Annual Report

2016-2017



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

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This Annual Report provides a summary of Medicines Australia's activities, initiatives and achievements for the financial year ending 30 June 2017. Contact: Medicines Australia, Level 1, 16 Napier Close, Deakin ACT 2600 Telephone 02 6122 8500 Facsimile 02 6122 8555 Website www.medicinesaustralia.com.au

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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 has been an absolute honour and privilege to be Chair of Medicines Australia throughout what has been a watershed year for the innovative medicines industry.

In 2017 I was once again proud to be a member of an industry that offers hope and changes the lives of Australians and their families.

On behalf of its Members, Medicines Australia continues to be at the forefront of this ongoing effort to ensure that all Australians have first class, universal access to breakthrough treatments on the Pharmaceutical Benefits Scheme (PBS). Our focus has been steadfast in ensuring that Australia has the right policies and environment that make it easier to bring new medicines to Australians who need them; that rewards innovation; and encourages investment. I want to acknowledge the hard work of the Board, the secretariat and the numerous committees and working groups populated by experienced professionals from our member companies that have all played an important role in supporting the industry over the past twelve months.

The year saw significant change within Medicines Australia, the industry it represents, government and the public service - all of which played a role in the most significant outcome of the year, the signing of a five year Strategic Agreement with the Commonwealth.

Australia in 2016/17

This year saw the Coalition led by Malcolm Turnbull returned to Government following a double dissolution federal election. As anticipated, health policy played a significant role in the election, in particular, the Labor Party's Medicare campaign. It highlighted just how much the Australian public values its universal healthcare system, including the PBS. As a result, health remains a high profile policy area for not only the Parliament but for all Australians.

As such, Medicines Australia continues to strongly advocate for good health policy. As a leading industry body, we remain committed to working transparently in partnership with members of the Coalition Government, the Shadow Minister of Health, The Hon. Catherine King MP and members of Labor, Senator Richard Di Natale and members of the Greens, minor parties, independents and key stakeholder groups from across the broader policy community.

Another election on the other side of the world has also had an impact on Australia and our industry. The election of Donald Trump as President of the United States saw the immediate death of the Trans Pacific Partnership (TPP) including its changes to intellectual property arrangements for data exclusivity. President Trump also implemented reviews of all Free Trade Agreements including the AUSFTA signed with Australia that includes an important chapter on the medicines industry. He also signalled medicines access and pricing reforms for Americans as well as promising significant cuts to corporate tax that could have ramifications for investment around the globe, including Australia.

Back home, unexpectedly we saw a change of Federal Health Minister in January 2017. Medicines Australia would like to acknowledge The Hon Sussan Ley MP for her work as Health Minister and for her professional relationship with the industry. Ms Ley oversaw a number of significant changes to the pricing of medicines on the PBS that could not have been achieved without a close dialogue with Medicines Australia and its Members.

I would also like to acknowledge her role in instigating the Government's reforms to the Therapeutic Goods Administration (TGA) and the regulation of medicines and medical devices that continue to be implemented by the current Minister, the Hon. Greg Hunt MP. These reforms will help to improve regulatory processes and are a significant step towards faster access to new medicines for Australians. Medicines Australia has been working closely with the Government and the TGA on the implementation of these important reforms.

As an important stakeholder of the industry in his portfolio of Minister for Industry, Innovation and Science, Minister Hunt already possessed a sound understanding of the innovative medicines industry before he took on the Health portfolio in January 2017.

As a result, one of his first acts as Minister was to contact Medicines Australia to acknowledge the importance and strength of the relationship and the value of this industry to the health of the community. Within weeks of his swearing in as Minister, the industry continued to build a strong and open relationship and in good faith began negotiations on a long-term a compact between the industry and the Government.

The Strategic Agreement

The Strategic Agreement was signed between Medicines Australia, Minister Hunt and the Department of Health on 27 April 2017 and was announced by the Treasurer in the Federal Budget in May.

The five-year compact provides the industry with policy stability and predictability along with agreed changes to medicines listing processes that will improve access to breakthrough treatments for Australians. Significantly, the industry has agreed in return to deliver \$1.8 billion in PBS savings to the Commonwealth through a series of price reductions to patented medicines. Most importantly, the Government has agreed to set aside these savings in a Contingency Reserve that will be utilised to support new medicines listings on the PBS.

This is the first agreement between industry and a Federal Government since 2010 and will have a significant effect on the confidence of the industry to continue to invest in Australia.

It ends a period of several years of uncertainty for our Members who had seen plenty of changes to the PBS without any of the savings set aside to help pay for more breakthrough therapies for Australians.

The signing of the Strategic Agreement highlights the fundamental role of Medicines Australia as the voice of the innovative medicines industry but also the importance of a strong, trusting relationship between industry and policymakers.

Reform is never easy and the Board recognises that this has come with a level of challenge for our industry, however I believe the right balance has been struck between certainty for industry, savings for taxpayers and access for patients.

I am incredibly proud of the efforts and expertise of the MA Secretariat, Managing Directors and senior policy colleagues from member companies who contributed to the negotiations. The commitment to work together and engage in frank discussions about the future of our industry was impressive and clearly validated what we can achieve when we work together.

And, while we should not underestimate the challenges we still face, I believe as a highly trusted partner in health policy, Medicines Australia is in a good position to offer and deliver genuine solutions.

Leadership at Medicines Australia

2016-17 was a period of change at Medicines Australia with the introduction of a new Chief Executive Milton Catelin and the implementation of a series of reforms recommended by the Board.

I would like to thank Lee Hill, our interim Chief Executive who finished his work at Medicines Australia following the appointment of Mr Catelin in October 2016. A smooth handover from Lee has allowed Milton to drive the reforms of the Board and the Secretariat that will help strengthen Medicines Australia. It has been a running start for Milton who had a leadership role in the discussions around the Strategic Agreement. Milton also led the creation of the Advisory Council whose eminent members, led by Dr Anna Lavelle, are a testament to the reputation of this industry within the broader community. The Advisory Council will provide independent, long-term horizon, strategic advice directly to the Board that will help to shape the direction of the industry and the parameters needed for the industry to succeed well into the future.

These changes have ensured that as an industry body, we are more agile and better equipped to consult, consider and ultimately shape health policy as it is being made.

