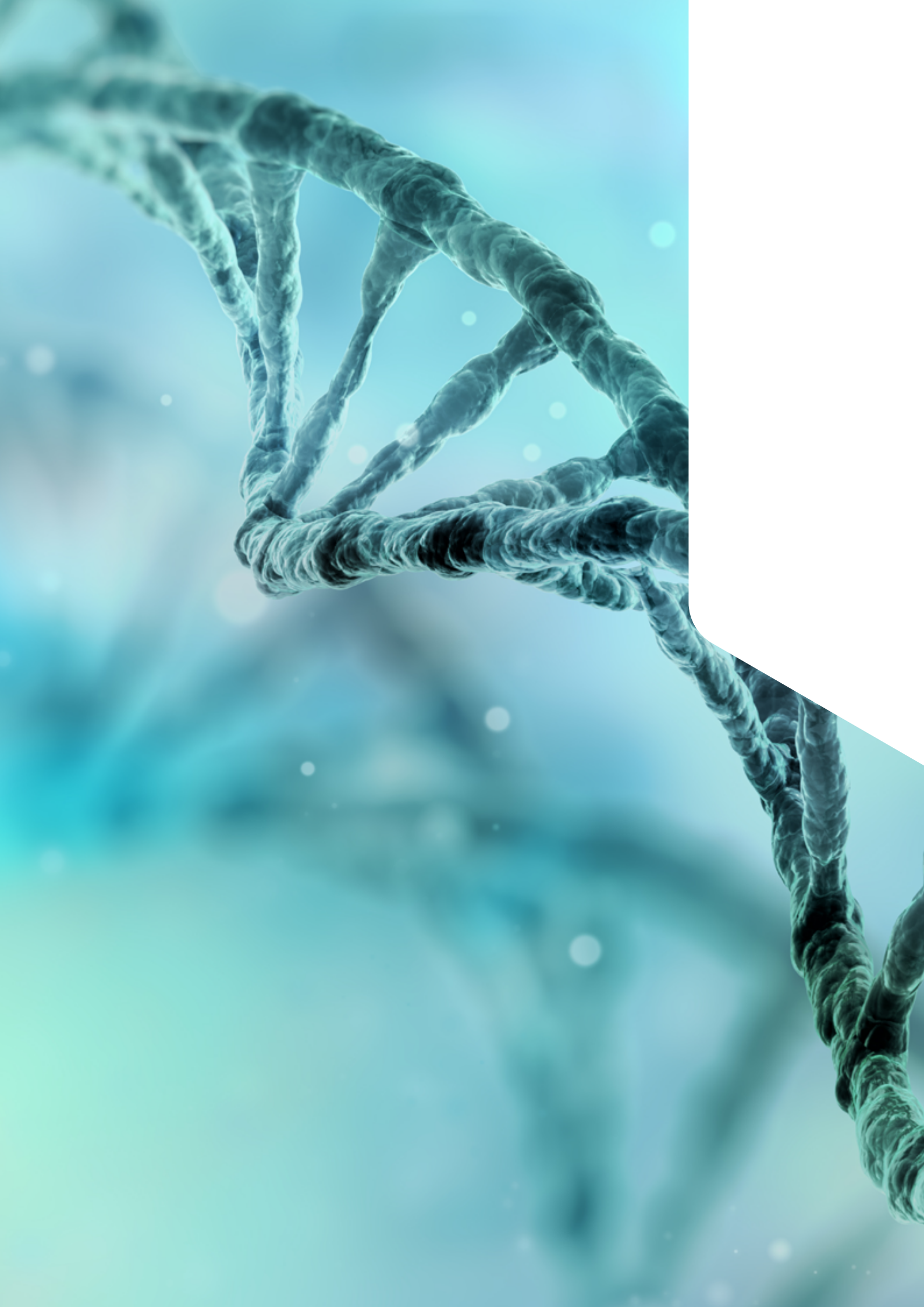


Annual Report

2017-2018



Medicines
Australia



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Medicines Australia vision, mission, leadership, strategic objectives

Vision

For all Australians to have access to world-leading medicines they need, when they need them.

Mission

To work with government and the community to ensure that Australia has universal, subsidised access to treatments that keep pace with advancements in medicine.

Leadership

Medicines Australia is a trusted source for industry information and policy development. We will maintain industry unity and be a voice for outcomes that benefit both industry and the Australian community. We support ethical and transparent business practices of our members in line with the Medicines Australia Code of Conduct.

Strategic Blueprint

1. Build community understanding of the value and benefits (health, social and economic) of new and emerging medicines and vaccines for Australia.
2. Increase investment in the Pharmaceutical Benefits Scheme (PBS) to ensure it can continue to provide Australia's ageing, growing population with universal, subsidised access to the latest innovative medicines that they need when they need them.

Chair's report

It brings me great pleasure to present the 2017-18 Medicines Australia Annual Report. There is no doubt that looking back on our significant achievements, Medicines Australia and member companies have had another momentous 12 months.

We have seen rapid and significant advances in the way medicines are being used to treat and even cure diseases, and in the way our policy environment continues to evolve to meet changing demands. We have witnessed the ongoing and challenging political and policy environment as we advocate for sound and stable health policy to ensure Australians have access to the best, new medicines they need, when they need them. I am again reminded of how proud I am to be part of this incredible industry.

As a leading industry body, we remain committed to working collaboratively with the Government and Opposition to maintain strong and enduring relationships. Medicines Australia has demonstrated this through our sustained engagement with the Minister for Health, the Hon. Greg Hunt MP, the Shadow Minister for Health, the Hon. Catherine King MP and other members of the Liberal, National and Labor Parties, as well as Senator Richard Di Natale and other members of the Greens, minor parties, independents and key stakeholder groups from across the broader policy community. In particular, our increased emphasis on engaging members in economic, finance and industry portfolios has led to a greater recognition of the significant contribution our industry makes to the economy.

With a focus on engagement, we have continued to strengthen our collaboration with the bureaucracy in our partnerships with the Department of Health and enhanced our engagement with other key Departments including the Central Economic Policy Agencies. Today Medicines Australia is considered a trusted partner and an industry body that can offer and deliver genuine policy solutions as demonstrated by the incredibly positive results seen in the Stakeholder Audit released to members early in the year – a dramatic turn-around for our industry.

It is critical that our focus on stakeholder engagement and collaboration be maintained into the future. Together with the Australian Government, we share a common goal to grow the social, health and economic

wellbeing of Australia. By working together to build the best possible operating environment, our aim is to not just be a viable industry, but a vibrant one into the future.

Over the past year Medicines Australia has undergone some structural and personnel changes with the departure of CEO Mr Milton Catelin and the appointment of long-time policy advocate and industry expert Ms Elizabeth de Somer as, firstly interim and then permanent, CEO from April 2018. Medicines Australia would like to thank Mr Catelin for his contributions to our industry during his 18 months in Australia. The organisation has placed a stronger emphasis on staff development and active succession planning as we build for the future, as evidenced by this smooth transition to our new CEO.

A new Board was elected in October 2017 and I was delighted to be offered, and accept, the ongoing role as Chair for the 2017-2018 year to oversee the implementation and completion of the Governance reforms commenced in 2016 to ensure continuity for the organisation. As part of this work, and after careful deliberation, the Board took a decision in July to have the role of Chair held by an Independent Board Member. The membership and broader health industry has warmly welcomed the announcement of Dr Anna Lavelle who brings a wealth of experience into this important role.

I would also like to acknowledge the valuable contributions of all the Board members and particularly thank those Directors who left the Board during this year: Brian Gladsden (Novartis) who served on the Board from October 2015 to October 2017, and Brent Pfeifferberger (Bristol-Myers Squibb) who was elected to the Board in October 2017 and departed in June 2018.

Both Brian and Brent gave considerable time to the Board and Medicines Australia and I would like to thank them on behalf of all our members for their leadership and willingness to contribute to the priorities of the industry.

Key Highlights

The signing of the Strategic Agreement in April 2017 has considerably strengthened the position of our industry as a policy partner with Government and we will take this into future discussions with existing and new Governments in the coming year.

Most particularly the Agreement, underpinned by changes to the National Health Act 1953 (the Act), was struck as a compact with the Commonwealth to provide medicines companies with a more stable and predictable operating environment to facilitate forward planning. Key to the Agreement was the formation of a contingency reserve to ensure savings derived from price related measures would be reinvested into listing new medicines. Importantly, the formation of a Joint Oversight Committee to ensure the intent of the Agreement is met by all parties is a significant win. However this is just the beginning. There is no doubt that as an industry we need to remain focussed on ensuring that the ongoing implementation of the Agreement will further improve the PBS listing processes and the time and quality of decision making for PBS listings.

The early part of the 2017-18 financial year was dedicated to bringing the Agreement into effect through amendments to the Act and, as the legislation was delayed until February this year, much of this work is still ongoing. I would like to thank the Board and our Working Groups and Committees for your tireless efforts in ensuring that these policy issues remain a top priority for both member companies and the government.

In May 2018, the then Treasurer, the Hon Scott Morrison MP delivered a broadly positive Federal Budget for our sector, reflecting a stronger economic outlook and increased revenues, leading to an optimistic forecast on the fiscal outlook for Australia and further reflected in a number of budget commitments.

As we are coming into an election year, Medicines Australia is doubling its efforts to highlight the incredible value our industry represents both within the health portfolio and beyond.

