



# Annual Report

2018/2019



**Medicines  
Australia**

Better health  
through research  
and innovation

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## Medicines Australia – Vision, Mission, Leadership, Strategic Objectives



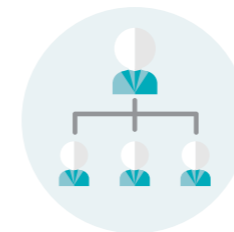
### Vision

To make a real difference to the health of Australians by ensuring they have access to world-class medicines when they need them.



### Mission

To drive policy outcomes in partnership with government, health sector organisations and the community which will ensure Australians have universal, affordable and fast access to treatments that keep pace with advancements in medicine.



### Leadership

Medicines Australia leads the research-based pharmaceutical industry of Australia. Our members discover, develop and manufacture medicines and vaccines that bring health, social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.



### Strategic Blueprint

1. Build stakeholder and community understanding of the value and benefits (health, social and economic) of new and emerging medicines and vaccines for Australia.
2. Ensure new medicines are universally available to Australians when they need them through:
  - Ensuring efficient assessment and evaluation methodologies to reflect ongoing developments in research, diagnostics and treatment
  - Ensuring funding mechanisms can adapt to meet the needs of, and deliver value to, government, patients and the community.

# Chair's Report

As Chair and on behalf of the Medicines Australia Board, and Executive, I am pleased to introduce the 2018-19 Annual report.

Having been appointed as Chair in August 2018, I have had the privilege and pleasure of leading the Board through what I consider to be one of the most important transition periods in the history of medicines development. We are seeing transformational medicines that are increasingly targeted and as a result, potentially curative. We are seeing the line between a therapy, a medicine and a delivery system become increasingly blurred and we are seeing these treatments, and more traditional medicines becoming approved through a range of increasingly flexible regulatory pathways.

Elizabeth de Somer has completed her first year as Medicines Australia CEO and I and the directors would like to congratulate her on a busy and successful year containing many achievements. In particular, energising the organisation and seamlessly relocating the team to modern premises whilst advocating for the sector, defining priorities and clarifying strategic issues using a collaborative framework. The Board and Executive team are working closely and have strengthened the quality of decision making and improved transparency to Member Companies.

Improving registration and reimbursement efficiency is a key strategic objective of the organisation and throughout this year we have taken several opportunities to argue for this, including effectively prosecuting commitments in our Strategic Agreement with the government, our pre-election negotiations, our strategic messaging and our public advocacy. Focus will not shift from these issues and I am hopeful of seeing improvements in the coming period.

During the past year the board has focused on high level issues such as strategic positioning, early planning for a future Strategic Agreement, evaluation of possible industry impact as a consequence of a review of the National Medicines Policy, and strengthening the governance practices of the Board and effectiveness of Medicines Australia.

Because of our dynamic environment, it is important to test assumptions by seeking input from independent sources. The work of the Board has been enhanced by the Strategic Advisory Council. The Council has been very effective and worked with the Board and Executive to debate priorities and options for future proofing Medicines Australia and the industry. As Chair of the Council, I extend my thanks to the highly valuable members of the Council for their insights and candour.

I would like to take this opportunity to thank Anne Belcher (GSK), Michala Fischer-Hansen (Novo Nordisk), James Jones (Takeda) and Svend Petersen (Roche) for their contributions to the Board during the 2018-19 financial year, and thank and reiterate my welcome to new Directors – Liz Chatwin (AstraZeneca) Michael Azrak (MSD) Chris Stemple (Biogen) and My Linh Kha (Amgen). I followed Wes Cook into the position of Chair and acknowledge his leadership and his contribution over more than six years as a Director and nearly three years as Chair. Wes has given a great deal to the sector and deserves our heartfelt thanks.

Smooth transitions, a commitment to stability, and the structure that underpins it, has enabled the Executive and Board to achieve remarkable things this year. I look forward with enthusiasm to an even better year to come.

I congratulate all Board Directors for their outstanding service and for going that extra mile when needed. I also acknowledge and thank our Member Companies who support Medicines Australia and are willing to release staff to work on specific industry relevant projects.

I again extend my congratulations to Elizabeth de Somer and her team at Medicines Australia. Their commitment to striving for best practice in policy development and stakeholder engagement on behalf of the medicines industry is to be commended, and the past year has illustrated just how tireless they are in achieving this goal.



**Dr Anna Lavelle**  
Medicines Australia  
Independent Chair

# CEO's Report

Medicines Australia has worked hard this year to build strategic internal capabilities and capacity, as well as enhancing partnerships and highlighting the importance of innovative medicines and the need for investment.

This year saw several key projects prepared and undertaken by the executive in line with our strategic objectives.

I am proud and pleased to have completed my first year as the CEO and to be leading this organisation, supported by Dr Anna Lavelle as Chair, and a committed and passionate Board and Members, at a time of great change. The innovative pharmaceutical industry is a dynamic and evolving sector that demonstrates the ability to adapt to rapidly changing environments. The industry in Australia is part of a global sector that is committed to delivering innovative treatments to meet unsolved burdens of disease and unmet clinical need. In the last year alone, we have seen transformational changes in the treatment options being brought to Australia. Patient access to these transformative options have proved challenging for the Medicines sector but have reaffirmed our intent to ensure that Australia has the best possible policy settings to facilitate early, rapid and efficient access to medicines and all treatments.

Medicines Australia has successfully gathered the sector's thought leaders and experts to raise awareness of issues of mutual national significance, such as the National Medicines Policy Review, Clinical Trials barriers and solutions, and the importance of a strong and stable Intellectual Property system that recognises innovation and strives to deliver a growing and thriving pharmaceutical industry in Australia. In the last year the Board of Medicines Australia reaffirmed our Strategic Objectives; in summary, to build stakeholder and community understanding of the health, social and economic benefits of new and emerging medicines and to ensure new medicines are universally available to Australians, when the need them, through efficient assessments, and reimbursement mechanisms that meet community needs.

In 2018-19, the Medicines Australia Executive, under a strong and stable leadership, supported by the Board and Members, has gone a significant way to delivering on these objectives and key priorities, and in setting the road map for the future.

## Strategic Agreement

Medicines Australia has continued to work with the Department of Health on the implementation of the Strategic Agreement (the Agreement) and development of metrics to ensure the outcomes deliver on the intent of the Agreement. Successful implementation of the Agreement is required prior to negotiation of a future Agreement expected in 2022. Much of the work on implementing the Agreement has been conducted with Ministerial oversight through the Access to Medicines Working Group (AMWG) and four AMWG sub-groups. These groups are supported by Members through the standing working groups, such as the the Health Economics (HEWG) and Regulatory Affairs Working Groups (RAWG). The AMWG sub-groups met regularly throughout the year to continue progressing commitments to efficiencies, cost-recovery, comparator selection and biosimilar policy. The most intensive effort has been focussed on development of new streamlined pathways to reduce submission churn and improve the pre and post PBAC Listing processes.