Thanks

I would like to acknowledge the contribution of my fellow Board Members. I have had the privilege of working alongside an impressive team of passionate Managing Directors who each bring significant experience and a diversity of thought to the industry body. I would also like to thank and pay tribute to those who left during 2016-17. David Gallagher (Pfizer), Geoff McDonald (GSK), James Priour (Amgen) and Paul Spittle (AstraZeneca) have not only given incredible amounts of their time to be part of the Board, but have worked tirelessly in the interests of our members and Australian patients. On behalf of the Board I would like to thank them for their service, support and fearless advice.

Finally, I would like to thank every member of the innovative medicines industry for your passion and commitment to improving the lives of Australians. Across the industry there is a real sense of excitement for our future.

There is no doubt that with the right investment in science, innovation, clinical research and high-tech manufacturing there is a strong belief that our industry has the talent, expertise and experience to lead the way to a brighter future. I look forward to continuing on this journey with all of you.



Mr Wes Cook Chairman Medicines Australia

Chief Executive's report

The 2016/17 financial year represented the culmination of a two year plan to build the reputation of Medicines Australia and the industry, to strengthen our engagement with stakeholders and deliver a more predictable, stable environment for our Members.

Building a strong reputation takes more than one person to achieve, it takes a whole industry to make it happen. From the secretariat, to the Board led by Wes Cook and, most importantly, our members whose dedication and passion for the people that rely on innovative medicines to live longer, healthier lives is a testament to this great industry.

There is no doubt that the direction taken over the last two years has put this industry in a much better position. In fact, the signing of the Strategic Agreement with the Turnbull Government would not have been possible without it.

While the five year agreement may be the headline for the year, we should not forget that 2016/17 was a busy and productive year for Medicines Australia on many other important fronts.

Medicines Australia's achievements

The innovative medicines industry is an important sector for Australia's health, wealth and future prosperity and because of this there are many demands on Medicines Australia to provide policy and thought leadership across a broad range of issues confronting the nation.

We remain committed to our strategic objectives and their focus on improved access and appropriate funding for innovative medicines for all Australians, a better understanding of the value of investing in these treatments, and a vibrant local industry that can invest in research and development.

Medicines Australia delivered more than 20 submissions into various inquiries instigated by the Government in 2016/17. These included reviews into intellectual property (IP) arrangements, pharmacy remuneration and regulation, the R&D tax incentive, Medicines and Medical Devices Review (MMDR) along with the Senate Committee inquiry into the government's related reforms to the Therapeutic Goods Administration (TGA). We collaborated with our Members on these submissions to ensure they reflected the experiences and insights of the companies and I would like to thank all who gave up their own time to contribute.

Medicines Australia will continue to work closely with the Government and Departments to ensure that these reviews and related reforms are implemented in the best interests of our Members and the Australian people.

We want to ensure that registration (TGA) and reimbursement (PBAC and PBS) processes are fit-forpurpose, and are appropriate to meet the challenges of 21st century medicine.

2016/17 also saw Medicines Australia continue work to highlight the value of the sector including our modeling with Prof. Deborah Schofield on the productivity benefits of medicines and our Members' survey on the economic contribution of the industry in Australia.

It was a significant year regarding our Code of Conduct with the beginning of compulsory reporting of transfers of value between our member companies and the doctors they engage with. These improvements to our Code mean we remain at the forefront of global transparency measures and that's something of which the industry should be extremely proud.

Changes to Medicines Australia in 2016-2017

In the lead up to my time as Chief Executive a lot of work was undertaken by the Board and secretariat to reform the way we operate and work for our Members. Since I became Chief Executive I have worked to implement and build on these reforms to create an even more Membercentric organisational and governance structure.

These have been designed to deliver greater oversight and accountability, improve engagement with Members and key stakeholders, and enhance the ability of the Board to be more proactive in shaping the longer-term strategy of Medicines Australia. "There is no doubt that the direction taken over the past two years has put industry in a much better position."

Milton Catelin

These initiatives have included the appointment of an Independent Director to the Medicines Australia Board, the establishment of the Medicines Australia Advisory Council and the establishment of the Chief Executive's Advisory Group.

In addition to this, we've instituted a set of constitutional changes that reduced the size of the Board, in line with best practice.

Internally Medicines Australia has worked hard this year to refine our five year financial model to more accurately predict future outcomes.

Thank you

It has been an exciting year for our industry, and I feel privileged to have been able to contribute to the incredible outcomes we have achieved. I would like to take this opportunity to thank the Board, with a special thank you to Wes Cook as Chair and Dr Anna Lavelle as Deputy Chair.

I also extend my thanks to the staff of Medicines Australia for their commitment, tireless effort and enthusiasm.

And finally, to staff within our member organisations, I would like to thank you for your dedication and irrepressible drive for the betterment of our industry and the health of all Australians. Your passion is inspiring – thank you.



miltonatchis

Milton Catelin Chief Executive Medicines Australia

About Medicines Australia

Board of Directors

The names of each person who has been a director during the year and to the date of this report are:

Medicines Australia Board Members 2016-2017		
Mr Wes Cook	Chair	
Dr Anna Lavelle	Independent Directory & Deputy Chair (appointed 16/12/2016)	
Mr Brad Edwards		
Mr Brian Gladsden		
Mr Bruce Goodwin	(appointed 19/12/2016)	
Mr James Jones		
Ms Melissa McGregor	(appointed 19/12/2016)	
Ms Kirsten O'Doherty		
Mr Svend Petersen		
Departed		
Mr Geoff McDonald	(ceased 01/11/2016)	
Mr James Priour	(ceased 09/12/2016)	
Mr Paul Spittle	(ceased 09/06/2017)	



Mr Wes Cook Medicines Australia Chair Boehringer Ingelheim Pty Ltd Managing Director



Dr Anna Lavelle Independent Directory & Deputy Chair (appointed 16/12/2016)



Mr Brad Edwards Vice President and General Manager ANZ Shire Australia Pty Ltd



Mr Brian Gladsden Country President/ Managing Director Novartis Australia Pty Ltd



Mr Bruce Goodwin Managing Director Janssen-Cilag Pty Ltd



Mr James Jones Managing Director Takeda



Ms Melissa McGregor Managing Director Pfizer Australia Pty Ltd



Ms Kirsten O'Doherty General Manager AbbVie Pty Ltd



Mr Svend Petersen Managing Director Roche Products Pty Ltd

"Our focus has been steadfast in ensuring that Australia has the right policies and environment that make it easier to bring new medicines to Australians who need them."