The Ethics and Compliance team has spent the majority of the past year preparing for the next edition of the Medicines Australia Code through the Future of the Code Working Group and have been conducting a series of Member briefings and consultations. We are well on our way to Edition 19 of the Code of Conduct and look forward to being able to share it with you.

We have also made good progress across the policy landscape, for example on the Life Saving Drugs Program where we have achieved greater certainty. MA continues to be energised by the many opportunities to shape the innovative medicines industry in Australia.

Thank you

In closing, on behalf of the Board I would like to thank the Executive team for not just your hard work but your commitment and passion as Medicines Australia continues to meet ongoing challenges. In our journey to be a purpose-led organisation, I am confident that over the next year under the strong leadership of Anna and Liz, Medicines Australia will continue to thrive.

And finally, I would like to thank the staff within our member companies for their incredible contribution to both Medicines Australia Executive and industry. There is no doubt that when the industry is focussed on patients, working together and approaching issues with a united voice, we can achieve great things.

We are incredibly fortunate to be able to tap into a mix of extraordinary talent and experience, coupled with enthusiasm, dedication and passion that is, I believe, unique to our industry and is ultimately driving better outcomes for Australian patients.

Regards

A stylized, handwritten signature in blue ink, consisting of several loops and a long horizontal stroke at the end.

Wes Cook

Chair
Medicines Australia

2017-18 Board of Directors

The Directors during 2017-18 to the date of this Annual Report are:



Mr Wes Cook
Chair

Managing Director
Boehringer Ingelheim Pty Ltd



Dr Anna Lavelle
Independent Director
and Deputy Chair



Ms Anne Belcher

Vice President/General Manager
GlaxoSmithKline Australia
Pty Ltd



Mr Brad Edwards

General Manager ANZ
Shire Australia Pty Limited



Ms Michala Fischer-Hansen

VP and General Manager –
Oceania
Novo Nordisk
Pharmaceuticals
Pty Ltd-Australia



Mr Bruce Goodwin

Managing Director
Janssen-Cilag Pty Limited



Mr James Jones

Managing Director
Takeda Pharmaceuticals
Australia Pty Ltd



Ms Melissa McGregor

Managing Director
Pfizer Australia Pty Ltd

Departed During 2017-18



Ms Kirsten O'Doherty

General Manager
AbbVie Pty Ltd



Mr Svend Petersen

Managing Director
Roche Products Pty Limited



Mr Brian Gladson

Country President/
Managing Director
Novartis Australia Pty Limited



Mr Brent Pfeifferberger

Managing Director Australia/
New Zealand
Bristol-Myers Squibb
Australia Pty Ltd

Medicines Australia Leadership Team



Elizabeth de Somer

Chief Executive Officer, from
June 2018

Director, Policy and Research
until 12 June 2018

Interim CEO April – June 2018



James Boyce

Director, External Relations
& Communications

Until February 2018



Kim Bessell

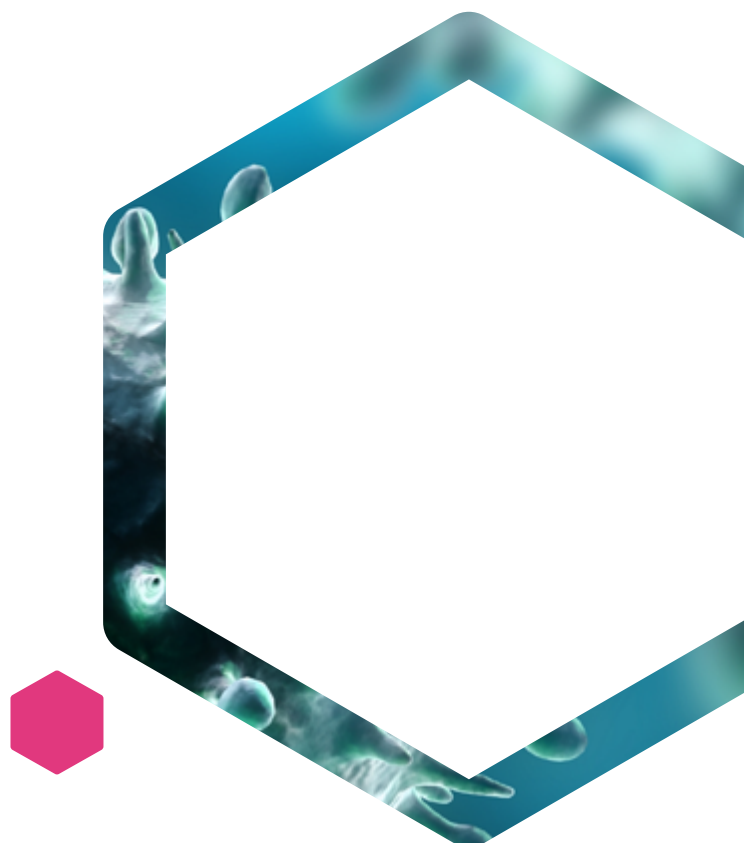
Director Public Affairs

From March – July 2018



Deborah Monk

Director, Ethics and Compliance



Medicines Australia membership as at 30 June 2018

Class 1

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

Class 2

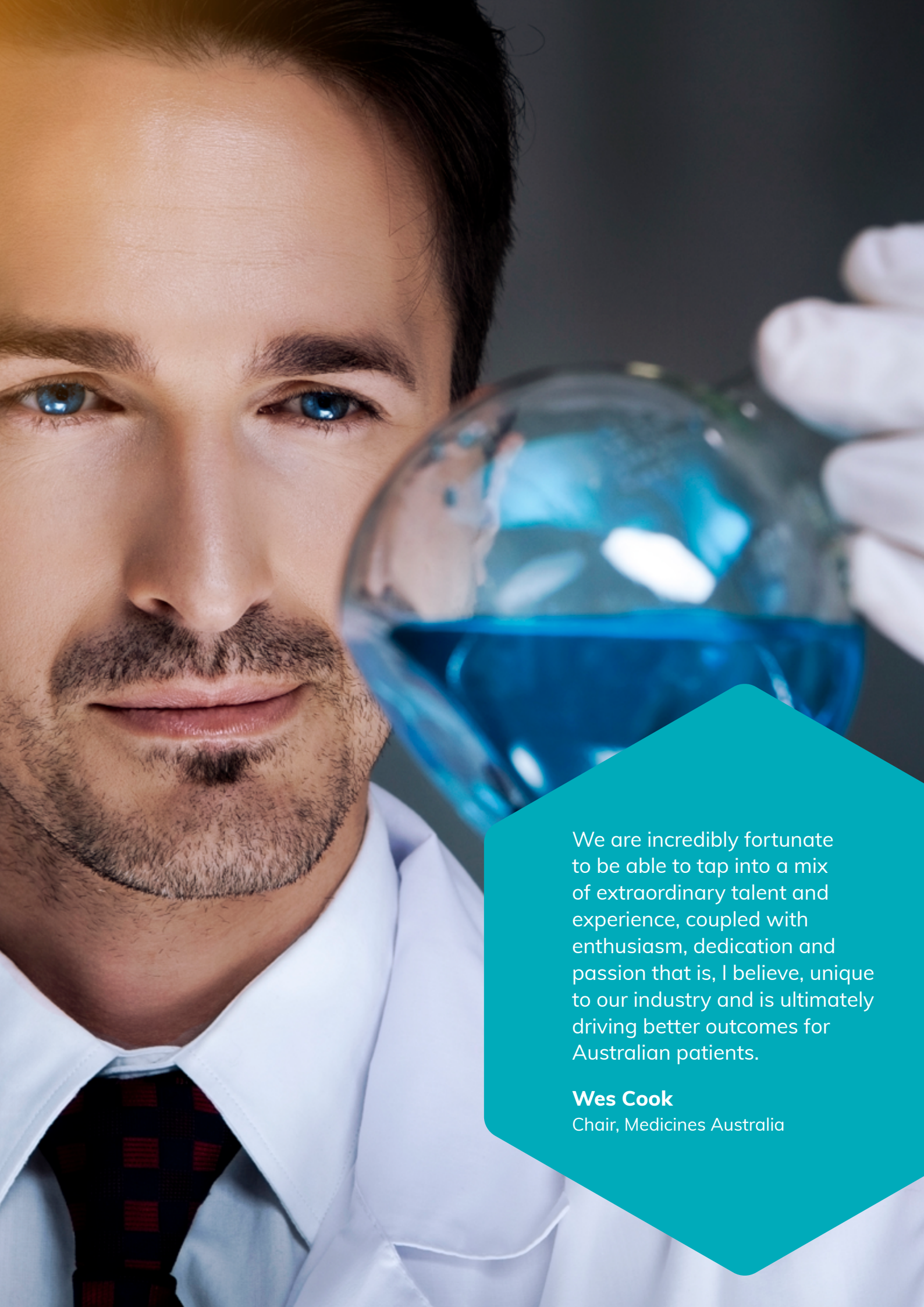
Besins Healthcare Australia Pty Ltd	Pfizer Australia Pty Ltd
Norgine Pty Ltd	

Class 3

FIT-BioCeuticals Ltd	Medlab Pty Ltd
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Class 4

Commercial Eyes Pty Ltd	IQVIA Solutions Pty Ltd
Covance Pty Ltd	Princeton Health
Hahn Healthcare	Prospection Pty Ltd
IQnovate Ltd	Symbion Pty Ltd



We are incredibly fortunate to be able to tap into a mix of extraordinary talent and experience, coupled with enthusiasm, dedication and passion that is, I believe, unique to our industry and is ultimately driving better outcomes for Australian patients.