The National Health Amendment (Pharmaceutical Benefits – Budget & Other Measures) Act 2018 was passed 21 February 2018. These amendments to the National Health Act 1953 implemented the agreed increases to statutory price reductions upon the first new brand listing on the PBS of an existing pharmaceutical, an extension and introduction of statutory price reductions

applying on certain anniversaries of an F1 formulary drug being listed on the PBS; an introduction of ministerial discretion in relation to the application of statutory price reductions in certain circumstances; and price disclosure amendments.

The strategic agreement workstream continues to take up a significant amount of Executive and member resources, however, we have seen significant progress and will continue to do so in the coming year.

## Strategic Communications

Strategic Communications were a key focus throughout the year with Medicines Australia delivering a key priority with the launch of a compelling narrative around the value and benefits of innovative medicines in the industry and Australia; "Medicines Matter". The Medicines Matter campaign, in some part based on a comprehensive Consumer Sentiment Survey conducted by Nielsen, and the associated comprehensive toolkit, are designed to highlight three critical pillars of communication messaging that align with industry's broad objectives of highlighting value of medicines and the need for an improved access environment.

This messaging framework was extensively tested with stakeholders and Members and we continue to work on embedding this with both groups, and through improved media relations to a wider audience, including closer engagement with HCOs.

## Federal Election

The Federal Election on 18 May 2019 was an important milestone to work toward for much of the year. We were heartened to hear frequent and regular mention of medicines and the importance of the PBS by representatives of the Coalition and ALP. The attention that the PBS has received during this pre-election period was unprecedented.

Medicines Australia sought to capitalise on this attention and use it as a platform for expressing and furthering our strategic communications framework and election commitments. Working with the Government Working Group (GWG), Medicines Australia developed five key asks from all major political parties, namely that should they be successful they would:

1. Commit to undertake a multi-stakeholder review of the National Medicines Policy to ensure new therapies could be effectively accommodated;
2. Continue the practice of a Strategic Agreement;
3. Commit to list all positive PBAC recommendations within 6 months of pricing agreement;
4. Propose a plan for clinical trial harmonisation to COAG within the first 12 months of forming government; and
5. Commit to retain the R&D Tax incentive in a form that supports clinical trials and boosts Australian research.

We also received strong pre-election commitments from the Government and Opposition parties to maintain confidential pricing arrangements, to retain current criteria for seeking a Special Pricing Arrangement and to not implementing changes to the Supply Chain Payment Arrangements that would have a detrimental impact on the sector. These issues are of local and global concern to the industry as they may effect Australia's access to innovative medicines in the future.

## Code of Conduct

Medicines Australia's Ethics and Compliance activities in 2018-2019 continued to ensure the administration of the Code of Conduct, Edition 18, which has been effective since it was authorised by the Australian Competition and Consumer Commission (ACCC) in May 2015. Significant effort has also been applied to the review of the Code of Conduct Edition 18, in preparation for Edition 19. The Ethics and Compliance team in the Executive, assisted by the Future of the Code Working Group and widespread member consultation, has made significant progress in its thorough review of the Code to ensure Edition 19 reflects the maturity of the industry and is modernised and fit for purpose in the future. Medicines Australia has also engaged with the Therapeutic Goods Administration (TGA) and the ACCC throughout the review process. Further engagement is anticipated with health consumer organisations (HCO) and health care practitioners (HCP) in the coming financial year.

I am confident that the development of a new code deliver a modern format that reflects the mature industry and the highest ethical standards that Medicines Australia represents today.

## What Lies Ahead

The 2019-20 financial year will see us continue to tackle issues around implementing the intent of the Strategic Agreement, to ensure that our registration and reimbursement pathways remain agile and that your medicines are getting listed and reimbursed as quickly as possible.

We will work on furthering the commitments achieved during our election campaign around the National Medicines Policy review and getting a plan for clinical trials harmonisation to COAG. We are also looking forward to contributing to a plan for access to emerging therapies to ensure that our members and the broader industry are well represented as treatment paradigms evolve.

We will also continue to share our story around the exceptional value that the Government derives from medicines, through keeping people participating in the workforce and in the community, contributing to their retirement savings, reducing welfare dependence, and keeping them out of hospital, freeing up resources for those who need them.

We will continue to show that this is a passionate and compassionate industry full of people with extraordinary talent, that have patients at the heart of everything they do, and this is reflected by our drive to ensure medicines are available in Australia.

## Thank You

I would like to thank the Board, Executive and our Working Groups, Committees and Special Interest Groups for your tireless efforts in ensuring that medicines policy remains a top priority for both Member companies and the government. Medicines Australia is a small organisation being able to tap into your capabilities and extend our reach as an organisation is invaluable.

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 will continue to thrive.



**Elizabeth  
de Somer**

Medicines Australia  
Chief Executive  
Officer

# 2018-19 Board of Directors



**Dr Anna Lavelle**

Medicines Australia  
Independent Chair.  
Independent Director.



**Ms Melissa McGregor**

Deputy Chair.  
Managing Director, Pfizer  
Australia Pty Ltd



**Mr Brad Edwards**

Vice President and General  
Manager ANZ, Takeda  
Pharmaceuticals



**Mr Wes Cook**

Managing Director,  
Boehringer Ingelheim  
Pty Ltd



**Ms Anne Belcher \***

Vice President and General Manager,  
GlaxoSmithKline Australia Pty Ltd



**Ms Michala Fischer-Hansen \***

Vice President and General  
Manager, Oceania, Novo Nordisk  
Pharmaceuticals Pty Ltd-Australia



**Mr Bruce Goodwin**

Managing Director,  
Janssen-Cilag Limited



**Mr Christopher Stemple**

Managing Director,  
Biogen Australia



**Ms Kirsten O'Doherty**

Managing Director,  
AbbVie Pty Ltd



**Mr James Jones \***

Managing Director, Takeda  
Pharmaceuticals Australia Pty Ltd



**Mr Svend Petersen \***

Managing Director,  
Roche Products Pty Ltd

\* Left during 2018-19



**Ms Liz Chatwin**

Country President Australia & New  
Zealand, AstraZeneca Pty Ltd



**Michael Azrak**

Vice President & Managing Director  
ANZ, Merck Sharp &  
Dohme (Australia)



**My Linh Kha**

Managing Director,  
Amgen Australia

## Medicines Australia Leadership Team



**Elizabeth de Somer**

Chief Executive Officer



**Deborah Monk**

Director, Ethics and  
Compliance



**Jamie Snashall**

Director, Public Affairs –  
Commenced Oct 2018



**Vicki Gardiner**

Director, Policy and  
Research – Commenced  
Nov 2018

# Medicines Australia Membership

AS AT 30 JUNE 2019

## Class 1



## Class 2

BESINS HEALTHCARE



## Class 3



## Class 4



# Public Affairs Highlights

## Working with Government and the Parliament

Medicines Australia attended business forums of the major political parties throughout the year and hosted a handful of events for Members where a Minister or Shadow Minister was the special guest. Participation in these events is vital for Members to discuss issues of interest in detail with our political stakeholders.