Wes Cook

Leadership team



Milton Catelin Chief Executive



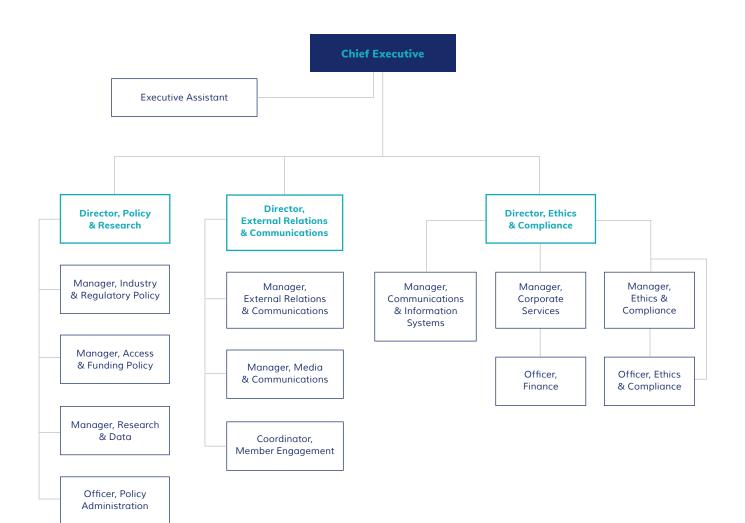
Elizabeth de Somer Director, Policy and Advocacy



James Boyce Director, External Relations and Communications



Deborah Monk Director, Ethics and Compliance



Medicines Australia Membership as at 30 June 2017

Class 1

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

Class 2

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

Class 3

FIT-BioCeuticals Ltd

Medlab Pty Ltd

Class 4

Clinical Research Corporation (CRC) Commercial Eyes Pty Ltd Covance Pty Ltd Farmaforce Pty Ltd Hahn Healthcare Pty Ltd IQnovate Ltd Princeton Health Prospection Pty Ltd Quintiles IMS Pty Ltd (Merged January 2017) Symbion Pty Ltd



Highlights for the 2016/17 Financial Year

"There is no doubt that with the right investment in science, innovation, clinical research and high-tech manufacturing there is a strong belief that our industry has the talent, expertise and experience to lead the way to a brighter future."

Wes Cook

Highlights in 2016/17 Financial Year

The 2017 Strategic Agreement

Following significant preparation during 2016, Medicines Australia entered into formal negotiation for a Strategic Agreement with the Government in early 2017. The newly appointed Minister for Health, Hon. Greg Hunt MP, indicated his desire to reach agreement with the sector over a range of matters. Medicines Australia, on behalf of our members sought to achieve greater policy predictability and certainty for the industry.

Medicines Australia signed a Strategic Agreement with the Australian Government on 27 April 2017 and it was announced with the Budget on 9 May 2017. The Agreement will support ongoing access to the latest innovative medicines for patients and provide much needed stability for the innovative medicines industry. The Strategic Agreement will take effect from 1 July 2017 and expire on 30 June 2022.

The five year agreement will deliver \$1.8 billion in savings that will be reinvested into the supply of medicines, including more breakthrough therapies on the Pharmaceutical Benefits Scheme (PBS). The Agreement also incorporates significant process improvements to update the PBS, as well as measures that will help to accelerate access to the latest medicines for Australian patients.

Australian patients have a world class health system and access to world class medicines. With this common goal, a Strategic Agreement (the Agreement) between the Australian Government and Medicines Australia (MA) as the peak medicines industry body will support the National Medicines Policy and the sustainability of the Pharmaceutical Benefits Scheme.

This Agreement will deliver more certainty for the medicines industry through a stable PBS environment, where funding for new listings is further supported through agreed statutory price reductions for on-patent medicines that are reaching the end of their patent life, and again when these medicines come off patent and become subject to competition.

This certainty will strengthen the medicines ecosystem by encouraging companies to continue to bring innovative, life-changing, medicines to Australia, build partnerships with Australian researchers, and encourage innovator companies to invest in local clinical trials and manufacturing. This will ensure Australia remains at the forefront for the launch of new and innovative medical treatments.

The Agreement is underpinned by the shared principles of:

- Stewardship of the health system, particularly the PBS, and a shared responsibility for its ongoing sustainability;
- Partnership in the delivery of the National Medicines Policy;

- Stability and certainty for the investment in innovative medicines, including recognition;
- The role that a predictable and stable PBS plays in encouraging investment;
- Transparency and efficiency of processes for listing medicines on the PBS; and
- Integrity of Australia's world class health system, including patient safety and high value clinical care.

Working with Government

As the industry association representing the innovative medicines companies Medicines Australia has an important role in fostering a strong, constructive dialogue with the Parliament.

Governments, parliamentarians and departments rely on industry associations to provide sector-wide advice and insights into the benefits and impacts of policy on public access to innovative medicines, investment in local research and Australia's workforce in medical science.

Medicines Australia engages with policymakers on a regular basis through one to one meetings with politicians, parliamentary hearings and inquiries, as well as at relevant functions and events such as the Parliamentary Friends of Medicines group.

During 2016-17, Medicines Australia was able to work with policymakers on a number of important issues that have an impact on our members including, the development of the Strategic Agreement, the review and implementation of reforms to the Therapeutic Goods Administration (TGA), government reviews of the R&D tax incentive and Intellectual Property (IP), and changes to the skilled migration visa program.

Medicines Australia's regular Annual Dinner in the Parliament did not go ahead in 2016-17 as it was replaced by a new annual event named PharmAus to be held for the first time in September 2017. PharmAus brings together a series of events at Parliament on behalf of the Medicines Australia membership and includes a policy symposium and innovation showcase.

PharmAus will give the Parliament a much greater insight into the value of the innovative medicines industry. It will bring together policymakers, industry and the broader health and medical science sectors to discuss the current and future landscape for the industry and the future of access to innovative medicines for Australia.

The policy environment

VALUE

Objective one:

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

Medicines Australia believes it is important to engage a range of stakeholders across the community to discuss the benefits of innovative medicines to creating a healthier and more prosperous society. These stakeholders include not only government and government departments but also health consumer groups and health professionals to develop health, medicines and industry policy.

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

Member Survey

To build on our evidence based advocacy, Medicines Australia reinstated the member survey in 2017. This survey is the first in a series that will capture data from member companies about their economic footprint in Australia. Topics that were covered included the number of clinical trials, local investment and research collaborations, and number and distribution of employees. The report analysing the results is being progressed and will be available in early 2017-18.