Wes Cook

Chair, Medicines Australia

Highlights in 2017-18

Working with Government and the Parliament

Australian Chamber of Commerce and Industry (ACCI) Health Industry Forum, August 2017

This was an inaugural exclusive event hosted by ACCI with The Hon Dr David Gillespie MP, Assistant Minister for Health, and was well attended by the health sector including some of our Members. Assistant Minister for Health, Dr Gillespie provided an update on clinical trial reforms and assured the attendees that the Government remains committed to seeing the reforms realised. It is clear that the challenges arise from the need for support across all the states and territories.

Mr Gillespie also highlighted the importance of data for decision making, to improve health outcomes and sent a pointed message to everyone that the Government wants more areas of health expenditure to be subject to the same kind of evidence-based rigour that applies to the innovative medicines industry.

Bennelong Health Forum

In December 2017, Medicines Australia, in conjunction with the Labor Party, hosted the Bennelong Health Forum with Labor candidate Kristina Keneally. This event provided staff of the innovative pharmaceutical companies in the Bennelong electorate to meet with Ms Keneally and hear first-hand her views of our industry, its future in Bennelong as well as the health and industry policy platform of the Labor party should it form a future government.

Bennelong Breakfast Briefing

Medicines Australia sponsored a Liberal Party event ahead of the Bennelong by-election for their candidate John Alexander in December 2017. This event enabled attendees to hear from the Government about their agenda for the innovative medicines industry and what they will do to support the Bennelong member companies and their staff.

Parliamentary Friends of Medicines

In May 2018, Medicines Australia attended the Parliamentary Friends of Medicines event at Parliament House. Also in attendance were Mr John Alexander MP Member for Bennelong and Dr Mike Freelander MP Member for Macarthur. The topic discussed was 'Giving

Australians with cancer faster access to life-saving immunotherapy treatments'. Presentations included: an overview of immunotherapy treatments, and the importance of providing faster access to immunotherapy treatments for patients.

Parliamentary Staffers Drinks

In July 2018, Medicines Australia hosted its inaugural networking drinks for parliamentary staffers. The drinks were well attended by over 100 guests from all political parties. Medicines Australia is grateful to the numerous personnel from Member companies for their support and assistance at this event. Medicines Australia runs events such as this to ensure we are engaging with all levels and all political parties.

Bio 2018

In June 2018, Medicines Australia participated in the BIO International Convention, which is hosted each year by the Biotechnology Innovation Organization (BIO), as part of an Australian contingent comprising Medicines Australia, AusBiotech, MTPConnect, representatives of the Australian government and many members of industry – about 300 Australian biotechnology representatives in total.

It was gratifying to see a strong representation from State and Federal Government with the Federal Minister for Health, the Hon Greg Hunt MP, Queensland Premier Anastacia Palaszczuk and Queensland Minister Kate Jones, the Hon John Brumby representing Victoria and a large number of Australians from the sector from early start-up companies to the major innovative pharmaceutical companies in attendance.

Of particular highlight was where Minister Hunt and the Secretary of Health Glenys Beauchamp held a number of significant round table meetings with senior pharmaceutical executives and global heads of our Member companies. The Minister listened to their issues and committed his Department to work with Medicines Australia to consider and resolve many of them. Medicines Australia looks forward to sharing these projects with Members in the coming months as they progress.

CEO Elizabeth de Somer was invited to join a panel discussion at BIO 2018 on the regulation of biosimilars and was able to describe the challenges and opportunities from creating a competitive biosimilar market in Australia, balanced with the ability to bring innovative biologics to market. The other speakers were from Brazil, South Korea and the USA.

The Policy environment

Strategic Objective:

Increase investment in the Pharmaceutical Benefits Scheme (PBS) to ensure it can continue to provide Australia's ageing, growing population with universal, subsidised access to the latest innovative medicines that they need when they need them.

The Strategic Agreement implementation progress

The *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018* (the Act) amended the *National Health Act* to implement measures negotiated with Medicines Australia as part of the Strategic Agreement (the Agreement) on behalf of the innovative pharmaceutical industry and announced in the 2017 Budget.

Medicines Australia has since worked with the Department of Health (the Department) on the implementation of the measures in the Agreement aimed at reducing PBAC submission churn and improving the time to listing medicines. Much of this work will be ongoing through the Access to Medicines Working Group (AMWG), which has spent a considerable time throughout the year developing streamlined pathways for PBS listing applications and important improvements to the pre- and post-PBAC listing processes. Other measures of significant importance relate to the ability to seek concessions on statutory price reductions (SPRs) and the development of a contingency reserve to ensure savings delivered are preserved for investment in new medicines on the PBS.

The passing of the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* was another notable achievement. This Act provides the legislative amendments that will allow the TGA to utilise the work of comparable overseas regulators in the course of making assessments without compromising patient safety. Medicines Australia has also worked with the Department on the implementation of the Therapeutic Goods Administration (TGA) provisional and priority review pathways which resulted this year with the first priority review designation and a rapid registration success.

These pieces of legislation have potential to create a far more efficient system for companies to introduce new products to the Australian market. The TGA legislation delivers a long-standing legislative reform priority that

Medicines Australia has been advocating strongly to politicians on all sides of politics to deliver for nearly a decade.

Key legislative reforms relating to the Strategic Agreement

Feb 2018 – Passing of the *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018*. This Act amended the *National Health Act* to implement measures negotiated with Medicines Australia on behalf of the innovative pharmaceutical industry and announced in the 2017 Budget

March 2018 – The second set of legislative changes (passed on 15 February 2018) to implement the Medicines and Medical Devices Review (MMDR) received Royal Assent and therefore became law on 5 March 2018. These changes focused on a provisional approval pathway for prescription medicines and reforms to the regulation of therapeutic goods advertising and complementary medicines.

Ministerial Discretion Guidelines

In April 2018, a key milestone for industry was reached with the Department of Health advising Medicines Australia that the Guidelines for applying for Ministerial Discretion were approved.

Following that, the Department of Health published Guidance material on Anniversary Price Reductions and Ministerial Discretion arrangements, (refer to the [PBS Pricing webpage](#)). This includes the lists of medicines that took 10 and 15 year Anniversary Price Reductions on 1 June 2018.

In late 2017, less than six months after signing the Agreement, the Government approached Medicines Australia with several new and important consultations that were not foreshadowed during the Agreement negotiation.

The first was seeking a compact on the processes and administration of the Life Saving Drugs Program (LSDP).

The second was a proposal to revise the payment arrangements for PBS listed medicines through the supply chain to eliminate the payment of rebates caused by the differential between published PBS list price and confidential PBS net effective price. The purpose of eliminating the rebates from Government accounting aims to resolve a reporting issue for the Finance Department which distorts revenue and expenditure figures against GDP in the budget. The accumulating level of rebates highlighted this as an issue for Government.

Finally, the Department proposed to increase cost recovery for PBS listing processes, to establish 100% cost recovery processes, increase the fees to cover costs more fully, to eliminate any shortfall between activity and revenue and to introduce new, previously unrecovered fees.

Despite the surprise nature of these new proposals, the Medicines Australia Board, echoed in the strategic priorities, determined to be a constructive partner and to participate in good faith in the consultations with the Department.

LSDP Compact

Following extensive consultation with Member (rare-disease) companies that have products on the LSDP (and including non-Member rare disease companies) the Medicines Australia Board endorsed the signing of a compact with the Commonwealth on the administration of the LSDP. The purpose of the LSDP Agreement is intended to ensure the future sustainability of the program and introduces a range of administrative and pricing changes that mirror PBS measures. The compact also introduces an expert panel to provide advice on the listing of medicines on the LSDP and includes improvements to processes and timeframes. The implementation of these changes is ongoing.

Access to Medicines Working Group (AMWG)

Medicines Australia and the Department of Health reinvigorated the AMWG with the aim of working more effectively together to consider issues impacting the timely and appropriate access to new medicines through the PBS. The AMWG met three times this year – in July 2017, October 2017 and February 2018.

In 2017, it was agreed to consult through the AMWG to address priorities of the Agreement; streamlined PBS processes, transparency & efficiencies, comparator selection, and biosimilars policy.

Streamlined PBS processes

A key activity of the AMWG during 2017, as previously mentioned, was the development of new pathways for PBAC consideration of medicines for PBS listing. A revised pathways framework was proposed to the Minister for Health in line with the Agreement and these will be consulted on and implemented in the ensuing years.

Comparator Selection Subgroup

The Comparator Selection subgroup considers the growing misalignment between the intent of the PBS Reform and application of the lowest cost comparator selection from the multi-brand and commodity market. This year the Subgroup focused on issues affecting the selection of comparators for new medicines.

AMWG / GMWG PBS Transparency and Efficiencies Subgroup

This combined Subgroup works towards improvements to the PBAC evaluation and PBS listing process to improve their efficiency and transparency, which will contribute to the timely availability of medicines. Consultation continued on revised cost recovery proposals to better reflect the real costs of activity within PBS processes and consultation with the streamlining pathways project for any changes that arise from that work.

AMWG / GMWG Biosimilar Policy Subgroup

This combined Subgroup considers ways to support the formation of a functioning and competitive biosimilar market in Australia, assesses the impact of current biosimilar policy within the Australian market and aligning with principles of the National Medicines Policy and Strategic Agreements. The Subgroup discussed biosimilar policy including PBS data, uptake drivers and active ingredient prescribing to support biosimilar uptake; its work continues on ways to measure the impact of policies supporting biosimilar uptake.