CEO and/or Director Public Affairs conducted a rolling program of 1:1 meetings with MPs and Senators before the election was called. We have ensured a broadened focus to include, not only Minister and Shadow Minister for Health, but also Ministers and Shadow Ministers for Trade & Investment, Minister and Shadow for Industry, and Ministers and Shadows for Central Economic Portfolios of Finance, Treasury and the Prime Minister's Office.

In December 2018, Medicines Australia hosted a bipartisan networking event for political staffers and Members. We had very good attendance from across the Parliament and we are grateful for the assistance and support of Members for the event. Medicines Australia runs these events at least once annually for staffers and Members to meet and chat.

Medicines Australia has continued to leverage its National Press Club (NPC) membership by hosting tables at relevant NPC Addresses and inviting a range of key stakeholders, which usually comprise a combination of political advisers, bureaucrats, HCOs, HCP groups, and Medicines Australia Executive staff.

## BIO 2019 + US + Europe

The CEO and Director Public Affairs visited the United States, United Kingdom and Europe attending the BIO conference and meeting with our international counterparts, including PhRMA, ABPI, EFPIA and IFPMA.

We also took the opportunity to meet colleagues from our member company affiliates and connect with Australian Government missions, Austrade representatives, US and UK Government officials and relevant health consumer organisations. These activities enable Medicines Australia to build stronger networks; advise and educate our counterparts on the challenges for industry in Australia; ensure Medicines Australia is educated on global industry challenges; and to identify common ground and techniques in responding to domestic and global issues.

Our time at BIO made clear the need for Medicines Australia to strengthen engagement with Australia's State and Territory governments. The Public Affairs team has begun to develop a comprehensive engagement strategy in conjunction with the Medicines Australia Policy & Research team and aligned to the Strategic Objectives.

## 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.



## PharmAus 2018

PharmAus18 was held at Parliament House in Canberra on the 17th of September 2018. It brought together over 250 participants from across Australia. These included leaders from the pharmaceutical sector, the medical technology and biotechnology sectors, as well as policymakers, health experts, and advocates for patients and patient groups. The event also included presentations from the Hon. Greg Hunt MP, the Minister for Health; the Hon. Catherine King MP, the Shadow Minister for Health and Medicare; and Senator Richard Di Natale, the leader of the Australian Greens. The symposium provided an opportunity to discuss the past achievements, ongoing strengths and future challenges of Australia's healthcare system.

PharmAus is Medicines Australia's annual Policy Symposium and Industry Showcase. PharmAus18, brought together experts from across the pharmaceutical industry and its partner sectors. Like its predecessor PharmAus17, the goal of the Symposium was to facilitate an open dialogue between industry and policymakers, promoting collaboration that will see better health outcomes for all Australians. It included a full day of presentations, panel discussions, and showcase material, with the aim to shape the path forward for the Australian pharmaceutical sector in the changing health landscape. In the words of Medicines Australia's Chair, Dr Anna Lavelle, PharmAus18 addressed the need for



a dedicated day where experts collaborate to discuss medicines, healthcare delivery, and plans for the future. Over the course of the day, nine speakers, three panellists, the Federal Minister for Health, and senior leaders from the Australian Labor Party (ALP) and the Australian Greens—representing varied sectors and perspectives—contributed their perspectives on key issues facing the pharmaceutical industry and broader health sector in 2018. The key themes and ideas that emerged from these talks, and from the question and answer sessions that followed, are summarised in this report.

## Key Themes of the Policy Symposium:

1. The future of medicines must be person-centred
2. Balanced regulation and review deliver the highest value
3. Emerging technologies and treatments enable state-of-art healthcare
4. Investment in local R&D will underpin industry success

# Strategic Communications & Election Messaging

Throughout the past year, Medicines Australia undertook a review of our strategic messaging and commenced working with a third-party supplier to draw the threads of our evidence base together to create a compelling narrative for industry.

In conjunction with this, was the development of key election asks that Medicines Australia Members could unite behind and advocate for. Having achieved this, Medicines Australia launched the “Medicines Matter” framework to Members at the Federal Budget Breakfast Briefing in March 2018. Members

are encouraged to adopt and integrate this messaging into their own communications and advocacy framework.

The messaging framework is supported by key evidence cards. Much of the work going forward into the 2019-20 financial year will be to continue to build on the communications framework, regularly update the evidence base as data is generated and released and embed the messaging within Medicines Australia and our Member organisations. Further work will be undertaken to ensure that the messaging is amplified by our key stakeholders.



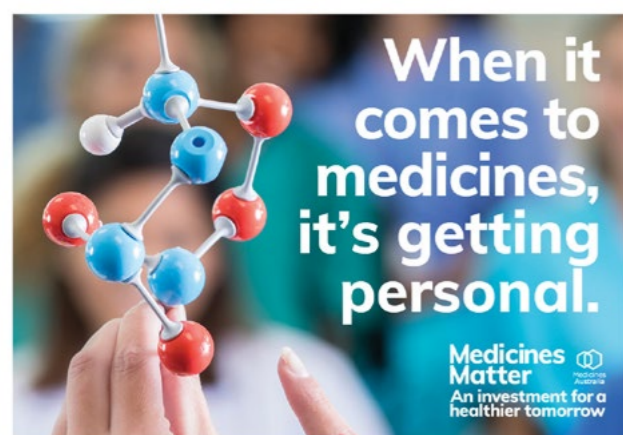
## Stakeholder Relations

Consumers are at the centre of our health system. Health issues matter to them and they are mobilising a stronger consumer voice that is influencing and shaping health policy. Our Industry shares significant common ground with consumers regarding the value of improved health outcomes, as well as the importance of fair, equitable and timely access to medicines. A strategically coordinated, industry dialogue with Health Consumer Organisations (HCOs) and their members, has never been more critical.

Medicines Australia re-established the Consumer Advocacy Working Group (CAWG) with the aim of working more effectively with consumers. The role of the CAWG is to provide

strategic advice and support on all relevant Health Consumer Organisation (HCOs) matters at the industry level in Australia. The CAWG will be an inclusive and collaborative forum of industry members to connect best practice, emerging issues and activities of mutual interest with HCOs to support the patients they serve.

One of the key outcomes of the CAWG looking forward will be to select a Consumer Advisory Panel (CAP) made up of HCOs and patients to provide input and support to the CAWG to ensure the group continues to augment the patient voice on relevant issues within industry.



# Policy Highlights

With a growing and ageing population, investment in the PBS remains the principle Government mechanism to enable Australian patients to receive timely access to the latest medicines, in a cost-effective way, when they need them.