University of Sydney – Economic impact of medicines to productivity

During this year, the productivity project commissioned by Medicines Australia and led by Chair and Professor of Health Economics, Deborah Schofield at the University of Sydney, was completed. This research examined how medicines contribute to labour force participation and create broader economic benefits. The project forms part of our seminal work to understand, quantify and advocate for improved value measures and highlights the economic benefits of medicines through increased work force participation and tax revenue; reduced welfare dependence; and increased GDP for the Australian Government.

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.

ACCESS

Objective two:

Australians have early access to new medicines

Medicines Australia has worked with member companies and the Australian Government on a range of ways to improve healthcare outcomes for Australians through timely and affordable access to medicines, not least through the signing of the Strategic Agreement.

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 listings of medicines keeps pace with international best practice.

Improving the regulation of therapeutic goods Sansom Review

The Australian Government responded to the Sansom Review and committed funding in the 2016/17 budget to bring medicines onto the Australian market faster, by up to two years sooner through streamlining of regulations and processes.

A number of Medicines Australia's key recommendations form the centrepiece of these reforms, including:

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

Implementing these changes commenced in early 2017. Medicines Australia has been integral to the reform consultations and provides regular advice to the TGA through the joint TGA - Medicines Australia Industry Working Group, and through multiple submissions to public consultation processes, to ensure that the intent of the reforms meet the expectations of the Government, the Industry and the Community. Medicines Australia will continue to focus on working with the Government as reforms are implemented over the coming years.

Continuing to enhance the operation of the PBS

Access to Medicines Working Group

Medicines Australia re-convened the Access to Medicines Working Group (AMWG), the first such meeting with senior government officials since the signing of the Strategic Agreement. Following the successful signing of the Strategic Agreement, the AMWG will focus on a revised set of priorities as follows:

- Streamlined medicines listing processes The Streamlined Medicines Listing Processes Sub-group will work to improve the efficiency, transparency and timeliness of the PBS listing processes.
- The uptake of biosimilar medicines The Biosimilar Policy Sub-group will review and work towards the development of policies for appropriate uptake and use of biosimilars to create a competitive biosimilars market within Australia;
- Comparator selection The Comparator Selection Sub-group will work towards examining and proposing options to address the new issue of comparator selection.; and
- Section 99ACB/D The 99ACB/D Sub-groups will monitor the implementation of policy solutions through legislative amendments to the National Health Act and assist in developing necessary guidance on the implementation.

Funding for Research into Cancers with Low Survival Rates

Medicines Australia appeared at the Senate Hearing into Funding for Research into Cancers with Low Survival Rates on 8 June in Canberra. MA was supported by representatives from member companies to provide insight into experience from Australia and across the region.

Medicines Australia advocated for:

- establishing a national coordinating office for clinical trials;
- implementing MMDR recommendations speedily; and
- fit for purpose evaluation of medicines to improve access for patients.

Review of Pharmacy Regulation

Medicines Australia worked with members to develop a submission on the Review of Pharmacy Regulation (King Review) including advocating for retaining the varied wholesale supply arrangements rather than a "one size fits all" supply model, and arrangements that support access for patients, and improved cost-effectiveness across other areas of the health system.

FUNDING

Objective three:

Ensure sustainability of funding for prescription medicines

Medicines Australia is a strong advocate for the Pharmaceutical Benefits Scheme (PBS) and its core principal of universal access to subsidised prescription medicines. Through our engagement and advocacy with key stakeholders we seek to collaborate on ways to ensure that funding can not only remain sustainable but also keep up with the rapid developments in medicines. This is further strengthened through arrangements under the Strategic Agreement.

Submission to the Federal Budget

Medicines Australia member companies also 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 Governments 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.

Our Federal Budget Submission called for a number of measures that would make reporting of PBS expenditure more transparent. This included the publishing of the aggregated rebates from companies and reporting PBS expenditure against different areas of the supply chain. The submission also proposed the Government develop measures that take into account the productivity and other gains realised by investing in medicines. This was based on the modeling produced by Prof. Deborah Schofield for Medicines Australia.

INVESTMENT

Objective four:

Australia to become a vibrant pharmaceutical investment worthy destination to increase investment, jobs and economic growth for Australians

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 the R&D tax incentive, clinical trial reforms, skilled migration visas, corporate tax issues, and intellectual property.

Intellectual Property

Medicines Australia continues to advocate for policies that strengthen Intellectual Property (IP) and highlight the benefits to Australia.

Following the Productivity Commission's final report into Australia's IP arrangements released in December 2016, Medicines Australia made a submission advocating for the need to maintain patent term extension and regulatory data protection. Medicines Australia was supported by a member working group in preparing this submission and in advocacy activities. Medicines Australia continued to work with our colleagues from the IFPMA and PhRMA in ensuring developments in the Australian intellectual property environment was understood. Medicines Australia continues advocating for a strong and stable intellectual property system in Australia and looks forward to the Australian Government's response to the Productivity Commissions final report.

During the year Medicines Australia also commissioned research to examine the link between the strength of an IP system and the level of innovation that occurs across ten OECD countries. Work on this research was significantly progressed and will form part of Medicines Australia's advocacy platform for IP.

Skilled Migration Visa Program

A skilled migration program is essential to a global industry such as the innovative medicines sector. It ensures that Australia can continue to benefit from the investment in local medical science as well as important infrastructure such as advanced manufacturing facilities. Workers on skilled visas help to support the Australian workforce by filling skills gaps but also providing knowledge sharing, training and development of local staff.

In April 2017 the Australian Government announced that it was abolishing the 457 skilled migration visa and replacing it with a Temporary Skills Shortage Visa (TSS) as part of comprehensive reforms to the skilled migration program.

The TSS allowed companies in Australia to obtain working visas for workers whose role could be identified on a new occupations list. The list was split into occupations that qualified for either a short term TSS visa or a medium to long term TSS visa.

The initial occupations list disqualified numerous positions that were of critical importance to the local operations of Medicines Australia's members.

Following discussions initiated by Medicines Australia and other representatives of the broader medical science sector, the TSS lists were amended to include a number of occupations directly relevant to the pharmaceutical industry.

Clinical Trial Reforms

Medicines Australia has continued to advocate for tangible clinical trial reform that meets the bipartisan commitments to improve the clinical trial environment in Australia. This includes appearing before the hearing into Research for Cancers with low survival rates, mentioned earlier but also includes supporting a Tele-Trial model and joining a consortium, with the Clinical Oncology Society of Australia (COSA) to roll out the Tele-Trial model to bring clinical trials access to remote and regional Australia.

