenous Health Unit, Nura Gili Indigenous Programs and the School of Public Health and Community Medicine at UNSW.

The first two students sponsored under the program were Dr Laura Fitzgerald and Dr Brendan Phillips. In 2014, Laura graduated from Medicine and her achievement was acknowledged at our Parliamentary Dinner in March 2015.

Dr Brendan Phillips was sponsored throughout 2010 and 2011, after which time he relocated to Coffs Harbour. He completed the second part of his degree at the UNSW Rural Clinical School's Coffs Harbour Campus.

Medicines Australia is proud to announce Dr Brendan Phillips qualified as Bachelor of Medicine/Bachelor of Surgery in 2015. He is presently doing his internship at Nepean Hospital.

On graduation he said, "A greater focus on expanding the indigenous medical workforce is crucial if indigenous health and life expectancy is to improve. Indigenous Australians are likely to better understand the social concerns, health issues and family dynamics specific to indigenous people. The lower life expectancy is down to their reluctance to approach healthcare providers and a lack of access to health professionals."

Medicines Australia currently supports the studies of Luke Walker, now in his fifth year of study, and India Kinsey who is in her fourth year.

Since 2010, Medicines Australia has supported a total of six students through the scholarship program.



## Working with our members

The Strategic Committee has made a significant contribution as Medicines Australia has continued to advance and refine our operational plan in order to deliver on our strategic objectives. Medicines Australia acknowledges the support received from all of the committee members over the past year.

### STRATEGIC COMMITTEE\*

REPRESENTATIVE	COMPANY
Michelle Burke	Bristol-Myers Squibb (Industry Co-Chair)
Christian Sellars	MSD (Industry Deputy-Chair)
Sue Alexander	Roche
Alissa Brown	Sanofi
Kathy Cargill	AbbVie
Andrew Carter	Commercial Eyes
Peter Germanos	Boehringer Ingelheim
David Herd	GlaxoSmithKline
Sara Pantzer	Amgen
Albert Spanos	Celgene
Peter Vermeer	Eli Lilly
Charles Waterfield	AstraZeneca

\* Members at 30 June 2016

### Departed representatives

- Mendel Grobler departed October 2015
- Nic Kurstjens departed January 2016
- Steve Crowley departed October 2015

### MEDICINES AUSTRALIA WORKING AND ISSUES GROUPS

A number of standing Working Groups and topic specific Issues Groups have helped advance specific goals on behalf of the innovative based industry. Medicines Australia acknowledges the contribution that members in these groups have made in helping to supplement our resources by providing expert and technical advice on a range of policy matters.

#### Industry Policy Working Group\*\*

REPRESENTATIVE	COMPANY
Duncan Purvis	Janssen (Industry Co-Chair)
Andrew Carter	Commercial Eyes
Luke Cornish	MSD
Julia Jenkins	Novartis
Paul Lindsay	Merck Serono
Kristin Trace-MacLaren	GlaxoSmithKline
Claire Willmott	Roche

\*\* On 8 February 2016 the Industry Policy Working Group was placed in abeyance due to a period of internal restructuring

#### Regulatory Affairs Working Group

REPRESENTATIVE	COMPANY
Sue Alexander	Roche (Industry Co-Chair)
Helen Critchley	Sanofi (Industry Co-Chair)
Brain Hewitt	Pfizer
Elizabeth Joshi	Bayer
Kirpal Kaur	Bristol-Myers Squibb
George Lillis	Novartis
Michael Parker	AstraZeneca
Mark Rowland	Amgen
Carolyn Tucek-Szabo	GlaxoSmithKline
Emma Williams	CSL Limited

## Health Economics Working Group

REPRESENTATIVE	COMPANY
Greg Cook	Bristol-Myers Squibb (Industry Co-Chair)
Geoffrey Chin	Novartis
Peter Germanos	Boehringer Ingelheim
Louise Graham	Amgen / Pfizer
Michael Haberl	GSK
Sean Lybrand	Amgen
Natalia Price	AbbVie
Carlene Todd	Roche
Kate Webb	Takeda