## The Strategic Agreement Implementation Progress

*The National Health Amendment (Pharmaceutical Benefits – Budget & Other Measures) Act 2018* was passed on 21 February 2018. These amendments to the National Health Act 1953 resulted in:

- an increase to the pre-existing statutory price reductions that apply when the first new brand of an existing pharmaceutical item is listed on the Pharmaceutical Benefits Scheme (PBS);
- an extension and introduction of statutory price reductions applying on certain anniversaries of an F1 formulary drug being listed on the PBS;
- an introduction of ministerial discretion in relation to the application of statutory price reductions in certain circumstances;
- the making of minor amendments to price disclosure arrangements.

This year Medicines Australia has continued to work with the Department of Health on the implementation of the Strategic Agreement with an eye towards the next Strategic Agreement due in 2022. Much of the work has

been conducted through Working Groups such as the Access to Medicines Working Group and the Health Economics Working Group. These Working Groups have been meeting regularly throughout the year to continue progressing new streamlined pathways, submission churn, and important improvements to the pre and post PBAC Listing processes.

## Ministerial Discretion Guidelines

Changes to the *National Health Act 1953* in 2018 provided new ministerial discretionary powers in relation to Statutory Price Reductions. Now listed on the PBS website, sponsors can request that their submission (drug) not be subjected to scheduled Anniversary Price reductions. The closing date for these requests will be on 1 December 2019 (and subsequent years after that) with a date of effect being enacted on 1 April of the following year.

Medicines Australia welcomed these initiatives as they will result in significant savings through changes to pricing arrangements negotiated via agreements with key industry stakeholders. This has and will continue to provide at least five years of stability in relation to PBS pricing policy.

## Key Legislative Reforms relating to the Strategic Agreement

Changes in relation to Cost Recovery passed on 1 July 2019.



## Policy Scanning Working Group (PSWG)

The Policy Scanning Working Group was formed this year and held its first meeting in May 2019.

The purpose of this group is to provide advice and support relating to international policy trends, issues and initiatives which may impact on the pharmaceutical industry, and by extension, timely access to innovative prescription medicines for all Australian patients.

The group's key focus for the year was to deliver a compelling narrative around the value and benefits of innovative medicines and the industry in Australia.

## Health Economics Working Group (HEWG)

The Health Economics Working Group meets at least 4 times per year and its purpose is to provide clear advice and support on areas of health economics and market access trends.

It also aims to advance issues and initiatives which impact on the pharmaceutical industry and play a pivotal role in providing direction.

The group's key focus for the year was to contribute to the implementation of the next Strategic Agreement between Medicines Australia and the Australian Government specifically regarding market access, pricing, and reimbursement.

## Access to Medicines Working Group (AMWG)

The Access to Medicines Working Group is one of our longest running and most successful working groups. From its inception over 10 years ago in 2006, this group was jointly formed by Medicines Australia and the Department of Health to work together more effectively to address policy issues facing the industry and act on policies to underpin timely and affordable access to new medicines for all Australians. In 2017 a compact was entered

between the Commonwealth Government and Medicines Australia which allows for the ongoing collaboration of the group through to July 2022.

The AMWG met by Teleconference in July 2018, and face to face in November 2018 and March 2019. The AMWG is co-chaired by the Chair of Medicines Australia and the Deputy Secretary of the Department of Health. Four AMWG subgroups, that meet more regularly, are dedicated to delivering the key AMWG priorities. The Priorities for the year were focused on the terms of the Strategic Agreement, namely; improving efficiencies in the PBS listing process through the development of streamlined PBAC pathways and review of the cost recovery arrangements. Other priorities include consideration of comparator selection issues and biosimilar policy. Further information on each of these subgroups is listed below.

- **Streamlined Pathways Subgroup**

A key subgroup of the AMWG is the Streamlined Pathways Subgroup (SPS). This group has been meeting approximately every 2 – 3 weeks during 2018-19 with the intention of progressing improvements to the PBS process.

Phase 1 (one) of these changes was completed in March 2019 for implementation in July 2019. An update report was provided to the Minister for Health in March who endorsed the plan for implementation in July. The second phase of progression is currently scheduled to be implemented on 1 July 2020.

- **Comparator Selection Subgroup**

Another subgroup of AMWG is the Comparator Selection Subgroup. The subgroup works on the incidence and nature of choice of comparators in relation to submissions made to the PBAC. The intent is to consider the misalignment between the intent of PBS reform and application of

the lowest cost comparator selection from the multi brand and commoditised market.

The subgroup continues to review and report on the impact of comparator selection in line with the objectives outlined in the National Medicines Policy. There is growing understanding of the industry concerns and acknowledgement of the need for improved education on the issues.

- **AMWG & GMWG Transparency Subgroup**

The AMWG Transparency Subgroup has joint membership with members of the Generic Medicines Working Group (GMWG) represented by the Generic & Biosimilar Medicines Association (GBMA). This subgroup has been considering the impacts of policies that effect both the innovative and the generics industry members, such as the changes to cost-recovery. Through this working groups the joint industry Members obtained improved consultation processes on the cost-recovery proposals and won some significant concessions on the timeframe, magnitude and implementation of cost-recovery. Work continues identifying further improvements that can be made to the PBAC consideration process.

New proposals related to transparency of Public Summary Documents (PSD) have been brought into this working group under the auspices of the Agreement commitment to transparency and improved efficiency of processes.

- **AMWG & GMWG Biosimilars Policy Subgroup**

This second joint Medicines Australia, GBMA subgroup continued its work on identifying ways to support the formation of a functioning and competitive biosimilars market in Australia, in line with the objectives set out in the Strategic Agreement. Data on biosimilar uptake arising from the policy changes in the

Agreement have been slow to materialize and further work is required to understand the impact of those policies.

### **Life Saving Drugs Program (LSDP)**

After reaching an agreement between Medicines Australia and the Commonwealth Government in 2018, the LSDP programme implemented PBS-like anniversary price adjustments at 5, 10 and 15 years. Medicines Australia welcomed the establishment of an Expert Panel with terms of reference that include:

- assessment of how the medicine addresses the LSDP criteria;
- guidelines for use, pricing arrangements; and
- future data collection requirements.

The programme is currently chaired by Professor Andrew Roberts. As a result of the agreement, \$5.4 Million has been allocated over the next 5 years to continue to facilitate improvements to the administration of the programme.

### **Cost Recovery Proposals**

Medicines Australia formally responded to proposals that were made at the Cost Recovery meeting held on 9 November 2018 between Medicines Australia and the Department in relation to '*Draft cost recovery implementation statement (CRIS) 1 July 2019 – 30 June 2020.*' Medicines Australia suggested that further consultation will be required for successful new pathway processes to be implemented. Medicines Australia had accepted that 100% cost recovery should apply to the enhanced pre-submission meetings and the intent to apply processes which commenced during phase one proceedings on 1 July 2019.

In relation to vaccines, Medicines Australia requested further clarity on the new proposed process changes. We supported these charges being omitted from the current CRIS to allow

for further discussion until an agreement had been reached and potential duplication during the ATAGI and PBAC processes was addressed. The Department has agreed to delay the implementation of these fees to January 2020.