Medicines Australia has also reinvigorated the Research and Development Taskforce that comprises members from MA and non-member stakeholders. The RDTF are focussing their work plan on the need for harmonised and coordinated clinical trial governance and patient recruitment.

MTPConnect

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, Medicines Australia has partnered with a number of other organisations within the pharmaceutical ecosystem on two projects: the Bridge Program and COSA Tele Trials (above). These two projects highlight Medicines Australia's commitment to contributing to the sector and ensuring that there is further collaboration between Government, industry and peak bodies.

The Bridge Program

The Bridge Program launched in June 2017, with 100 participants from across Australia selected to take part in face-to-face and online training in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to research translation and the commercialisation of medicines.

International Trade Agreements

Medicines Australia made two submissions to parliamentary reviews of international trade agreements. The first was to the Senate standing committee on Foreign Affairs, Defence and Trade References Inquiry into the Trans-Pacific Partnership Agreement. This submission highlighted the importance of aligning our intellectual property system to our other major trading partners, including extending regulatory data protection.

The second submission was to the Joint Committee Inquiry into Australia's Trade and Investment Relationship with the United Kingdom. This submission outlined the need for a principles based approach to the formation of new trade agreements.

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 with other industry associations in making a submission to the R&D tax incentive review led by Innovation and Science Australia (ISA). This submission called for continuation of the tax incentive and for the ISA review to consider how any recommended limitations on the tax incentive will impact 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. Medicines Australia has continued to engage and discuss the R&D Tax Incentive with the Government at regular intervals and awaits its decision. We will continue to engage with the Government and key stakeholders on how Australia might best improve the R&D incentive and other tax provisions to encourage investment, deliver more high-skilled STEM jobs and provide Australians with improved access to medicines.

2016/17 SUBMISSIONS

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

2016

• December

<u>Medicines and Medical Devices Review – Response</u> to TGA's consultation paper 2016 on Comparable <u>Overseas Regulators</u>

December

<u>Medicines and Medical Devices Review – Response to</u> <u>TGA's consultation paper 2016 on Expedited Pathways</u>

November

Response to TGA's Consultation Paper on Orphan Drug Medicines

November

Submission to the Senate Standing Committee on Foreign Affairs, Defence and Trade References Inquiry into the Trans-Pacific Partnership Agreement

• October

R&D Tax incentive Review Report Consultation 2016

September

Review of Pharmacy Remuneration and Regulation Discussion Paper

September

Submission to Senate Inquiry into the Omnibus Bill 2016

2017

• June

MA Submission to the Final Report of the Ezetimibe Post Market Review

April

Medicines Australia Submission to the Joint Committee Inquiry into Australia's Trade and Investment Relationship with the United Kingdom

• March

MA submission to the Select Committee into Funding for Research into Cancers with Low Survival Rates, 31 March 2017

March

Submission to the Senate Committee Inquiry on the Therapeutic Goods Amendment Bill 2016

February

Medicines and Medical Devices Review – Response to TGA's consultation paper on SAS B notifications and Authorised Prescribers Paper

• February

2017-18 Federal Budget Submission for The Innovative Medicines and Vaccines Industry

February

Medicines Australia submission on PC Inquiry into IP Arrangements Final Report

• February

Medicines Australia's submission on the Draft Report of the Ezetimibe Post Market Review

January Submission to the 2017-18 Federal Government Budget

One united voice for our members

Code of Conduct report

On behalf of our members, Medicines Australia's Ethical Conduct activities in 2016-2017 continued to focus on ensuring effective implementation of the Code of Conduct Edition 18.

The Ethics and Compliance team assisted Medicines Australia Member Companies to prepare and publish their first reports under the new transparency model implemented under Code Edition 18. This transparency model continues to demonstrate the Australian innovative medicines industry's leadership in delivering even greater transparency for the Australian community about the support provided to healthcare professionals to engage in educational activities and to compensate healthcare professionals for the valuable expertise and advisory services provided to Member companies.

Medicines Australia member companies remain aligned with global standards by demonstrating high levels of compliance with the Code and an ongoing commitment to improved transparency of interactions with healthcare professionals. Further, members maintained their commitment 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.

TRANSPARENCY REPORTING

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 were made with each healthcare professional's consent to publish the information. On 1 October 2016 reporting became 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 the transparency model covered the period 1 October 2015 to 30 April 2016. On 31 August 2016, 35 Medicines Australia Member Companies published their reports on their Australian corporate websites. These reports showed that of the nearly 9,000 healthcare professionals that the industry engaged during that time, almost two thirds of them consented for those interactions to be reported. The second publication of these reports covering the period 1 May 2016 – 30 October 2016 was made on 28 February 2017 by 33 Medicines Australia Member Companies. During this period, our Member Companies engaged with some 9,000 healthcare professionals, with a consistent two thirds of healthcare professionals giving their consent.

In the lead up to the first publication of these new reports, the Ethics and Compliance team focussed its efforts on communicating with healthcare professionals, as well as healthcare professional and consumer peak organisations. 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.

Third Party Meeting and Symposium Sponsorship Reports

In 2016-2017, the publication of Third Party Meeting and Symposia Sponsorship reports was initiated. Introduced as part of the transparency model in Code of Conduct Edition 18, this report focuses on the Australian innovative medicines industry's sponsorship of educational meetings and symposia organised by third party organisations, such as medical, pharmacy and nursing colleges or societies. The activities captured in this report include where a company has provided a lump sum sponsorship to the event, have financially assisted an institution to hold a journal club, grand round, or in-institution meeting, and the purchase of trade displays in association with an educational event. The reporting periods for this report align with the Payments and Transfers of Value to Healthcare Professionals reports (above), with the reports published on Medicines Australia's website.

There were 1,371 events sponsored by 34 Member companies in the period October 2015 – April 2016, and published on 31 October 2016. The second report was published on 30 April 2017, for the period May 2016 – October 2016, which reported on 1,758 events sponsored by 34 Member companies in that six month period.

Health Consumer Organisation Support Reports

In June 2017 Medicines Australia published the fourth annual reports of Member companies' financial support for Health Consumer Organisations (HCO). Member companies supported 127 different HCOs across Australia in calendar year 2016, ranging from national consumer organisations to small local groups, relating to 368 different projects or events to the total value of \$8,243,903 of support.

COMPLAINTS, APPEALS AND MONITORING

Complaints handling

In 2016-2017, Medicines Australia received six new complaints. This is a decrease from 2015-2016, when nine new complaints were received.