Supply chain; reforms to payment arrangements for medicines with SPA

Medicines Australia has spent a great deal of time over the past financial year working through proposals for changes to the Supply Chain payment arrangements. It is critical to ensure that we balance the needs of the industry, broader stakeholders, patients with the stated intent of Government.

Medicines Australia engaged PWC to examine the cost, process and accounting implications associated with all the proposals being considered. These were shared with Members and provided to the Minister and the Departments of Health and Finance. The information highlights the significant complexities with the proposed changes and confirmed that the initial proposed 1 July 2018 implementation of a trial programme was unfeasible. Without sufficient time for medicines

manufacturers to implement the extensive and necessary changes and systems for effective operation of the medicines supply chain, there was significant risk that unintended consequences to Australian patients could occur – such as medicines shortages. We were pleased when the Government agreed to delay implementation of the proposals in response to our concerns. This consultation is ongoing.

Cost recovery proposals

In February 2018, the Department invited Medicines Australia and GBMA to review updated cost recovery proposals for PBS listing processes, for implementation in July 2018. Whilst the industry broadly support a cost recovery model, the quantum, timeframe for implementation, and impact of the proposals were significant. Medicines Australia reiterated the need for appropriate consultation and reasonable timeframes for business planning and indicated that the Department needed to deliver greater transparency and process to justify the proposed increases. The Government agreed to delay revised cost recovery fees until 2019 and agreed to further consultation. This consultation process is ongoing.

Market Access and Policy: Updates, Learnings & Insights

This Medicines Australia Health Economics Working Group (HEWG) Workshop provided attendees with updates, insights and shared learning opportunities, as well as to identify topics and issues that Medicines Australia may seek to raise with the Department of Health, or potentially use to design future, education sessions for Industry in collaboration with the Department

Improving Information to Clinicians on Access to Unapproved Medicines and Indications.

The HEWG once again met in Feb 2018 – to consider options to enable appropriate information on compassionate access programmes to be more accessible to clinicians.

Medicines and Medical Devices Review (MMDR) – key outputs and highlights 2017-18

The Medicines Australia Regulatory Affairs Working Group has collaborated closely with TGA on MMDR implementation and the TGA Bill No. 2 (Proposed fees and charges; number of priority applications; provisional approval; GMP; PI leaflets & CMI) and the Code of Conduct. The Priority Review Pathway was implemented in July 2017 as part of the MMDR reforms. Work continues on the Black Triangle Scheme in promotional material, Medicines Shortages, PI reformat and Orphan drugs.

Medicines Australia had representatives attend both the TGA-Industry Working Group on GMP and Prescription Medicines Industry Working Group, in our continued collaboration with the TGA:

- We contributed ten (10) submissions in response to TGA's targeted consultation papers (this excludes responses made to targeted consultations on guidances)
- Medicines Australia was invited to, and participated in, three TGA targeted workshops
- We responded to six TGA public consultation papers,
- Medicines Australia made a submission to and appeared before a Senate Committee Inquiry examining the first MMDR Bill (March 2017), which ultimately recommended the Bill be passed and saw Priority Review made a reality
- Medicines Australia was consulted by the TGA on Exposure Draft Bills leading to the eventual enactment into law of provisional approval (September 2017)
- We made a submission to the Senate Committee Inquiry into the second MMDR Bill (January 2018).

In less than 18 months since the Australian Government announced its response to the MMDR, we now have:

- two expedited regulatory approval pathways (Priority Review (effective from 1 July 2017) and provisional approval
- simplified notifications procedures
- the potential to use reports from Comparable Overseas Regulators
- streamlined and efficient Special Access Schemes
- revised orphan designations criteria
- reforms to the non-prescription advertising rules
- scheduling policy reforms, and enhanced post-market monitoring.

TGA – Key Outputs and highlights

Medicines Australia was involved in a number of submissions on the regulation of therapeutic goods including:

- The response to the Therapeutic Goods Administration “Nomenclature of Biological Medicines” Consultation Paper (Sept 2017). In this submission Medicines Australia highlighted support for the Medicines Australia Board-endorsed position with regard to biological medicines that states “an effective system of pharmacovigilance relies upon the ability to distinguish every biologic medicine, including every biosimilar, through unique identification mechanisms”
- Proposal to change the current Good Manufacturing Practice (GMP) fees and charges (March 2018). Medicines Australia has been working with the TGA to improve standards and services in the area of GMP (considering recent changes to fees and charges), including the increased ability for the TGA to leverage off comparable overseas regulators, target evaluation times and measurement of improvements in relation to the evaluation of GMP Clearance applications.

Shortages legislation

Medicines Australia has welcomed the introduction of the *Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018* into the Parliament on 28 June 2018.

This Bill was the culmination of working together with the sector to review the issue of medicines shortages in Australia. The Medicines Partnership of Australia and a broader group of stakeholders, led by the Therapeutic Goods Administration, have developed a comprehensive protocol, which is being implemented through this legislation.

Joint Standing Committee on Treaties (JSCOT) review of TPP-11 – Medicines Australia appearance

Medicines Australia provided a submission to the ‘Joint Standing Committee on Treaties Inquiry into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11) (April 2018)’. Medicines Australia strongly supports the principles underlying free trade and recommended in our submission that any expansion of the TPP 11 should revisit the need for stronger IP provisions including: strengthening regulatory data protection, and ensuring a strong and enforceable patent notification scheme.

In June 2018, Medicines Australia made an appearance before the JSCOT in relation to our submission regarding the TPP-11. Medicines Australia reiterated its support for better and more enforceable patent notification and longer periods of data exclusivity in the context of all trade agreements, including the soon to be negotiated EU-Australia FTA.

Red Tape Reduction

Medicines Australia provided a submission to the ‘Select Committee on Red Tape Inquiry into the effect of red tape on health services (Jan 2018)’. Medicines Australia reiterated its support for further reduction of red tape in areas such as:

- Clinical trials – harmonisation of and more efficient regulatory processes for approval for clinical trials, faster patient recruitment, lower clinical research costs
- Payroll tax – reduce the rate of payroll tax for STEM graduates who are working in identified innovative industries such as pharmaceuticals
- Health Technology Assessment – patient access to cost-effective health technologies, keeping pace with evolving technologies and HTA processes
- Harmonisation of all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public
- Communication between regulators
- Key Performance Indicators at the Commonwealth level
- Sunsetting of regulations.

Medicines Australia, in addition to Member company Roche, appeared at the public hearing of the Senate Select Committee’s inquiry into the effect of red tape on health services in Canberra in February 2018.

457 Visa Advocacy

In June 2017, Minister for Home Affairs, the Hon Peter Dutton MP announced changes to the Skilled Migration list that will allow our industry to once again, source talent on a global scale.

Since the government’s initial announcement in April 2017, Medicines Australia and member companies had worked proactively with the Department of Immigration, Minister Dutton and his Ministerial Office and other advocates to address what were clearly unforeseen consequences of changes to Australia’s skilled migration program.

Intellectual property and International trade

Medicines Australia continues to develop policies to strengthen intellectual property and highlight the benefits to Australians, the economy, research and development and increased access to life-changing and life-saving medicines for Australian patients. Medicines Australia made a submission to IP Australia on the 'Public consultation regarding several IP policy matters (Nov 2017)'. These were:

- Amending the inventive step requirements for Australian patents
- Introducing an Objects clause into the Patents Act 1990
- Amending the provisions for Crown use of patents and designs
- Amending the provisions for compulsory licensing of patents.

In implementing the Government's response to the Productivity Commission's 2016 report, Medicines Australia urged IP Australia to recognise that a strong, effective and stable IP system is critical to fostering pharmaceutical innovation, investment, productivity and competitiveness.

Medicines Australia is looking forward to working with Government, Member companies and our key stakeholders to continue to offer Australians fast access to the latest medicines subsidised through the PBS.

VALUE

Strategic Objective:

Build community understanding of the value and benefits (health, social and economic) of new and emerging medicines and vaccines for Australia.

Clinical Trials

Medicines Australia is a member of the Clinical Trial Collaborative Forum which met in May 2018. Medicines Australia was tasked in this meeting to develop a standard confidentiality agreement template in collaboration with the NSW Office for Health and Medical Research. With significant input from Medicines Australia Members, in particular members of the Research and Development Taskforce, the templates are now being developed by the NSW Department.

COSA Australasian Tele-Trial model Initiative

Medicines Australia, along with representatives from several of its Member companies are involved in the COSA tele-trials project. The project will implement a feasible and effective tele-health strategy to increase access to clinical trials closer to home, while at the same time ensuring the proper conduct of cancer clinical trials. Consortia partners in addition to Medicines Australia include its Member companies, AbbVie Pty Ltd, Janssen, Novartis Pharmaceuticals Australia Pty Ltd, Pfizer Australia Pty Ltd, as well as MTPConnect, Rare Cancers Australia, Cancer Voices Australia, Australian Institute of Tropical Health and Medicine (AITHM), the Garvan Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research (WEHI), Icon Group, c/-Icon Consolidated Holdings P/L and St John of God Hospital.