Medicines Australia further recommended that cost recovery changes to the existing model and new cost recovery processes to the new streamlined pathway processes must be addressed and communicated to the industry.

### **2019 Bridge Program**

The Bridge program was launched in 2017. It selects participants from across Australia to take part in educational programs and seminars designed for academics, researchers, entrepreneurs and associated professionals to gain further knowledge regarding clinical, regulatory and reimbursement elements of pharmaceutical commercialisation. The program provides detailed practical know-how to accelerate participants' development.

Furthermore, in 2019 the program was awarded funding through MTP Connect's Biomedical Translation Bridge (BTB) to continue upskilling researchers and entrepreneurs to further enhance the Australian Pharmaceutical research sector on the global stage.

The program has evolved to be a highly competitive vessel that selects up to 100 of the top applicants and this year will focus on protecting intellectual property, structuring biotech financial deals, regulatory approval processes in clinical trials, and reimbursements.

### **Clinical Trials**

Medicines Australia continues to be a strong advocate for Clinical Trials in Australia and is a member of the Clinical Trials Collaborative Forum.

The purpose of this forum is for government and industry bodies to collaborate and identify issues, with a view to removing duplication and improving the overall clinical environment.

A focus of the last meeting in November 2018 was the work being done by The Australian Clinical Trials Alliance (ACTA) to strengthen clinical trial networks across the country for clinician investigator led clinical trials (not industry sponsored trials), while being strategically focussed on being efficient and effective.

The Clinical Trials Collaborative Forum is anticipated to reconvene again in 2019, and Medicines Australia looks forward to continuing its active participation.

In various submissions Medicines Australia has advocated for:

- Harmonisation of state and territory differences in clinical trial governance and process requirements
- Increased focus on next generation treatment modalities and precision medicine
- Enhancing Australia's reputation as an attractive research destination
- Early clinical translation of innovative collaborative health technologies into commercial ideas.

In pre-election letters from both the major parties there is bipartisan commitment to resolve the variability across the States and Territories and to improve Clinical Trial governance and harmonisation with a goal of improving the time to trial initiation and patient recruitment. Following the Liberal National Coalition forming Government in May 2019, the Minister for Health announced the development of a National "Front Door" for Clinical Trials and has requested that Medicines Australia assist in the development of solutions and engagement on this issue across the States.

### Intellectual Property, Trade and Tax

Medicines Australia has continued to advocate for policies that support investment in the health of Australians and enhance the

Australian economy. During the year Medicines Australia provided submissions to Departments and to the Parliament that:

- Reiterated support for a strong, stable intellectual property environment that rewards industry's niche strengths in research and advanced manufacturing, and is consistent with international IP norms
- Promoted harmonisation of regulatory standards across key trading partners
- Encouraged policies and incentives that attract investment in R&D
- Endorsed mechanisms to monitor, strengthen and improve trade relations.

In March 2019 Medicines Australia provided a submission to the Senate Standing Committee on Economics and welcomed the opportunity to respond to the inquiry into Intellectual Property Laws Amendment Bill 2019. Several points were highlighted for their importance:

- Retaining innovation patents
- Unambiguous object clauses that is consistent with international obligations
- Granting of compulsory licences only in exceptional circumstances and only when in accordance with international rules and;
- The application of Crown use provisions only where consistent with Australia's obligations under international treaties.

In providing these recommendations, Medicines Australia strongly believes these would maintain and strengthen the intellectual property environment which will continue to support Australian scientists, researcher organisations, universities and biotechnology companies to continue to allow for innovation in medicines, for the benefit of all Australians.

Medicines Australia urged the committee to reconsider the proposed amendments outlined in the Australia's Patents Act to ensure the bill supports innovation and provided certainty to investors, consistent with Australia's international obligations.

Another major submission made by Medicines Australia in (month?) 2019 was the response to the European Commission Directorate-General for Trade. Response was made in providing additional input to the Sustainability Impact Assessment – Negotiations on a free trade agreement between the EU and Australia.

Medicines Australia welcomed the opportunity to provide an overview of the state of the Pharmaceutical Benefits Scheme in Australia and its position as an integral part of Australia's health care system, as well as how the PBAC evaluates submissions.

Our submission also demonstrated that claims of an AUSFTA being detrimental to the PBS resulting in higher pharmaceutical prices in Australia were false and we disputed that this would occur through a free trade agreement with the EU, pointing out that it would have no effect on Australia's ability to manage its domestic health policy.

Medicines Australia enhanced our international engagement in 2018-19 to reinforce the need for a strong IP regime in Australia and met with colleagues in the USA, UK and Europe from PhRMA, BIO, ABPI, EFPIA, IFPMA. Subsequently, our international colleague reinforced Australia's submissions with their own.

### Regulatory Affairs and TGA

Medicines Australia and the Regulatory Affairs Working Group (RAWG) have continued to work on expanding access to innovative medicines in the regulatory affairs space. Key priorities have included:

- Optimise the existing registration pathways to be fully fit for purpose

- Establish a pipeline partnership with the TGA to build capabilities and future pathways for new innovative medicines
- Continue to build strategic relationships with key stakeholders to effectively shape the future environment
- Optimise the CMI and PI format to support QUM and better health outcomes
- Improve health literacy so that key stakeholders understand the value and benefits of our Members
- Empower consumers with better understanding of the process and timelines to access new medicines.

### Key achievements included:

- Medicines shortages – Collaboration with the TGA to support guidance development to assist sponsors to comply with the new requirements for medicines shortages that were implemented in 2019.
- Consumer Medicine Information (CMI) – Progress on the development and implementation of a new CMI template in collaboration with the TGA and other stakeholders.
- Evolving the Regulatory Framework for the Future – Working with the TGA on how the regulatory framework may need to evolve to integrate evolving technologies and new innovations. It was recognised there was a need to reassess how the framework could remain fit for purpose with some challenges already identified in the area of advanced cell and gene therapies.
- Transparency Reforms – whether the TGA should publish that a prescription medicine is under evaluation – A submission was developed to support the Medicines Australia position that full transparency of all submissions ie new molecular entities,

generics and biosimilars is the only policy option that can withstand public scrutiny and benchmarks with schemes by comparable overseas regulators e.g. EU and Canada.

- Prescription Medicines Registration Process (PMRP)/Variations Workshops – creation of new pathways for the registration of prescription medicines to provide certainty on issues throughout the registration process and better align with international best practice. Updates to the current variations scheme were workshopped to allow more options for evaluation of major variations of widely differing complexity. and benchmarks with schemes by comparable overseas regulators e.g. EU and Canada.
- Prescription Medicines Registration Process (PMRP)/Variations Workshops – creation of new pathways for the registration of prescription medicines to provide certainty on issues throughout the registration process and better align with international best practice. Updates to the current variations scheme were workshopped to allow more options for evaluation of major variations of widely differing complexity.