Two of the new complaints received this year were submitted by Member Companies, one complaint received from the Monitoring Committee, and one complaint was submitted by a healthcare professional. Two complaints were not finalised before the end of the financial year.

Of the four new complaints received and finalised in 2016-2017, three were found not in breach of the Code and one complaint was found to be in breach of some aspects of the alleged breaches.

There was one appeal against the Code of Conduct Committee's decisions during the year. The appeal was not upheld.

Details of the complaints considered and finalised in 2016-2017 and the outcomes are reported in the Code of Conduct Annual Report, published on the Medicines Australia website. The outcome of the two complaints not finalised will be published in the July-September Quarterly Report.

Monitoring of Member Company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2016-2017. The Committee undertook five reviews of materials associated with specific therapeutic areas:

- Advertisements, Printed Promotional Material and E-Ads in the Analgesia therapeutic class
- Starter Packs (policies and procedures) in all therapeutic classes
- HCP websites in all therapeutic classes (reviewed over two meetings)
- Advertisements in audio-visual, internet, eNewletters in the Alimentary therapeutic class
- Journals Advertisements in the Ear, Nose, Throat and Eye therapeutic classes

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 2015 and 30 September 2015 reported by 37 companies. One event was referred to the Code of Conduct Committee, outcomes of this complaint can be found in the Code of Conduct Annual Report.

In addition to these reviews, the Monitoring Committee conducted a review of Member companies' policies and procedures relating to the provision of hospitality to healthcare professionals, to confirm Member Companies' compliance with the monetary limit on hospitality provided to healthcare professionals.

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 2016-2017 financial year, 1,951 individual students enrolled in one or more Programs offered under the CEP; of these, 675 enrolled in their first CEP Program. This demonstrates the real value of the CEP to our Members and others. In 2016-2017, 373 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 Greg Peterson, Dr Corinna Dwan and the team at the University of Tasmania who delivered the CEP in 2016-2017 for our Members.

Medicines Australia in the community

SHALOM GAMARADA NGIYANI YANA RESIDENTIAL SCHOLARSHIP PROGRAM

Medicines Australia has funded medical degree scholarships for indigenous students since 2010. Shalom Gamarada began in 2009 and is a college at UNSW which assists with the food and accommodation for the students for the duration of the 6 year medical degree course.

In 2010, Medicines Australia announced its sponsorship of two Indigenous medical students through the Shalom Gamarada Ngiyani Yana Residential Scholarship Program. In 2012, Medicines Australia announced the funding of a further two students, an initiative that has continued yearly. The long-term aim of the program is to increase the number of Aboriginal health professionals who will work in Indigenous communities and help improve their health outcomes. The program results from 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. It commenced with one student moving into Shalom College in January 2005. It has grown rapidly since then and, in 2012, has 24 Indigenous students living at Shalom College under Shalom Gamarada scholarships.



Front row: Deborah Monk; Melissa McGregor, Pfizer; Dr Sean Westbury, Gamarada graduate; Brylie Frost, Gamarada Student; Dr Jenniffer Fiore-Chapman, Staff Specialist, Dubbo Base Hospital; Dr Khyarne Biles, Gamarada Graduate; Dr Colin McClintock, Staff Specialist, Dubbo Base Hospital Back row: Bruce Goodwin, Janssen; Dr Laura Fitzgerald, Gamarada graduate; India Kinsey, Gamarada Student; Luke Walker, Gamarada Student; Milton Catelin; Prof. Tony Kelleher, UNSW Acting Dean of Medicine ; Prof. Brad Frankum, President AMA NSW

Medicines Australia sponsorships:

2010 - Two Students 2011 - Two Students 2012 - Four Students 2013 - Four Students 2014 - Four Students 2015 - Two Students 2016 - Two Students 2017 - Two Students 2018 - One Student

During the 2016/17 financial year, Sean Westbury returned after two years and completed his studies.

AUSTRALIAN CLINICAL TRIALS ALLIANCE

Medicines Australia was a key supporter of the Australian Clinical Trials National tribute and awards Ceremony. Held in May 2017, the awards pay tribute to Australia's outstanding achievements in clinical trials and celebrate International Clinical Trials Day.

BRIDGE PROGRAM

The Bridge Program is a consortium of 15 companies, universities and industry associations aiming to transfer practical skills on pharmaceutical commercialisation through training and direct exposure to industry practitioners.

The Bridge Program aims to address a key barrier in Australia's life sciences sector - lack of commercialisation skills and business acumen across researchers and life science entrepreneurs. Across the innovation ecosystem, start-up businesses struggle to identify and employ managerial talent who possess the necessary business development skills.

Launched in June 2017, the program will select 100 participants annually from across Australia each year for two years. They will take part in face-to-face and online training in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to research translation and the commercialisation of medicines, including a three-day residential study course aligning with the AusBiotech conference. In addition to this, regional information and networking events will be organised for the participants with top pharmaceutical companies operating globally.



Working with our members

Advisory Council (as at 30 June 2017)

Role

Chair
Independent
Industry Rep
Industry Rep
Industry Rep

Member name Dr Anna Lavelle

Catherine McGovern Mark McCrindle David Grainger **Carol Bennett** Dr Jeff Harmer AO Prof Ian Chubb AC David Herd Andrew Carter Nicola Richards

Company

Independent Independent Independent Independent Independent Independent Independent GlaxoSmithKline Commercial Eyes Merck Sharp & Dohme

Chief Executive Group (as at 30 June 2017)

Role
Member

Member name Wade McMonagle Sara Pantzer Michael Smith Chris Stemple Kristin Trace-MacLaren Christian Sellars Mitch Kirkman Louise Graham

Company

AbbVie Amgen AstraZeneca Biogen GlaxoSmithKline Merck Sharp & Dohme Novartis Pfizer

STANDING WORKING GROUPS

Government Working Group (as at 30 June 2017)

Role	Member name	Company
Member	Adrian Dolahenty	Bayer
Member	Amy Hefford	AbbVie (joined May 2017)
Member	James McAdam	Bristol-Myers Squibb
Member	Josh Bihary	Pfizer
Member	Kieran Schneemann	Astra Zeneca
Member	Cameron Milliner	Shire
Member	Penny George	Sanofi Aventis
Member	Peter Murphy	Novartis
Member	Sara Pantzer	Amgen
Member	Josh Bihary	Pfizer (joined May 2017)
Member	Todd Stephenson	Janssen-Cilag
Member	Andrew Thirlwell	Pfizer (departed January 2017)
Member	Kristin Trace-MacLaren	GlaxoSmithKline (departed May 2017)