Medicines Australia is an active participant on the Executive Committee and Steering Committee for the project through which Medicines Australia has also convened a small standing group of industry experts called the 'Medicines Australia Industry Advisory Group' to lend technical level assistance to the COSA project. Members include Helen Aunedi (Roche), Tyron Johnson (Eli Lilly) and Majella O'Leary (Pfizer). Medicines Australia has been tasked to facilitate the development of a standard Clinical Trial Research Agreement (CTRA) that enables tele-trials to be conducted, as well as a subcontract for use between the primary and satellite sites.

2018 Bridge Program Launch

The Bridge Program 2018 was launched in Melbourne on Monday 9 April 2018. The Program launch was well attended, with 98 participants across Australia participating in this competitive program. Now entering its second year, the Bridge Program aims to boost the commercial outputs of Australian pharmaceutical research, by improving the quality and quantity of commercial deals that arise from Australia's pharmaceutical research sector and deepening collaboration between Australian researchers, venture capitalists, research institutes and global pharmaceutical companies.

GBMA education stakeholder engagement

Medicines Australia, as a key stakeholder, along with other representatives from the medical, pharmacy, industry and consumer representative bodies and the Department of Health is a member of the GBMA Education Limited Biosimilar Education Stakeholder Group. The Group was formed to advise GBMA Education on its plan and materials for the Biosimilar Education Grant activities for 2018-19. A number of Medicines Australia member companies, through the Medicines Australia Biologics and Biosimilars Issues Group, have been involved as part of the engagement process, providing valuable input and feedback on the content of the various education materials being developed.

Review of Pharmacy Remuneration and Regulation

Medicines Australia worked with members to develop a submission to the Review of Pharmacy Remuneration and Regulation's Interim Report (July 2017). Medicines Australia commended the Review and its aim to provide recommendations to support future Government decisions on the remuneration and regulation of community pharmacy. Medicines Australia also supported achieving arrangements which are transparently cost-effective for Government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines.

Community Service Obligation consultation

The Department of Health commenced a review of the current CSO Funding Pool obligations for CSO Distributors. The review sought to identify opportunities for the CSO Funding Pool to better support the objectives set out in the Sixth Community Pharmacy Agreement, the National Medicines Policy and broader Government priorities that seek to improve access to medicines. Medicines Australia provided a submission to this consultation 'Consultation on the Community Service Obligation (CSO) funding pool obligations (June 2018)'. Medicines Australia reiterated support for timely access to medicines for all patients including the most efficient distribution models, which includes support for manufacturers' ability to distribute medicines directly to pharmacies.



Submissions made in 2017-18

- Submission to the Review of Pharmacy Remuneration and Regulation's Interim Report (July 2017)
- Response to TGA Consultation on proposed Schedule 3 Advertising Reforms and Advertising Code (October 2017)
- Development of a Framework for Secondary Use of My Health Record (MHR) Data Public Consultation Paper (November 2017)
- Public consultation regarding several Intellectual Property policy matters (November 2017)
- 2018-2019 Federal Budget Submission for the Innovative Medicines and Vaccines Industry (November 2017)
- Select Committee on Red Tape Inquiry into the effect of red tape on health services (January 2018)
- Input into the Department of Health guidelines for industry to support the PBS legislation enacting new statutory price reductions outlined in the Strategic Agreement.
- Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response (March 2018)
- Response to the TGA public Consultation on the Management and Communication of Medicines Shortages (March 2018)
- Response to TGA Proposal to change the current Good Manufacturing Practice (GMP) fees and charges (March 2018)
- Review of proposed Guidelines for Ministerial Discretion and draft Application Form (March 2018)
- Joint Standing Committee on Treaties Inquiry into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11) (April 2018)
- Consultation on the Community Service Obligation (CSO) funding pool obligations (June 2018)
- Options for the implementation of a claimer for efficacy assessed non-prescription medicines (June 2018).



To view any of these submissions, please visit:

www.medicinesaustralia.com.au/policy/publications/submissions/

Code of Conduct report

The Year in Review

Medicines Australia Member Companies remain aligned with global standards of ethical conduct by demonstrating high levels of compliance with the Code

The Ethics and Compliance team assisted Medicines Australia Member Companies to prepare and publish their reports on the payments and transfers of value made to healthcare professionals. From 1 October 2016, companies must not make a payment or transfer of value to a healthcare professional without the healthcare professional having the reasonable expectation of the disclosure of that information. 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. Making these activities transparent reinforces the value of the engagement and the appropriateness of compensating healthcare professionals for their valuable expertise and advisory services provided to Member Companies.

Medicines Australia's Ethical Conduct activities in 2017-2018 continued to focus on ensuring ongoing implementation of Code of Conduct Edition 18, which

has been effective since it was authorised by the ACCC in May 2015. The Ethics and Compliance team also established the Future of the Code Working Group in mid-2017 to conduct a thorough review of the Code and recommend its future direction.

Complaints, Appeals and Monitoring

Complaints handling

Medicines Australia considered six complaints in 2017-2018, with all complaints finalised before the end of the financial year. The number of complaints received by Medicines Australia remains static year on year.

As shown in the table below, three complaints lodged in 2017-2018 were received against a non-member company. In accordance with Section 25 of Edition 18 of the Code, Medicines Australia invited the non-member to have the complaint adjudicated by the Code of Conduct Committee. In each instance, the non-member company declined that invitation. Medicines Australia exercised its right to refer the complaints to the Therapeutic Goods Administration (TGA) for its adjudication.

Complaint	Subject Company	Complainant	Outcome
1142	Medicines Australia Member Company	Healthcare Professional	No Breach
1143	Medicines Australia Member Company	Non-Member Company	No Breach (appeal not upheld)
1144	Non-Member Company	Medicines Australia Member Company	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA
1145	Medicines Australia Member Company	Medicines Australia Member Company	Breach
1146	Non-Member Company	Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA
1147	Non-Member Company	Healthcare Professional	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Complaint referred to TGA

Monitoring of Member Company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2017-2018. The Committee undertook five reviews of materials associated with specific therapeutic areas. The Monitoring Committee also undertook a review of Member Companies' HCO Support reports. 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.

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 to enable their participation in educational meetings and symposia and any honoraria, sitting or consulting fees. From 1 October 2016, 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 reasonably expects the information to be disclosed.

In 2017-2018 Medicines Australia Member Companies published reports on their Australian corporate websites which detailed activities for the periods 1 November 2016 – 30 April 2017 and 1 May 2017 – 31 October 2017. These were the first full reporting periods in which 'mandatory' reporting by companies was in effect. It is expected that a diminishing number of interactions were contracted during the period where healthcare professionals had provided consent for these data to be published, and the associated payments or transfers of value were made in a later reporting period. Therefore, these data were reported in aggregate where consent was not granted.

Central Reporting System

Medicines Australia completed its investigations into the establishment of a Central Reporting System and following a robust tender process Pacific Commerce Pty Ltd were engaged to build and implement a system to publish these data. Pacific Commerce Pty Ltd demonstrated they met the criteria described in the tender and could further enhance the system by providing their own secure data hosting facility in Sydney with the necessary infrastructure already in

place, and proactive systems for monitoring, daily back up and solid rotation, and clearly defined response times for any critical issues. Medicines Australia is in the processes of developing statements to assist members in obtaining consent from healthcare professionals to have their data collected and reported in the new system.

Third Party Meeting and Symposium Sponsorship Reports

Medicines Australia Member Companies continue to publish Third Party Meeting and Symposia Sponsorship reports. 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). The reports are published on Medicines Australia's website.

Reports published on 31 October 2017 showed that there were 1,302 events sponsored by 33 Member companies in the period 1 November 2016 – 30 April 2017. On 30 April 2018, Member Companies published reports for the period May 2017 – October 2017, which reported on 1,898 events sponsored by 33 Member companies in that six month period.

Health Consumer Organisation Support Reports

In June 2018 Medicines Australia published the fifth annual reports of Member Companies' financial support for Health Consumer Organisations (HCO). Member companies supported 210 different HCOs across Australia in calendar year 2017, ranging from national consumer organisations to small local groups, relating to 357 different projects or events to the total value of \$7,679,389 of support.

Communication and Training Activities

Medicines Australia regularly engages in communication activities to raise awareness, promote understanding of the Code and to encourage compliance. This is done in a variety of ways, including but not limited to, meetings with and educational seminars for pharmaceutical companies, healthcare professional organisations, consumers, health consumer organisations; and agencies and businesses working with the industry (such as advertising and public relations agencies, suppliers, event organisers).

In our communications with stakeholders external to the industry, we explain the standards by which the industry operates and the conduct that stakeholders should expect when engaging with individual companies. More information about Code training activities can be found on the Medicines Australia [website](#).

Continuing Education Program

Medicines Australia's Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. The CEP is offered as an online course through the University of Tasmania's Unit for Medication Outcomes, Research and Education (UMORE), which is backed by the resources of the University's School of Pharmacy. More information on these courses is available on the Medicines Australia [website](#).

In 2017-2018 1,839 individual students enrolled in one or more Programs offered under the CEP which demonstrates the real value of the CEP to our Members and others. In 2017-2018 183 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.

CEP 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 2017 were presented in March 2018.

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 two UTAS Prizes for Excellence were presented to Jennilee Davidson from Boehringer-Ingelheim, and Katie Barrett from Servier Laboratories

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.



Recipients of the 2017 Continuing Education Program awards.

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 Simon McErlane of Alexion Pharmaceuticals.