### Access and Pricing

Medicines Australia has continued to advocate for patient access to new medicines at a price they can afford, and for stable and predictable policies for the PBS which ensure that both patients and the medicines industry can effectively plan for the future.

In addition to working with the Department of Health and other stakeholders, Medicines Australia has been involved in submissions which emphasise key issues relating to the importance of access to medicines, including:

- Reviewing the reimbursement of PD-1 and PD-L1 immunotherapies for subsidy on the PBS
- Ensuring the availability of innovative funding models for novel antimicrobials and therapies to support further R&D and a sustainable marketplace

- Appropriate consultation and early engagement with sponsors regarding PBS process improvements and cost recovery to ensure effective business planning and that the medicines industry remains viable
- Advocating and working with stakeholders to deliver improvements in efficiency, transparency and timeliness of the PBS listing process.

### Submissions:

[PD-1 and PD-L1 checkpoint inhibitor immunotherapies: options for subsidy consideration for multiple cancer types \(August 2018\)](#)

[Medicines Australia – Consideration of proposed listing changes to antibiotic repeats on the Pharmaceutical Benefits Scheme \(Dec 2018\)](#)

[Medicines Australia response to the Draft Cost Recovery Impact Statement \(CRIS\) for Listing Medicines on the PBS and Designated Vaccines on the NIP 2019-20 \(Feb 2019\)](#)

[Medicines Australia's submission to the Consultations on PBS Process Improvements \(March 2019\)](#)

[Medicines Australia's submission on the Public consultation on Positive Recommendation Pathways process and guidance \(April 2019\)](#)

[Medicines Australia's submission on the consultation paper specific to the introduction of a consumer-friendly Medicines Status Website \(MSW\) \(April 2019\)](#)

### Broad Medicines Policy

Medicines Australia have also provided submissions to various consultations in the health and medicines industry, where we reiterated our support for:

- Enhanced systems and processes that support the quality use of medicine
- Investing and supporting further investment in the innovative medicines sector to continue to drive the demand for high-skilled jobs

- The social and economic benefits of investing in medicines
- Opportunities for public health initiatives such as NPS MedicineWise to deliver value for money, improve linkages with relevant stakeholders and achieve the QUM outcomes expected of Government.

### Submissions:

[Pharmaceutical Society of Australia \(PSA\) 2023 Discussion Paper – Medicines Australia submission \(Sept 2018\)](#)

[World Health Organization Global Patient Safety Challenge – Medication without harm – Medicines Australia response \(Sept 2018\)](#)

[Medicines Australia response to the Australian Government's Vocational Education and Training \(VET\) review \(Jan 2019\)](#)

[Medicines Australia's submission to the Discussion Paper: Co-designing and publishing a Digital Medicines Program Blueprint \(March 2019\)](#)

[Medicines Australia's submission to the Productivity Commission – The Social and Economic Benefits of Improving Mental Health \(April 2019\)](#)

[Medicines Australia's submission to the Department of Health's Review of the Quality Use of Medicines \(QUM\) Program Delivery by NPS MedicineWise \(Jan 2019\)](#)

### Regulatory Affairs and the TGA

The Medicines Australia Regulatory Affairs Working Group (RAWG) has continued to collaborate closely with the TGA on regulatory issues in order to streamline the medicines evaluation process and provide innovative medicines to patients. Medicines Australia has also provided responses to many TGA consultations throughout the year as a part of our engagement and collaboration with TGA.

[Medicines Australia submission on the Therapeutic Goods Administration \(TGA\) consultation paper 'Boxed Warning Guidance' \(Aug 2018\)](#)

[Medicines Australia response to the Therapeutic Goods Administration \(TGA\) consultation paper 'Transition to eCTD only for prescription medicines \(Dec 2018\)](#)

[Medicines Australia response on the Therapeutic Goods Administration \(TGA\) consultation paper 'Proposal for the regulation of IVD companion diagnostics \(Dec 2018\)](#)

[Therapeutic Goods Order 78 \(TGO78\) – Standard for tablets and capsules \(Feb 2019\)](#)

[Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 \(Prescription only\) to Schedule 3 \(Pharmacist only\) \(Feb 2019\)](#)

[Medicines Australia response to the Therapeutic Goods Administration \(TGA\) consultations relevant to Medical Devices \(Feb 2019\)](#)

[Medicines Australia's submission to the TGA Consultation: Good Clinical Practice Inspections Program \(March 2019\)](#)

[Medicines Australia's submission to the TGA Consultation on the reforms to the generic medicine market authorisation process \(March 2019\)](#)

[Medicines Australia's submission to the consultation on whether the TGA should publish that a prescription medicine is under evaluation \(March 2019\)](#)

[Medicines Australia submission to the New Zealand Ministry of Health Therapeutic Products Regulatory Scheme – draft Therapeutic Products Bill \(April 2019\)](#)

# Code of Conduct Report

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

Medicines Australia’s Ethical Conduct activities in 2018-2019 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 Future of the Code Working Group continued its thorough review of the Code taking a holistic approach to ensure that the next edition of the Code will be fit for purpose and represents the modern, mature industry that Medicines Australia represents today.

Continuing Medicines Australia’s focus on thought leadership in ethical behaviour in the pharmaceutical industry, the Ethics and Compliance team engaged in global activities

that spotlight Australia’s achievements to the world. The team participated in the APEC Business Ethics for SMEs in the biopharmaceutical and medical device sectors forum, held in Tokyo in July 2018, which provided an opportunity to share ideas and knowledge with industry and healthcare bodies across 18 APEC economies. At this forum, the Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector was launched. The framework is a consensus statement with almost 70 participating signatories that describes the values and ethical principles that form the basis for collaboration and interaction among organisations in the healthcare sector. This signing of this document during the plenary session at the APEC forum also culminated in the Australian delegation being awarded the Lighthouse Award for 2018, which celebrates strong ethical leadership in the region.



# Complaints, Appeals & Monitoring

## Complaints Handling

Medicines Australia considered 4 complaints in 2018-2019, with three complaints finalised before the end of the financial year, and one still under consideration at the close of the financial year. The number of complaints received by Medicines Australia remains has remained low this year.

**Subject Company:** Non-Member Company  
**Complainant:** MA Member Company  
**Outcome:** Withdrawn prior to committee hearing

**Subject Company:** MA Member Company  
**Complainant:** MA Member Company  
**Outcome:** Withdrawn prior to committee hearing

**Subject Company:** MA Member Company  
**Complainant:** MA Member Company  
**Outcome:** Breach (appeal not upheld)

**Subject Company:** MA Member Company  
**Complainant:** MA Member Company  
**Outcome:** No Breach

**Subject Company:** MA Member Company  
**Complainant:** MA Member Company  
**Outcome:** No Breach

**Subject Company:** MA Member Company  
**Complainant:** MA Member Company  
**Outcome:** Matter still under consideration

As shown in the table above, two complaints lodged in 2018-2019 were submitted to Medicines Australia and assigned complaint numbers, however, were withdrawn prior to the Code Committee hearing. Materials were not provided to the Code of Conduct Committee. No further information will be provided about these complaints.