Oncology Industry Taskforce (as at 30 June 2017)

MemberAdrian DolahentyBayerMemberAlissa BrownSanofiMemberCarlene ToddRoche ProductsMemberCarmel SpiteriMerck Sharp & Dohme (Australia)MemberDavid PullarRoche ProductsMemberGreg CookBristol-Myers SquibbMemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberLouise GrahamPfizerMemberMike SmithBayerMemberMuthew SlabbertBayerMemberPaul LindsayMerck Serono AustraliaMemberPhilip SpiersAstraZenecaMemberPhilip DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSam DevelinGlaxoSmithKlineMemberSam DevelinMagenMemberSean LybrandAmgenMemberSean Lybrand <td< th=""><th>Role</th><th>Member name</th><th>Company</th></td<>	Role	Member name	Company
MemberCarlene ToddRoche ProductsMemberCarmel SpiteriMerck Sharp & Dohme (Australia)MemberDavid PullarRoche ProductsMemberGreg CookBristol-Myers SquibbMemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgen-Cilag	Member	Adrian Dolahenty	Bayer
MemberCarmel SpiteriMerck Sharp & Dohme (Australia)MemberDavid PullarRoche ProductsMemberGreg CookBristol-Myers SquibbMemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMike SmithAstraZenecaMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSara PantzerAmgenMemberSean LybrandAmgen	Member	Alissa Brown	Sanofi
MemberDavid PullarRoche ProductsMemberGreg CookBristol-Myers SquibbMemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSara PantzerAmgenMemberSara LybrandAmgen	Member	Carlene Todd	Roche Products
MemberGreg CookBristol-Myers SquibbMemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMithew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgen	Member	Carmel Spiteri	Merck Sharp & Dohme (Australia)
MemberJodie ThomasNovartisMemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgen	Member	David Pullar	Roche Products
MemberJosie DowneyMerck Sharp & DohmeMemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAngenMemberTodd StephensonJanssen-Cilag	Member	Greg Cook	Bristol-Myers Squibb
MemberKate WebbTakeda PharmaceuticalsMemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilipa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Jodie Thomas	Novartis
MemberKieran SchneemannAstraZenecaMemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilip SpiersAstraZenecaMemberSam DevelinGlaxoSmithKlineMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Josie Downey	Merck Sharp & Dohme
MemberKristina TurnerAbbVieMemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilip SpiersGlaxoSmithKlineMemberSam DevelinGlaxoSmithKlineMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Kate Webb	Takeda Pharmaceuticals
MemberLouise GrahamPfizerMemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilip DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Kieran Schneemann	AstraZeneca
MemberMatthew SlabbertBayerMemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Kristina Turner	AbbVie
MemberMike SmithAstraZenecaMemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandJanssen-Cilag	Member	Louise Graham	Pfizer
MemberPaul LindsayMerck Serono AustraliaMemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Matthew Slabbert	Bayer
MemberPeter MurphyNovartisMemberPhilip SpiersAstraZenecaMemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Mike Smith	AstraZeneca
MemberPhilip SpiersAstraZenecaMemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Paul Lindsay	Merck Serono Australia
MemberPhilippa DelahoyPfizerMemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Peter Murphy	Novartis
MemberSam DevelinGlaxoSmithKlineMemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Philip Spiers	AstraZeneca
MemberSara PantzerAmgenMemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Philippa Delahoy	Pfizer
MemberSean LybrandAmgenMemberTodd StephensonJanssen-Cilag	Member	Sam Develin	GlaxoSmithKline
Member Todd Stephenson Janssen-Cilag	Member	Sara Pantzer	Amgen
	Member	Sean Lybrand	Amgen
Member Wes Cook Boehringer-Ingelheim	Member	Todd Stephenson	Janssen-Cilag
	Member	Wes Cook	Boehringer-Ingelheim

Code Development Project Team (as at 30 June 2017)

Role Chair

Member Member Member

Member name Laurie McAllister

Stuart Englund Jessica Kanevsky Dr Alan Paul

Company

Independent Consultant, former MA Board Member Janssen-Cilag AbbVie AstraZeneca

Central Database Working Group (as at 30 June 2017)

Role
Member

Member name Jon Moody Dr Alan Paul Elyse Quinn Matthew Rees Melanie Seeger Simon Shiels Grant Villaneuva Meredith Kennedy Vanessa Lim

Company

Bristol-Myers Squibb AstraZeneca Novartis Seqirus Celgene Janssen-Cilag AbbVie Roche Products Gilead Servier (departed Sept 2016)

CEP Working Group (as at 30 June 2017)

Role
Member

Member name Aaron Guttmann Ben Warner Cathryn Berry David Schlesinger Martina Ryan Melanie Seeger Sandra Coleman Simon Scott Tracey Payne

Brisol-Myers Squibb Pfizer Amgen AbbVie

Company

AbbVie Janssen-Cilag Celgene Eli Lilly Sanofi Aventis Merck Sharp & Dohme

Future of the Code Working Group (as at 30 June 2017)

Role Member name Company Member AbbVie Jessica Kanevsky Member Dr Alan Paul AstraZeneca Member Lisa Maguire AbbVie Member Dr Jonathan Anderson Brisol-Myers Squibb Member Melanie Seeger Celgene Member Sandi Coleman Eli Lilly Member Amanda Harris Hahn Healthcare Member Flor Sansano iNova Member Scott McIntyre Merck Sharpe & Dohme Member Shane McSpedden Pfizer Member Anna Argyropoulos UCB Member Stuart Englund Janssen-Cilag Member Dr Andrew Weekes GlaxoSmithKline

Health Economics Working Group (HEWG) (as at 30 June 2017)

Role
Deputy Co-Chair
Member

Member name Carlene Todd Greg Cook Geoff Chin Kate Webb Louise Graham Michael Haberl Natalia Price Peter Germanos Sean Lybrand

Company

Roche Products Bristol-Myers Squibb Novartis Takeda Pharmaceuticals Pfizer GlaxoSmithKline AbbVie Boehringer-Ingelheim Amgen

Medicines Australia Vaccines Industry Group (MAVIG) (as at 30 June 2017)

Role	Member name
Deputy Co-Chair	Kristin Trace-MacLaren
Member	Sheryl Page
Member	Lauren Adler
Member	Scott Williams
Member	Helen Concilia
Member	Stuart Harsley
Member	Roger Falconer-Flint
Member	Stephen Richardson
Member	Pirouz Adhami