CEP Achievement Award

CEP Achievement Award winners are the students who achieve the 10 highest aggregate marks. CEP Achievement Award recipients for 2017 are:

- John Seeto – Hahn Healthcare
- Anwar Johnson – Novartis
- Shaynora Prasad – Hahn Healthcare
- Joshua Lennox – Hahn Healthcare
- Marion Arnott – Mundipharma
- Nina Clifford – Boehringer Ingelheim
- Monica MacGregor – Sanofi
- Briar Tietjens – Novartis

The Year Ahead

The Ethics and Compliance Team remain committed to leading the charge towards transparency for the Australian innovative medicines industry. The year ahead will see the team continue engagements with healthcare professionals, industry groups, healthcare professional groups and other key stakeholders to enhance support for these measures. We will also maintain our support of Member Companies as they continue to forge new relationships with healthcare professionals under this transparency regime. It is our firm belief that these relationships, and the education provided by the industry are valued by healthcare professionals and deliver valuable information that ultimately benefits Australian patients.

In 2018-2019, the team will have a number of other key projects including the launch of the Central Reporting System, the ongoing review of the Code of Conduct, and a wholesale review of the Continuing Education Program.

Governance

Complaints received by Medicines Australia are considered by the Code of Conduct Committee and, when required, by the Appeals Committee. The Medicines Australia Board and the Secretariat staff do not adjudicate on complaints or appeals.

Conflict of Interest

A person participating on a Code-related Committee must not have a conflict of interest with the therapeutic area/s or company/ies against which a complaint has been lodged or with the Complainant, or in the case of the Monitoring Committee no conflict of interest with either the therapeutic area subject to review or the companies who have submitted materials for review. This also extends to financial matters or any perceived bias with any of the matters considered at the meeting which they attend.

In addition to the requirement to disclose a direct or indirect pecuniary interest in a matter about to be considered in a meeting of any Committee, members must also disclose a conflict of interest if a reasonable third party would conclude that there was a likelihood that a member of the Committee may be influenced in reaching a decision by factors other than the merits of the case.

The effective and equitable implementation and administration of the Code of Conduct relies on the commitment, skill and professionalism of the Medicines Australia staff and members of the Code, Appeals and Monitoring Committees. We are very grateful for their continued commitment to assisting Medicines Australia to ensure that industry self-regulation through a world class industry Code of Conduct remains strong and effective.

Short biographies of all permanent members of the Code, Appeals and Monitoring Committees, as well as a schedule of meeting dates, is available on the Medicines Australia [website](#).

Medicines Australia in the community

Shalom Gamarada Nginyani Yana Residential Scholarship Program

The Shalom Gamarada Indigenous Residential Scholarship Program was established in 2009 to make a contribution to closing the gap between Indigenous and non-Indigenous Australians through higher education and by increasing the number of Indigenous healthcare professionals. Medicines Australia has sponsored two students each year since 2010, increasing to four students per year from 2012 to 2014. Overall Medicines Australia has funded seven individual indigenous students between 2010 and 2018.

Originally concentrating on medical and health science students, in 2011 the program expanded to include students studying other disciplines. The long-term

aim of the Shalom Gamarada Indigenous Residential Scholarship program sponsored by Medicines Australia 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 2018, has 28 Indigenous students living at Shalom College under Shalom Gamarada scholarships supported by Medicines Australia and other donors.

India Kinsey and Luke Walker completed their studies in the 2017-18 Financial Year.

Wednesday 25th April
Shalom College
UNSW

Dear Medicines Australia,

I would like to take this opportunity to thank you for your ongoing support for my accommodation at Shalom College in the Shalom Gamarada Scholarship Program. Your support has enabled me to succeed in my studies as well as provide me with the opportunity to live in a warm homely environment.

Last year I completed research on Indigenous Eye Health in NSW. I presented this research at RANZO, the College of Ophthalmologists annual conference and COSSOM the Local Prince of Wales Ophthalmology department conference. I was also fortunate to travel to Bourke with the Royal Flying Doctors Service to Bourke, where I assisted with my supervisor on Cataract surgery and clinics. This rural experience enabled me to put some procedural skills into practice which was a fantastic opportunity. These experiences proved very insightful and sparked a respectful appreciation of the research field of medicine.

I'm very proud to advise you that early this year I was appointed one of the Tutors in Residence at Shalom College. This brings responsibilities of academic tutoring for all 130 resident students (not just the Indigenous scholarship holders) as well as pastoral care and administrative duties during out of office hours. I am proud to be giving back to the community I have called home for many years and feel the position will equip me with skills I can build upon and apply to my future endeavours.

This year I started my 5th of 6 years at UNSW. This marks the start of my full-time placement that I will undertake till the completion of my course. I began with Paediatrics in the Intensive Care Unit then moved to general Paediatrics, both at Sydney Childrens Hospital.

These placements were challenging and touching as I encountered many very sick children and I was able to understand the implications of an ill child on a family and appreciate how this was different to an adult patient. For example, I was able to recognise the importance of the patient's family's perspective and involvement in the patient journey as family members typically present the history and series of events leading to a child's admission.

In the last 7 weeks I have been completing my psychiatric rotation. The first part I was at the Kiloh Centre which is an acute care setting for mentally ill patients at Prince of Wales Hospital. For the second period I have been at the Forensic hospital next to Long Bay Correctional complex, this included a couple of days at Silverwater correctional complex.

This term has taught me the importance of psychiatry skills in history taking, specifically how to understand a patient's journey and how all elements of a person's life journey can be important in understanding their current presentation. I feel this skill will be applicable to every patient I come across in my time not only as a medical student but also a medical practitioner, so I have deeply valued my learning here.

Current reflections. A letter from Luke Walker to Medicines Australia. April 2018.

At the end of 2017 I graduated from UNSW with a Bachelor of Medical Studies and Doctor of Medicine. In 2018, I am working in the Emergency Department at Dubbo Base Hospital as an intern. For the entirety of my six years of study, I was fortunate to be staying at Shalom College on a Shalom Gamarada Scholarship sponsored by Medicines Australia.

Shalom College provided accommodation at a substantially subsidised rate, which included meals and internet. With the help of this scholarship I was able to focus on my studies without worrying about my finances or trying to balance my study load with additional work.

I first became interested in medicine when my father was diagnosed with renal cell carcinoma while I was in primary school. The next 12 months were a whirlwind of doctor's appointments ranging from our family GP to the treating oncologist at Royal Prince Alfred Hospital. The lasting impression from my interactions as a 12-year-old with these doctors is one of compassion, understanding and thoughtfulness.

Through these interactions my interest in medicine was born, though I knew I would have to move away from home to follow my dreams. Having been born and raised in the small rural town of Narromine, Central West NSW (pop. 3500), I had little experience of city living.

I completed the Nura Gili Medical Pre-program at the end of 2011 and was successful in gaining a place at UNSW Australia. At the same time that I learnt I was accepted into medicine, I also gained accommodation at Shalom College through the Shalom Gamarada Scholarship. My feeling of relief and gratitude cannot be explained in writing and I can only say it was great.

Like many of my fellow scholarship holders, I am the first in my family to attend university and neither I or my family had the financial means to support my dreams. Fortunately, with the aid of my residential scholarship, my socio-economic status was not a barrier to furthering my education.

Over the course of my studies, I was able to focus on my interests and excel academically with the publishing of my own research in 'Vaccine', an international medical journal. Furthermore, I presented this research to my professional colleagues at the Australian Indigenous Doctor's Association's Conference.

I completed a summer internship at the National Health and Medical Research Council where I mapped co-publishing networks of successful Indigenous researchers to identify role models for prospective researchers and presented at an all staff seminar.

Through a networking event held by Medicines Australia, I was able to organise an elective with The Purple House, who are also sponsored by Medicines Australia. During my time at The Purple House I gained first-hand experience of the epidemic of renal failure among Indigenous Peoples and the need for on-country dialysis.

Letters from India Kelsey and Luke Walker on their experience as a participant in the Shalom Gamarada Residential Scholarship Program.

Shalom Gamarada – Parliament House Event

On Tuesday 8 August, members of the Medicines Australia Executive, as well as members of the Board attended the Shalom Gamarada Scholarship Program Event, at Parliament House, Sydney.

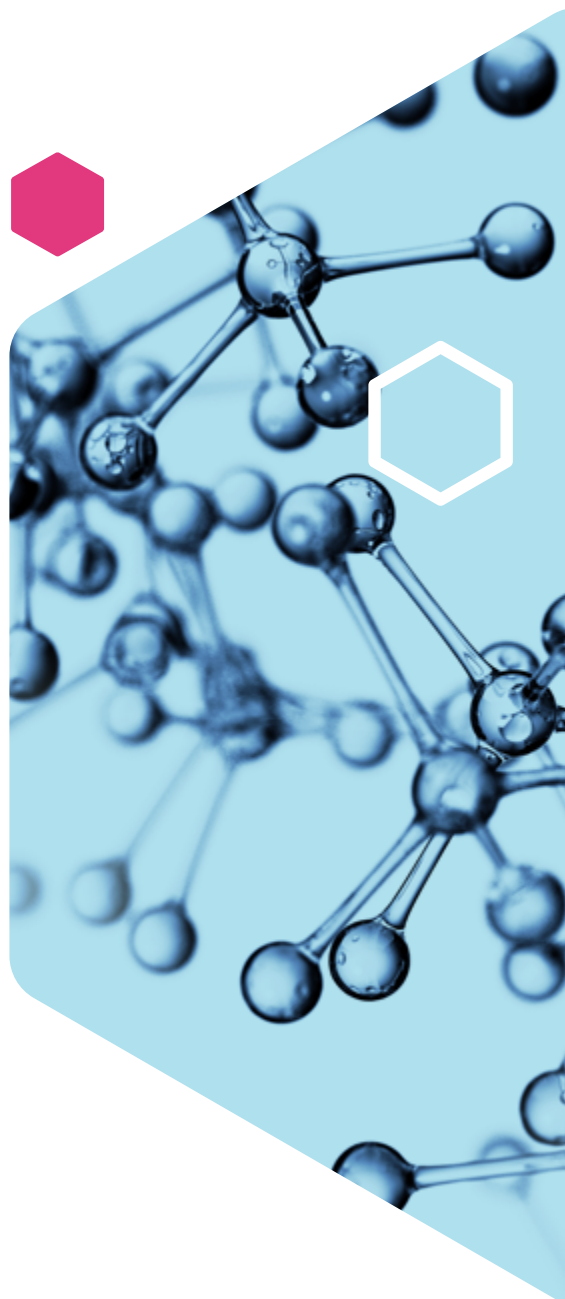
MA was able to meet many of the students we have supported over the years and hear amazing stories from current and past students.