The Code of Conduct Committee’s reasons for decisions for the complaints heard during 2018-2019 can be found in this annual report.

## Monitoring of Member Company activities

The Monitoring Committee continued its schedule of monitoring reviews during 2018-2019, reviewing materials associated with specific therapeutic areas, as well as Member Companies’ HCO Support Reports and policies and procedures relating to the provision of hospitality. Details of the Monitoring Committee’s activities can be found in this annual report.

# 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 2018-2019 Medicines Australia Member Companies published reports on their Australian corporate websites which detailed activities for the periods 1 November 2017 – 30 April 2018 and 1 May 2018 – 31 October 2018. These reports continue the 'mandatory' reporting by Member companies of all payments and transfers of value made to Australian Healthcare Professionals. As predicted, a diminishing number of interactions were reported where the activity was 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 continued the build of the Central Reporting System with Pacific Commerce Pty Ltd. Progress towards project completion was made, with major milestones met. Member

Companies engaged in beta testing of the system with already published information. A few technical challenges were discovered and resolved rapidly during testing. The Central Reporting System is on track for launch in August 2019 with the inclusion of data for the November 2018 – May 2019 reporting period.

## 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 2018 showed that there were 1,174 events sponsored by 33 Member companies in the period 1 November 2017 – 30 April 2018. On 30 April 2019, Member Companies published reports for the period May 2018 – October 2018, which reported on 1,789 events sponsored by 32 Member companies in that six-month period.

## Health Consumer Organisation Support Reports

In June 2019 Medicines Australia published the sixth annual reports of Member Companies' financial support for Health Consumer Organisations (HCO). Member companies supported 114 different HCOs across Australia

in calendar year 2018, ranging from national consumer organisations to small local groups, relating to 321 different projects or events to the total value of \$8,246,422 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 2018-2019 1,844 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 2018-2019 210 students 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 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 2018 were presented in March 2019.

### 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 Morgan Bouzaid from Seqirus, and Bernd Merkel from Biogen.

### Code of Conduct Award

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

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

### CEP Achievement Award

CEP Achievement Award winners are the students who achieve the 10 highest aggregate marks. CEP Achievement Award recipients for 2018 are:

|                            |                      |
|----------------------------|----------------------|
| Anna Barlo .....           | Bayer                |
| Jasmine Taylo .....        | Norgine              |
| Lachlan Gray .....         | GSK                  |
| Selcuk Yatmaz .....        | Boehringer Ingelheim |
| Pratheep Akilan .....      | Boehringer Ingelheim |
| Jan-Javier Lehnert .....   | Sanofi               |
| Astrid Lefringhausen ..... | Grifols              |
| Keegan Au-Yeung .....      | AstraZeneca          |

# Medicines Australia In The Community

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 studying medicine at UNSW 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 2018-19 Financial Year.

### Shalom Gamarada Parliament House Event

Medicines Australia attended the annual Shalom Gamarada NSW Parliament House Event in March 2011.

Brad Hazzard spoke about the incredible outcomes of the programme, with an 80 per cent completion rate. Moreover, he congratulated participants for their commitments to their communities.

A video of the event can be viewed here: <https://youtu.be/pvEZaGGt9mw>

# 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.

### ADVISORY COUNCIL

|                          |                         |
|--------------------------|-------------------------|
| Andrew Carter .....      | Commercial Eyes Pty Ltd |
| Dr Anna Lavelle .....    | Chair                   |
| Carol Bennett .....      | Independent             |
| Catherine McGovern ..... | Independent             |
| David Grainger .....     | Biointelect             |
| David Herd .....         | GlaxoSmithKline         |
| Elizabeth de Somer ..... | Medicines Australia     |
| Prof. Ian Chubb .....    | Independent             |
| Jeffrey Harmer .....     | Independent             |
| Mark McCrindle .....     | Independent             |
| Nicola Richards .....    | Merck Sharp & Dohme     |
| Dr Vicki Gardiner .....  | Medicines Australia     |

### CHIEF EXECUTIVES GROUP

|                          |                     |
|--------------------------|---------------------|
| Elizabeth de Somer ..... | Medicines Australia |
| Jodie Thomas .....       | Novo Nordisk        |
| Kelly Griffiths .....    | GSK                 |
| Louise Graham .....      | Pfizer              |
| Mitch Kirkman .....      | Novartis            |
| Nicola Richards .....    | MSD                 |
| Paul Lindsay .....       | Merck               |
| Penny George .....       | Sanofi              |
| Sara Pantzer .....       | Amgen               |
| Dr Vicki Gardiner .....  | Medicines Australia |
| Wade McMonagle .....     | AbbVie              |

### STANDARD WORKING GROUPS

#### Government Working Group (GWG)

|                         |                            |
|-------------------------|----------------------------|
| Adrian Dolahenty .....  | Bayer                      |
| Amanda McPherson .....  | Celgene                    |
| Amy Moore .....         | AbbVie                     |
| Anna Schulze .....      | CSL                        |
| Ben Gommers .....       | MSD                        |
| James McAdam .....      | BMS                        |
| Jamie Snashall .....    | Chair, Medicines Australia |
| Josh Bihary .....       | Pfizer                     |
| Kieran Schneemann ..... | AstraZeneca                |
| Paul Lindsay .....      | Merck                      |
| Penny George .....      | Sanofi                     |
| Peter Murphy .....      | Novartis                   |
| Sara Pantzer .....      | Amgen                      |
| Todd Stephenson .....   | Janssen                    |

#### Oncology Industry Taskforce

|                          |                      |
|--------------------------|----------------------|
| Aldina Aljukic .....     | Novartis Australia   |
| Alissa Brown .....       | Sanofi-aventis       |
| Amy Moore .....          | AbbVie               |
| Carlene Todd .....       | Roche Products       |
| Carmel Spiteri .....     | Merck Sharp & Dohme  |
| Darin Kottege .....      | Medicines Australia  |
| David Pullar .....       | Roche                |
| David Thomson .....      | Amgen Australia      |
| Elise Kelly .....        | Pfizer Australia     |
| Elizabeth de Somer ..... | Medicines Australia  |
| Greg Cook .....          | Bristol-Myers Squibb |
| James McAdam .....       | Bristol-Myers Squibb |

|                          |                        |
|--------------------------|------------------------|
| Josie Downey .....       | Merck Sharp & Dohme    |
| Kate Webb .....          | Takeda Pharmaceuticals |
| Katherine Rocks .....    | Takeda Pharmaceuticals |
| Kieran Schneemann .....  | AstraZeneca            |
| Kristina Turner .....    | AbbVie                 |
| Louise Graham .....      | Pfizer                 |
| Matthew Slabbert .....   | Bayer                  |
| Mike Smith .....         | AstraZeneca            |
| Nichollette Conway ..... | Eli Lilly              |
| Paul Lindsay .....       | Merck Serono           |
| Peter Murphy .....       | Novartis               |
| Philippa Delahoy .....   | Pfizer Australia       |
| Philip Spiers .....      | AstraZeneca            |
| Rebecca Stratford .....  | Novartis Australia     |
| Sara Pantzer .....       | Amgen Australia        |
| Sean Lybrand .....       | Amgen Australia        |
| Simon Dawson .....       | AbbVie                 |
| Simon Higgins .....      | Bristol-Myers Squibb   |
| Todd Stephenson .....    | Janssen-Cilag          |
| Vanessa Xavier .....     | Sanofi-aventis         |
| Dr Vicki Gardiner .....  | Medicines Australia    |
| Wes Cook .....           | Boehringer Ingelheim   |