Company GlaxoSmithKline

GlaxoSmithKline GlaxoSmithKline Pfizer Pfizer CSL CSL AstraZeneca Sanofi Aventis Sanofi Aventis

Regulatory Affairs Working Group (RAWG) (as at 30 June 2017)

Role	Member name	Company
Co-Chair	Sue Alexander	Roche Products
Co-Chair	Helen Critchley	Sanofi Aventis
Member	Brian Hewitt	Pfizer
Member	Carolyn Tucek-Szabo	GlaxoSmithKline
Member	George Lillis	Novartis
Member	Jagdish Ghadge	Shire
Member	Kirpal Kaur	Bristol-Myers Squibb
Member	Mark Rowland	Amgen
Member	Michael Parker	AstraZeneca
Member	Elizabeth Joshi	Bayer (departed Nov 2016)

Members Events

Industry Leader's events

Throughout the past year, and as part of our governance reforms, Managing Directors indicated they would like more opportunities to engage with the Board and for more collaborative engagement on matters of strategic importance to our industry.

In response to this, Medicines Australia designed seven Managing Director events to create such opportunities and to enable attendees to learn from guest speakers and subject matter experts on issues of particular interest to the leaders of Australia's innovative pharmaceutical industry.

We kick started our Board/MD Dinners with Ms Sue MacLeman, CEO of MTPConnect at our February Dinner. Sue discussed her progress in advancing MTPConnent objectives since assuming her role, what the future landscape might look like and how Medicines Australia could work collaboratively with MTPConnect in achieving success.

Other events

28 & 29 MARCH 2017 STRATEGIC AGREEMENT NEGOTIATIONS

Approaching the May Federal Budget saw a great deal of speculation regarding many health related topics. It was appropriate for Medicines Australia to provide a timely update and to invite Managing Directors to an open discussion forum.

25 & 29 MAY 2017 MANAGING DIRECTORS BRIEFING ON STRATEGIC AGREEMENT

Medicines Australia undertook a number of member briefings outlining the five year Strategic Agreement with the Commonwealth Government.

We look forward to expanding on this initiative in 2017-18.

MEDICINES AUSTRALIA STAKEHOLDER MEETING ON PATIENTS AND MEDICINES INFORMATION

On 3 August 2016, Medicines Australia hosted a multilevel Stakeholder Forum to discuss a range of issues relating to the provision of information to Australian health consumers about their medicines. Stakeholders from across the health sector attended, as well as representatives of the Australian Government. The meeting was an important opportunity for Medicines Australia to bring stakeholders together to discuss the key issues and opportunities relating to Consumer Medicine Information (CMI) and the broader policy opportunities relating to provision of adequate information about the safe and effective use of prescription medicines to consumers.

The Objectives of the Meeting were to:

- Build a shared understanding of the different stakeholder perspectives and issues relating to the provision of CMI
- Identify shared, positive and overarching principles for provision of information to consumers
- Explore opportunities and new approaches to provision of information, ensuring the patient is at the centre.

Stakeholders at the meeting determined upon a set of principles that should be used to guide further work in this area.

Medicines Australia agreed to lead a smaller group to further refine the principles and develop a strategy for further progress.





24 MARCH 2017 WOMEN IN LIFE SCIENCES LUNCHEON

Medicines Australia hosted 20 female rising stars and leaders from our member organisations at the second Annual AusBiotech NSW Women in Life Sciences Luncheon. Based on the theme of courage, this event was a fantastic affirmation for women in the STEM industry, an opportunity to highlight key achievements and success stories and engage with a supportive community for women who work in the life sciences.

Medicines Australia would like to thank all those who attended and we look forward to the next time we can host a similar event.

2016 ANNUAL GENERAL MEETING

The 2016 Medicines Australia Annual General Meeting was held on Tuesday, 18 October 2016 at Stage 5 in Macquarie Park Sydney, where members were presented with the Medicines Australia Financial Statements, the Medicines Australia Annual Report and the Medicines Australia Code of Conduct Annual Report.

Following the AGM, Medicines Australia held a Member Briefing where attendees were provided with an opportunity to consider and discuss the outcomes of the Medicines Australia Governance Framework review and the proposals the Board will put to a future meeting of members.

BOARD MEETINGS

MA also hosted a number of Board meetings throughout the 2016/17 financial year:

30 August 2016 Board Meeting

6 December 2016 Board Meeting

22 February 2017 Board Meeting

4-5 April 2017 Board Meeting and Strategic Planning Day

18 October 2017

Annual General Meeting and Board Meeting

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.

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 2016 were presented at an Awards Lunch in March 2017. Guest Speaker 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.

Mr Wes Cook, Managing Director of Boehringer-Ingelheim Australia, represented the Medicines Australia Board at the event. In his speech, Mr Cook 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.

UTAS PRIZE FOR EXCELLENCE

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.

The UTAS Prizes for Excellence were awarded to Ms Alex Pietzsch from Boehringer Ingelheim for Semester One; and to Ms Mandy Brown from GlaxoSmithKline for Semester Two.

Ms Pietzsch (pictured below, at centre) received the award from Professor Gregory Peterson , Head of UMORE and Associate Dean (Research), Faculty of Health, University of Tasmania (below, right) and Medicines Australia Chair Mr Wes Cook (below, left). Ms Brown was unable to attend.





CODE OF CONDUCT AWARD

Finalists for the Code of Conduct Award include all students who achieve the highest mark for Program one, 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 winner of the Code of Conduct Award for 2016 was independent student Dr William Ho (pictured above, at centre), who received the award from Dr John Gullotta (above, right) and Mr Wes Cook (above, left).

CEP ACHIEVEMENT AWARD

CEP Achievement Award winners are the students who achieve the ten highest aggregate marks for the five core programs (out of a possible total aggregate of 500). Program three 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 with Code of Conduct Award recipient Dr William Ho,are:

- Nishant Bakshi– Boehringer-Ingelheim
- Alex Pietzsch Boehringer-Ingelheim
- Judy Edmondson Hahn Healthcare
- Bessy Basso Boehringer-Ingelheim
- Catherine Van Daele Shire
- Matthew Douglas Commercial Eyes
- Irina Savinykh Seqirus
- Lucimar Nielsen AstraZeneca

CEP Achievement Award recipients not present at the awards event:

- Marissa Otley Mundipharma
- Matthew Jones 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.



Better health through research & innovation



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