Left to right: India Kinsey, Medicines Australia Scholarship medicine undergraduate; Ben Dixon, Commonwealth Bank; Mitch Heritage, Shalom Gamarada Bachelor of Commerce Graduate (2016) now working at Commonwealth Bank; Sarah Wellings, Shalom Gamarada undergraduate (Social Work/Criminology); Matt Rix, Commonwealth Bank.



Deborah Monk, second from left with Friends of Shalom Gamarada Lisa Maguire, AbbVie, Deon Schoombie, ASML, and Bill Curtis.



Working with our members

Medicines Australia acknowledges the incredible contribution that our Members make to collaborating with the Medicines Australia Executive. Your support is remarkable.

Wes Cook

Chair, Medicines Australia



Advisory Council

Advisory Council	
MEMBER NAME	COMPANY
Dr Anna Lavelle	Chair
Catherine McGovern	Independent
Mark McCrindle	Independent
David Grainger	Independent
Carol Bennett	Independent
Dr Jeff Harmer AO	Independent
Prof Ian Chubb AC	Independent
David Herd	GlaxoSmithKline
Andrew Carter	Commercial Eyes
Nicola Richards	MSD Australia

Chief Executive's Group	
MEMBER NAME	COMPANY
Milton Catelin	Medicines Australia
Elizabeth de Somer	Medicines Australia
Wade McMonagle	AbbVie
Sara Pantzer	Amgen
Michael Smith	AstraZeneca
Chris Stemple	Biogen
Kristin Trace-MacLaren	GlaxoSmithKline
Christian Sellars	MSD Australia
Mitch Kirkman	Novartis
Louise Graham	Pfizer

Standing Working Groups

Government Working Group (GWG)

MEMBER NAME	COMPANY
Adrian Dolahenty	Bayer
Amy Moore	AbbVie
James McAdam	Bristol-Myers Squibb
Kieran Schneemann	AstraZeneca
Cameron Milliner	Shire
Penny George	Sanofi Aventis
Peter Murphy	Novartis
Sara Pantzer	Amgen
Josh Bihary	Pfizer
Todd Stephenson	Janssen-Cilag
James Boyce	Medicines Australia
Allide Murphy	Medicines Australia
Amanda McPherson	Celgene

Oncology Industry Taskforce (OIT)

MEMBER NAME	COMPANY
Adrian Dolahenty	Bayer
Alissa Brown	Sanofi
Carlene Todd	Roche Products
Carmel Spiteri	Merck Sharp & Dohme (Australia)
David Pullar	Roche Products
Greg Cook	Bristol-Myers Squibb
Jodie Thomas	Novartis
Josie Downey	Merck Sharp & Dohme
Kate Webb	Takeda Pharmaceuticals
Kieran Schneemann	AstraZeneca
Kristina Turner	AbbVie
Louise Graham	Pfizer
Matthew Slabbert	Bayer
Mike Smith	AstraZeneca
Paul Lindsay	Merck Serono Australia

Oncology Industry Taskforce (OIT)

Peter Murphy	Novartis
Philip Spiers	AstraZeneca
Philippa Delahoy	Pfizer
Sara Pantzer	Amgen
Sean Lybrand	Amgen
Todd Stephenson	Janssen-Cilag
Wes Cook	Boehringer-Ingelheim

Health Economics Working Group (HEWG)

MEMBER NAME	COMPANY
Darin Kottege (Co-Chair)	Medicines Australia
Carlene Todd (Co-Chair)	Roche Products
Greg Cook	Bristol-Myers Squibb
Kate Webb	Takeda Pharmaceuticals
Louise Graham	Pfizer
Michael Haberl	GlaxoSmithKline
Peter Germanos	Boehringer Ingelheim
Sean Lybrand	Amgen
Rachael Anderson	AstraZeneca
Vanessa Stevens	Vifor Pharma
Matt Slabbert	Bayer
Tenille Manuele	Commercial Eyes
Natalia Price	AbbVie

Medicines Australia Vaccines Industry Group (MAVIG)

MEMBER NAME	COMPANY
David Herd	GlaxoSmithKline
Anne Norris	Pfizer
Valda Struwig	Pfizer
Tim Nunau	Pfizer
Darin Kottege	Medicines Australia
Elizabeth de Somer	Medicines Australia
Sheryl Page	GlaxoSmithKline
Lauren Adler	Pfizer
Scott Williams	Pfizer
Helen Concilia	CSL
Stuart Harsley	CSL
Roger Falconer-Flint	AstraZeneca
Stephen Richardson	Sanofi Aventis
Pirouz Adhami	Sanofi Aventis

Regulatory Affairs Working Group (RAWG)

MEMBER NAME	COMPANY
Helen Critchley (Chair)	Sanofi
Brian Hewitt	Pfizer
Carolyn Tucek-Szabo	GlaxoSmithKline
George Lillis	Novartis
Jagdish Ghadge	Shire
Kirpal Kaur	Bristol-Myers Squibb
Mark Rowland	Amgen
Michael Parker	AstraZeneca
Linda Ponkshe	Janssen-Cilag
Simon Byrne	Celgene
Natalie Touzell	Roche
Andrew Notley	Gilead
Sharon Leadbitter	Medicines Australia
Larissa Karpish	Medicines Australia

Regulatory Affairs Working Group – Pharmacovigilance group (RAWG-PV)

MEMBER NAME	COMPANY
Bianca Joo	Sanofi
Geraldine Peterson-Clark	Boehringer Ingelheim
Karen Battat	Astra Zeneca
Karthnik Somanath	Roche
Louise Davis	AbbVie
Lynne Puopolo	MSD Australia
Natassia Lukass	Novartis
SarahAnn Simpson	Pfizer
Sue Lee	AbbVie
Tamara Kahn	AbbVie
Betsy Anderson-Smith	Medicines Australia

Regulatory Affairs Working Group – GMP (RAWG-GMP)

MEMBER NAME	COMPANY
Albina Perri	GSK
Brian Hewitt	Pfizer
Cindy Chiddy	Roche
Claudia Opitz	Sanofi
Emma Dernelley	Amgen
Joy Pallis	AbbVie
Lisa Taylor	Boehringer Ingelheim
Lorraine Sutherland	Amgen
Natalie Corrick	AstraZeneca
Rakhee Gokai	MSD Australia
Ruby Joseph	Shire
Toula Boloutis	Ipsen
Wai Zin Wong	Bristol-Myers Squibb
Betsy Anderson-Smith	Medicines Australia

Issues groups

Biosimilars and Biologics Issues Group

MEMBER NAME	COMPANY
Sara Pantzer (Chair)	Amgen
David Thomson	AbbVie
Matthew Little (Co-Chair)	AbbVie
Anne-Maree Englund	MSD Australia
Annette Kerr	Roche Products
Carmel Spiteri	MSD Australia
David Pullar	Roche Products
Fei-Li Zhao	Novo Nordisk Pharmaceuticals
Josh Bowen	Roche Products
Kate Webb	Takeda Pharmaceuticals
Louise Graham	Pfizer
Dr Jamshed Ahmed	Novo Nordisk Pharmaceuticals
Mark Schulz	Novartis
Natalie Fitzpatrick	Pfizer
Paul Lindsay	Merck Serono
Penny George	Sanofi-Aventis
Peter Germanos	Boehringer Ingelheim
Peter Murphy	Novartis
Peter Vermeer	Eli Lilly
Roger Falconer-Flint	AstraZeneca
Stephen Richardson	Sanofi-Aventis
Stuart Englund	Janssen-Cilag
Tim Dow	Ipsen
Todd Stephenson	Janssen-Cilag
Andrew Bowskill	Medicines Australia

Intellectual Property Issues Group (IP Issues Group)

MEMBER NAME	COMPANY
Andrew Bowskill	Medicines Australia
Amy Moore	AbbVie
Dr Duncan Purvis	Janssen-Cilag
Kelly Griffiths	GlaxoSmithKline
Natalie Fitzpatrick	Pfizer
Sara Pantzer	Amgen
Stuart Englund	Janssen-Cilag
Vanessa Stevens	Vifor Pharma
Martin Snoke	Roche Products

Other Groups

Research and Development Taskforce (R&DTF)