### Departed representatives

- Ben Kluge. Departed October 2015
- Susan Phillips departed June 2016

## Government Working Group

REPRESENTATIVE	COMPANY
Sara Pantzer	Amgen (Industry Co-Chair)
Karen Barfoot	Bristol-Myers Squibb
Adrian Dolahenty	Bayer
Penny George	Sanofi
Cameron Milliner	Shire
Peter Murphy	Novartis
Kieran Schneemann	AstraZeneca
Todd Stephenson	Janssen
Andrew Thirlwell	Pfizer
Kristin Trace-MacLaren	GSK

### Departed representatives

- Nicola Richards departed March 2016

## Future Issues Planning Working Group<sup>†</sup>

REPRESENTATIVE	COMPANY
Mendel Grobler	Pfizer (Industry Co-Chair)
Alissa Brown	Sanofi
Terese Cole	Eli Lilly
Annette Kerr	Roche
Kelly Kirchmann	KMC Health Care
Cheryl Maley	Novartis
Kaylene O'Shea	Celgene
Brendan Price	MSD
Kristin Trace-MacLaren	GlaxoSmithKline
Nathan Walters	Janssen

<sup>†</sup> On 9 September 2015 the Future Issues Planning Working Group was placed in abeyance due to a period of internal restructuring

## PBAC Guidelines Review Working Group\*

REPRESENTATIVE	COMPANY
Greg Cook	Bristol-Myers Squibb (Industry Co-Chair)
Kate Adams	GSK
Liliana Bulfone	Shoten Consulting
Philippa Delahoy	Pfizer
Julie Ellis	Menarini
Kathryn Glase	Janssen
Adam Gordois	Covance
Michael Haberl	GSK
Andrew Manton	HEARS
Heather McElroy	Covance
Peter Moore	Commercial Eyes
Beth O'Leary	Covance
Carmel Spiteri	MSD
Carlene Todd	Roche
Jodie Wilson	Abbvie

\* Members at 30 June 2016

## Biologics and Biosimilars Issue Group\*

REPRESENTATIVE	COMPANY
Matthew Little	Abbvie (Industry Co-Chair)
Sara Pantzer	Amgen (Industry Co-Chair)
Ruchi Bakshi	Novo Nordisk
Alissa Brown	Sanofi
Stuart Englund	Janssen
Peter Germanos	Boehringer Ingelheim
Louise Graham	Pfizer
Charles Harvey	MSD
Annette Kerr	Roche
Paul Lindsay	Merck Serono
Peter Murphy	Novartis
David Pullar	Roche
Stephen Richardson	Sanofi
Mark Schulz	Novartis
David Thomson	Abbvie
Daniel Thut	Novo Nordisk
Peter Vermeer	Eli Lilly
Kate Webb	Takeda
Bronwyn West	MSD
Katy Williams Day	Merck Serono

## Oncology Industry Taskforce\*

REPRESENTATIVE	COMPANY
David Pullar	Roche (Co-Chair)
Todd Stephenson	Janssen (Co-Chair)
Alissa Brown	Sanofi
Greg Cook	Bristol-Myers Squibb
Wes Cook	Boehringer Ingelheim
Phillippa Delahoy	Pfizer
Adrian Dolahenty	Bayer
Kathryn Glase	Janssen
Louise Graham	Pfizer
David Grainger	Eli Lilly
Jane Kerr	Boehringer Ingelheim
Paul Lindsay	Merck Serono
Sean Lybrand	Amgen
Peter Murphy	Novartis
Sara Pantzer	Amgen
Delia Schaffer	Takeda
Kieran Schneemann	AstraZeneca
Matt Slabbert	Bayer
Mike Smith	AstraZeneca
Philip Spiers	AstraZeneca
Carmel Spiteri	MSD
Jodie Thomas	Novartis
Kevin Thomas	MSD
Carlene Todd	Roche
Kristina Turner	Abbvie
Kate Webb	Takeda

\* Members at 30 June 2016

## Members events



1 Parliamentary Dinner 2016: Kirsten O'Doherty, AbbVie; Sue MacLeman, MTP Connect; Health Minister, the Hon Sussan Ley; Prof Maree Smith, Centre for Integrated Preclinical Drug Development, University of Queensland; Kathy Connell, Johnson & Johnson Innovation

2 Parliamentary Dinner 2016, The Great Hall, Parliament House

3 Greens Leader Senator Richard di Natale addressing the Parliamentary Dinner 2016

4 Wes Cook, Medicines Australia Chairman, Boehringer Ingelheim, with Senator the Hon Kim Carr, Shadow Minister for Higher Education, Research, Innovation and Industry

### ANNUAL GENERAL MEETING 2015

The Medicines Australia Annual General Meeting 2015 was held on 20 October 2015. Members were presented with the Chairman's Report on the previous 12 month period as well as the Financial Report. Members were also informed of the 2015 Board election results. Following the AGM, a member briefing on the transparency measures in the Medicines Australia Code of Conduct was held.

Our Members' Reception provided members with the opportunity to congratulate the newly elected Board of Medicines Australia and to farewell outgoing Chairman Dr Martin Cross.

Dr Martin Cross advocated strongly for the medicines industry for many years and during his time as Chairman. He has worked incredibly hard in the interests of our members and we acknowledge him for his tireless effort.

### MANAGING DIRECTORS' DINNERS

Medicines Australia held our Managing Directors' Sydney and Melbourne dinner events "Reputation and Perceptions" in November 2015.

### MEDICINES AUSTRALIA'S PARLIAMENTARY DINNER

Medicines Australia's 2016 Parliamentary Dinner provided members with the opportunity to network and highlight the investments made by our members in Australian innovation and medical science.

The expert panel discussion on Australia's role in biopharmaceutical innovation was a highlight of the evening. Chief Executive Officer of MTPConnect Sue MacLeman, UQ Professor Maree Smith and Kathy Connell of J&J Innovation provided interesting insights and ideas about the current and future strengths of Australia's innovative biopharmaceutical sector and the role our members have in supporting it.

The Minister for Health, the Hon Sussan Ley, Shadow Minister for Innovation, Higher Education, Research and Industry, Senator the Hon Kim Carr and Greens Leader Senator Richard Di Natale all spoke about the role of the medicines industry in supporting innovation and delivering better health outcomes.

### MEMBERS ONLY CONFERENCE

In 2016, Medicines Australia held its members only conference in two stages. The first part, conducted in March, was a workshop style event where members actively engaged in a discussion on the industry's value. In June, the second stage was held to report back to members on the outcome of the March session; as well as update members on the extensive and thorough review of our organisation and governance.

We thank members for participating and sharing information on issues of importance. Briefing members through this forum has been a critical way of keeping members up-to-date with emerging developments and industry trends.

## Awards



1 Zarli French, MSD, recipient of the 2015 Pat Clear award

2 Wes Cook, Medicines Australia Chairman, Boehringer Ingelheim; Zarli French, MSD; and Riad El-Dada, Managing Director, MSD

3 Mr Brian Gladson, Novartis Australia Pty Ltd and Ms Amanda Dang, Mylan receiving the UTAS Prize for Excellence in the CEP for Semester 1 2015 from Professor Greg Peterson

### PAT CLEAR AWARD 2015

The recipient of the Pat Clear award for 2015 is Ms Zarli French of MSD. Zarli was chosen as this year's winner for her tireless work with patient organisations, in particular, her leadership in the review and update of the *Working Together Guide*, a collaboration between Medicines Australia and the Consumers Health Forum.

A thirty-year veteran of the innovative pharmaceuticals industry, Zarli has always had a passion and drive to work in the interests of patients first. No doubt her previous career as a nurse had an enormous role to play in this. However, Zarli is reflective of the passion displayed by all who are lucky enough to work for such an important industry.