MEMBER NAME	COMPANY
David Lloyd (Co-Chair, 2017)	Southern Star Research
Mitch Kirkman (Co-Chair, 2017)	Novartis
Andrea Kunca	Medicine Technology Association of Australia
Anita van der Meer	Medtronic
Carrie Bloomfield (Co-Chair, 2018)	GSK
Catherine Bourgeois	Abbott
David Wilks	Bristol-Myers Squibb
Edwin Ho	Medical Technology Association of Australia
Helen Aunedi (Co-Chair, 2018)	Roche
Jane Kelly	CMax
Lauren MacNaughton	Eli Lilly
Pedro Crisanto	Servier Laboratories Australia
Sara Pantzer	Amgen
Shanny Dyer	ARCS

Research and Development Taskforce (R&DTF)

Andrew Bowskill	Medicines Australia
Val Theisz	MTAA Secretariat Support

Continuing Education Program Working Group (CEPWG)

CURRENT MEMBERS

Sophie Hibburd (Chair)	Medicines Australia
Aaron Guttman	Bristol-Myers Squibb
David Schlesinger	AbbVie
Martina Ryan	Janssen
Simon Scott	Sanofi

RESIGNED DURING 2017-18

Ben Warner	Pfizer
Melanie Seeger	Celgene
Sandi Coleman	Eli Lilly
Tracey Payne	MSD

Future of the Code Working Group

MEMBER NAME COMPANY

Deborah Monk	Medicines Australia
Sophie Hibburd	Medicines Australia
Dr Alan Paul	Ipsen
Dr Andrew Weekes	GSK
Anna Argyropoulos	UCB
Ben Hopkins	Takeda
Calvin London	Celgene
Danielle Dowell	Seqirus
Dr Jonathan Anderson	Bristol-Myers Squibb
Lisa Maguire	AbbVie
Scott McIntyre	MSD
Shane McSpedden	Pfizer
Stuart Englund	Janssen

RESIGNED DURING 2017-18

Amanda Harris	Hahn Healthcare / Inspire HCP
Flor Sansano	iNova
Jessica Kanevsky	AbbVie
Melanie Seeger	Celgene
Sandi Coleman	Eli Lilly



Members' events

PharmAus 2017

In September 2017, approximately 250 members, industry stakeholders, non-members, Parliamentarians and Government officials descended on Canberra for the inaugural PharmAus2017.

There were many highlights, not least of which our MC Adam Spencer who made it such a standout event. The Policy Symposium was an important platform for discussion that left us all with plenty to think about as we look to the challenges and opportunities ahead.

The Members showcase in the Great Hall was spectacular and proudly showed our Parliamentarians, their staff and other stakeholders just how important this industry is to the health of all Australians, the medical research community and the local economy.

It was all brought to a close the next morning with our Medicines Australia and Health Consumers Leader's Breakfast which featured a presentation by PBAC Deputy Chair Jo Watson about the importance of the patient voice in the PBS process.

[Click here to view the picture gallery or visit https://medicinesaustralia.com.au/media-events/pharmaus2018/](https://medicinesaustralia.com.au/media-events/pharmaus2018/)



Left to right: Sharon McGowan, CEO Stroke Foundation; Professor Dominique Cadilhac, Florey Institute of Neuroscience and Mental Health, Monash University; Professor Chris Levi, Neurologist, Executive Director of Sydney Partnership for Health, Education, Research and Enterprise (SPHERE); Former Prime Minister, the Hon Malcolm Turnbull MP; and Wes Cook, Managing Director of Boehringer Ingelheim Australia and New Zealand.



Left to right: the Hon Catherine King MP, Shadow Minister for Health and Medicare; the Hon Bill Shorten MP, Leader of the Opposition; and Kevin Lim Anjaline Antony from Novartis.

2017 Annual General Meeting

The 2017 Medicines Australia Annual General Meeting was held on Wednesday 25 October 2017 at Shire Australia Pty Limited. Members received the Medicines Australia Financial Statements, the Medicines Australia Annual Report and the Medicines Australia Code of Conduct Annual Report.

In 2017 Medicines Australia conducted the biennial election of the Board Directors. The election was for the first time conducted through an online vote, administered by an independent third party. Sixteen nominations were received from Member company Managing Directors to fill the ten positions of elected Director for the 2017-2019 term. The results of the election were announced to Member companies at the AGM, including the re-election of Mr Wes Cook as the Chair of the Board and Dr Anna Lavelle re-endorsed as Independent Deputy Chair.

Following the AGM, Medicines Australia held a Member Briefing, where Managing Directors and other Member company personnel were provided with an overview of research commissioned by Medicines Australia on the economic footprint of the innovative prescription medicines industry. Members also received a report on consideration of the future of the Code of Conduct and were invited to comment on the proposal to establish a Central Reporting System for publishing members' reports on their payments and transfers of value to healthcare professionals.

2017 General Meeting

On 25 July 2017 Medicines Australia held a General Meeting. At the GM Members passed a special resolution to amend the Constitution of Medicines Australia Limited, effective from that date. The main changes to the Constitution were to reduce the number of elected Directors to 10, to formally establish the position of Deputy Chair and to make other amendments to clarify the Constitution and ensure that it remains in line with the Corporations Act 2001.

Board Strategic Planning Day

In November 2017, the Board met for a strategic planning day. The purpose of the day was for the newly elected Board to take stock of the current state of the industry and its Strategic priorities and set a clear direction for Medicines Australia for the coming years.

The primary outcome from the day was that the primary focus of Medicines Australia needs to be funding of the PBS with the clear vision that all Australians have access to the medicines they need when they need them.



Medicines Australia members attending the 2017 Annual General Meeting.

Board Meetings

Medicines Australia convened a number of Board meetings during the 2017-2018 financial year:

- 26 July 2017 – Board Meeting
- 25 October 2017 – Board Meeting
- 21 November 2017 – Board Strategic Planning Day
- 21 February 2018 – Board Meeting
- 8 May 2018 – Board Meeting
- 18-19 July 2018 – Strategic Planning Day and Board Meeting

PAGE Workshop

In November 2017, the newly formed gender equity group held its first meeting in Sydney. Pharma-Australia-Gender-Equity (PAGE) was established by Abbvie, Pfizer and Janssen, who make up the Steering Committee.

PAGE is a project team of 15 member companies that will develop and deliver on the objective to improve gender equality in the Australian pharmaceutical industry. The aim is to help:

1. Increase the number of women in senior leadership roles;
2. Improve the journey over career milestones, including opportunities for professional development, mentoring, sponsorship, promotion and recognition; and
3. Support an equitable working environment for all.

Australia has made significant strides toward gender equality in recent decades. At schools, in workplaces, in boardrooms and in government, a growing number of women have taken on leadership roles, forging pathways for others to follow. This is true of the pharma industry too, as evidenced by the significant number of women recently elected to our new Board.



Front, left to right: Mariela Gonzalez, Penne Carter, Petra Moroni-Zentgraf and Junko Komatsu.

Back, left to right: Maria Allart, Elizabeth de Somer, Kirsten O'Doherty, Kathy Connell, Melissa McGregor, Sabrina Barbic, Kylie Bromley, Kimberly Elliot, Anthea Cherednichenko, Adam Bullock and Alice Moginie.

Absent: Maria McManus, Kathy Cargill and Lauren Carey.

Clinical Trials 2018: National Tribute and Awards Ceremony

On 16 May 2018, Medicines Australia attended the Clinical Trials 2018: National Tribute and Awards Ceremony.

The winner of the 2018 Trial of the Year Award was the Australian Placental Transfusion (APT) Trial which is the largest ever randomised controlled trial of delayed placental cord-clamping for premature infants, which has already led to significant improvements in premature infant health simply by “waiting a minute” during delivery.

Speaking at the awards ceremony, Minister for Health, the Hon. Greg Hunt MP reaffirmed the Government's commitment to the research with the announcement of the “Helping our Health” clinical trials campaign which aims to promote clinical trials to all Australians as a way to increase awareness and recruitment in Australian clinical trials.

Medicines Australia's Super Working Group Day

On 28 June 2018, over forty Member company representatives of Medicines Australia Working Groups met together at Pfizer's Lord Florey Learning and Conference Centre in West Ryde. The objectives of the day were to:

- Update Working Groups' progress in addressing key strategic issues for industry

- Identify options for increased collaboration and communication
- Reach consensus on how Working Groups can work most effectively to support Medicines Australia's strategic objectives.

There was an enormous sense of collegiality and collaboration between the six working groups' members, as they were split into small, multi-disciplinary subgroups during the day. The super working group meeting was tremendously facilitated by Rosie Yeo from Public Affairs Network who kept everyone focused and drew together clear consensus direction for Medicines Australia's working groups. Everyone expressed the desire to do more collaborative work together. This was reflected in the collective Vision for success for the Working Groups over the next year and a half:

- We understand the Board's strategic priorities and have contributed to achieving them.
- We can point to a list of specific outcomes from Working Group activities, many of which have been achieved in collaboration.
- There is clear reporting about Working Group activities and priorities.
- There is an increased sense of partnership between members of Working Groups, and it is easier to source information and expertise across the groups.
- We know where we fit in the jigsaw puzzle and we understand more about the big picture.

Medicines Australia plans to reconvene the Working Groups for another “Super Day” in early 2019, to continue to pursue the implementation of the strategic priorities.



Representatives of Medicines Australia Working Groups at Pfizer's Lord Florey Learning and Conference Centre.



Better health
through research
and innovation

Annual Report 2017-2018



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