Medicines Australia would like to congratulate Zarli on her award. Zarli truly reflects the values of Pat Clear, former Chairman and Chief Executive of Medicines Australia, whom the award is named after. Pat's association with Medicines Australia was characterised by his determination, commitment and dedication. The award was established in 2002 to commemorate the substantial contribution he made to the industry during his career spanning 40 years.

### CONTINUING EDUCATION PROGRAM AWARDS

Medicines Australia hosts an annual awards ceremony to celebrate the achievements of students in the Continuing Education Program. The CEP awards are presented annually to sales representatives who achieve the highest marks in the course. Additionally, the University of Tasmania offered a prize to students based on the level of engagement and quality of participation in the course.

The CEP Awards for 2015 were presented at an Awards Lunch in March 2016. Guest Speaker Associate Professor Dr John Gullotta, Chairman, AMA Council of General Practice, highlighted the importance of a highly trained and ethical workforce interacting with healthcare professionals. Medical representatives are the ambassadors for the industry and provide reliable and accurate information on medicines to these healthcare professionals.

The Medicines Australia Continuing Education Program has been in existence for over forty years. Commencing in 1973 with the Medical Representatives Education Program, or MedREP. In that first year 48 candidates sat for the inaugural exams. In 1997 the new Continuing Education Program, or CEP, commenced, first at Monash University, before moving to Deakin University and the University of Queensland. In 2012 the University of Tasmania was awarded the contract to deliver and develop the CEP following a competitive tender process.

At the CEP Awards event, Medicines Australia Chief Executive Mr Tim James congratulated all students who completed the course, and in particular the recipients of the awards. The fact that so many students had been recognised for their high achievement in this program shows pride in the industry, a passion to deliver quality education to healthcare professionals with the purpose of ensuring patients get the best use out of medicines that are available today.





- 1 Mr Brian Gladson, Novartis Australia Pty Ltd with Ms Chie Chansavang, Boehringer Ingelheim receiving the UTAS Prize for Excellence in the CEP for Semester 2 2015 from Professor Greg Peterson
- 2 Mr Brian Gladson, Novartis Australia Pty Ltd with Ms Pinky Dharmshaktu from Amgen receiving the Code of Conduct Award from Dr John Gullotta

- 3 CEP Achievement Award recipients, left to right: Steve Graham, Apotex; Stu Fillman, Genzyme; Chris Gaffee, AstraZeneca; Kristyn Walton, Bristol-Myers Squibb; Jana Moody, Lundbeck; and Fiona Davis, AstraZeneca

## UTAS PRIZE FOR EXCELLENCE

The two UTAS Prizes for Excellence were presented to Amanda Dang, Mylan and Chie Chansavang, Boehringer Ingelheim.

CEP Course Facilitators at the University of Tasmania nominate one finalist for each semester from their program based on the level and quality of participation in group discussions and personal reflections in the online tutorials. The winners are selected by a panel from the University.

## CODE OF CONDUCT AWARD

Finalists for the Code of Conduct Award include all students who achieve the highest mark for Program 1, excluding anyone who has achieved final mark via resubmission or supplementary assessment.

Among finalists, the winner is determined through review of learning log book and online participation by a panel from the University of Tasmania which is made up of Program facilitators and program administration staff, with Medicines Australia to make final decision if it is difficult to identify a clear winner.

The Code of Conduct Award was presented to Ms Pinky Dharmshaktu from Amgen (pictured receiving the award from Dr John Gullotta).

## CEP ACHIEVEMENT AWARD

CEP Achievement Award winners are the students who achieve the 10 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 his or her marks via resubmission or supplementary assessment.

CEP Achievement Award recipients pictured:

- Steve Graham – Apotex
- Stu Fillman – Genzyme
- Chris Gaffee – AstraZeneca
- Kristyn Walton – Bristol-Myers Squibb
- Jana Moody – Lundbeck
- Fiona Davis – AstraZeneca

CEP Achievement Award recipients not present at the awards event:

- Sam Watkins – GlaxoSmithKline
- Ben Maliszewski – Independent Student
- Philippa Riddell – AstraZeneca

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

# Inside Medicines Australia

## MEDICINES AUSTRALIA BOARD MEMBERS 2015-2016



### DIRECTORS

1	Mr Wesley Cook (Chairman)	Boehringer Ingelheim Pty Limited	Chairman (as at 20-10-2015)
2	Mr Brad Edwards	Shire Australia Pty Limited	(appointed 20-10-2015)
3	Mr David Gallagher	Pfizer Australia Pty Ltd	
4	Mr Brian Gladsden	Novartis Australia Pty Ltd	(appointed 20-10-2015)
5	Mr James Jones	Takeda Pharmaceuticals Australia Pty Ltd	
6	Mr Geoff McDonald	GlaxoSmithKline Australia Pty Ltd	
7	Ms Kirsten O'Doherty	AbbVie Pty Ltd	
8	Mr Svend Petersen	Roche Products Pty Limited	(appointed 20-10-2015)
9	Mr James Priour	Amgen Australia Pty Ltd	
10	Mr Paul Spittle	AstraZeneca Pty Ltd	(appointed 20-10-2015)

### Departed

Dr Martin Cross	Appointed Chairman (ceased 20-10-2015)
Dr Susanne Fiedler	(ceased 22-01-2016)
Mr Chris Hourigan	(ceased 01-01-2016)
Mr Laurie McAllister	(ceased 20-10-2015)
Mr Anthony Mancini	(ceased 12-10-2015)
Mr Jason Smith	(ceased 31-07-2015)
Mr George Varkanis	(ceased 20-10-2015)

## MEDICINES AUSTRALIA SECRETARIAT 2015-2016



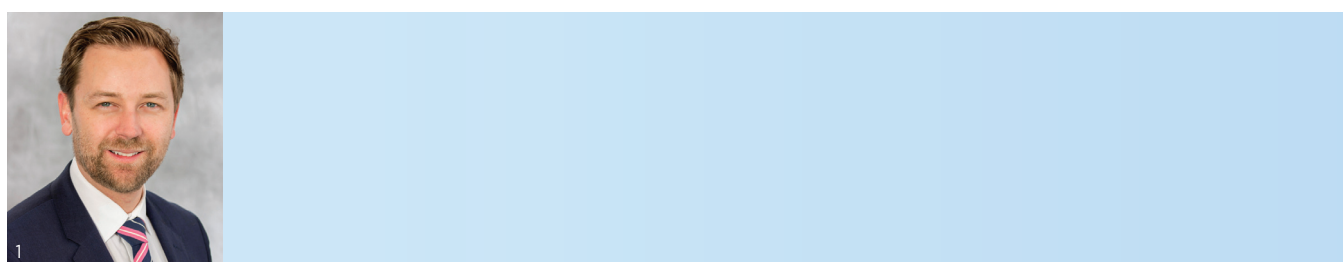
### CORPORATE

1	Mr Lee Hill	Interim Chief Executive
2	Ms Colette Peris	Executive Assistant to the Chief Executive & Chairman
3	Ms Katie Whitehead	Director, Corporate Services
4	Mr David Newman	ICT Manager



### POLICY & ADVOCACY

1	Ms Elizabeth de Somer	Director, Policy & Advocacy
2	Mr Samuel Develin	Reimbursement Manager
3	Dr Martin Snoke	Policy and Research Manager



### COMMUNICATIONS

1	Mr James Boyce	Director, Communications & Government Relations
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## COMPLIANCE

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

## Staff who departed in 2015-2016

Soelily Consen-Lynch	Research & Policy Officer
Zoe Croker	Access to Medicines Policy Officer
Tim James	CEO
Amna Khanzada	Office Administrator
Rochelle Pelaez	Executive Officer
Clair Petrie	Executive Assistant to the CEO & Appointed Chairman
Alexia Vlahos	Public Affairs Officer
Caroline Wood	Finance Manager