#### Health Economics Working Group (HEWG)

|                     |                      |
|---------------------|----------------------|
| Carlene Todd .....  | Roche Products       |
| Darin Kottege ..... | Medicines Australia  |
| Greg Cook .....     | Bristol-Myers Squibb |
| Jodie Wilson .....  | AbbVie               |
| Kate Webb .....     | Takeda               |
| Louise Graham ..... | Pfizer Australia     |

|                        |                      |
|------------------------|----------------------|
| Matthew Slabbert ..... | Bayer                |
| Michael Haberl .....   | GlaxoSmithKline      |
| Peter Germanos .....   | Boehringer Ingelheim |
| Rachael Anderson ..... | AstraZeneca          |
| Sean Lybrand .....     | Amgen                |
| Tenille Manuele .....  | Commercial Eyes      |
| Vanessa Stevens .....  | Vifor Pharma         |

#### Medicines Australia Vaccines Industry Group (MAVIG)

|                          |                     |
|--------------------------|---------------------|
| Anne Harris .....        | Pfizer              |
| Danielle Dowell .....    | CSL                 |
| Darin Kottege .....      | Medicines Australia |
| David Herd .....         | GlaxoSmithKline     |
| Paul Hester .....        | Merck Sharp & Dohme |
| Sheryl Page .....        | GlaxoSmithKline     |
| Stephen Richardson ..... | Sanofi-aventis      |
| Stuart Harsley .....     | CSL                 |
| Valda Struwig .....      | Pfizer              |
| Vanessa Xavier .....     | Sanofi-aventis      |
| Vicki Gardiner .....     | Medicines Australia |

#### Regulatory Affairs Working Group (RAWG)

|                            |                     |
|----------------------------|---------------------|
| Andrew Notley .....        | Gilead Sciences     |
| Andrew Bowskill .....      | Medicines Australia |
| Betsy Anderson-Smith ..... | Medicines Australia |
| Brian Hewitt .....         | Pfizer Australia    |
| Carolyn Tucek-Szabo .....  | GlaxoSmithKline     |
| George Lillis .....        | Novartis Australia  |
| Helen Critchley .....      | Sanofi-aventis      |
| Jagdish Ghadge .....       | Shire               |

Kirpal Kaur ..... Bristol-Myers Squibb  
Linda Ponkshe ..... Janssen-Cilag  
Mark Rowland ..... Amgen Australia  
Michael Parker ..... AstraZeneca  
Natalie Touzell ..... Roche  
Peter Komocki ..... Medicines Australia  
Simon Byrne ..... Celgene  
Sylvia Roins ..... Novartis  
Vicki Gardiner ..... Medicines Australia

**RAWG-Pharmacovigilance Subgroup**

Bianca Joo ..... Sanofi-aventis  
Christine Marshall ..... Bristol-Myers Squibb  
Denise Dolan ..... GlaxoSmithKline  
Geraldine Peterson-Clark .. Boehringer Ingelheim  
Harriet Jones ..... Janssen-Cilag  
Jane Crick ..... Shire Australia  
Karen Battat ..... AstraZeneca  
Karen Clayton ..... Roche Products  
Karen Whitelock ..... AbbVie  
Leigh Kessler ..... Amgen  
Lynne Puopolo ..... Merck Sharp & Dohme  
Mounir Mina ..... Novartis  
Nick Wright ..... GlaxoSmithKline  
Peter Komocki ..... Medicines Australia  
Sarahann Simpson ..... Pfizer  
Vicki Gardiner ..... Medicines Australia

**RAWG GMP Subgroup**

Albina Perri ..... GlaxoSmithKline  
Betsy Anderson-Smith ..... Medicines Australia  
Cindy Chiddy ..... Roche Products  
Claudia Opitz ..... Sanofi-aventis  
Emma Dernelley ..... Amgen  
Joy Pallis ..... AbbVie  
Lisa Taylor ..... Boehringer Ingelheim  
Lorraine Sutherland ..... Amgen Australia  
Natalie Corrick ..... AstraZeneca  
Peter Komocki ..... Medicines Australia  
Rakhee Gokai ..... Merck Sharp & Dohme  
Ruby Joseph ..... Shire  
Toula Boloutis ..... Ipsen

Vicki Gardiner ..... Medicines Australia  
Wai Zin Wong ..... Bristol-Myers Squibb

**Consumer Advocacy Working Group (CAWG)**

Anna Karelas ..... Bayer  
David Green ..... Vifor  
Hayley Anderson ..... Bristol Myers Squibb  
Katherine Tocchini ..... Novartis  
Leigh Lawrence ..... Pfizer  
Lisa Julian ..... Eli Lilly  
Michele Robbins ..... Celgene  
Zarli French ..... MSD

**Continuing Education Program Working Group (CEPWG)**

Aaron Guttman ..... Bristol-Myers Squibb  
Ben Warner ..... Pfizer Australia  
David Schlesinger ..... AbbVie  
Martina Ryan ..... Janssen-Cilag  
Simon Scott ..... Sanofi-aventis  
Sophie Hibburd ..... Medicines Australia  
Tracey Payne ..... Merck Sharp & Dohme

**Future of the Code Working Group**

Anna Argyropoulos ..... UCB  
Alan Paul ..... Ipsen  
Andrew Weekes ..... GlaxoSmithKline  
Ben Hopkins ..... Takeda Pharmaceuticals  
Calvin London ..... Celgene  
Danielle Dowell ..... CSL  
Deborah Monk ..... Medicines Australia  
Jonathan Anderson ..... Bristol- Myers Squibb  
Lisa Maguire ..... AbbVie  
Shane McSpedden ..... Pfizer Australia  
Sophie Hibburd ..... Medicines Australia  
Stuart Englund ..... Janssen-Cilag  
Scott McIntyre ..... Merck Sharp & Dohme

**ISSUES GROUPS**

**Biosimilars and Biologics Issues Group**

Andrew Thirlwell ..... Pfizer Australia  
Anne-Maree Englund .... Merck Sharp & Dohme  
Astrid Macassey ..... AbbVie  
David Pullar ..... Roche Products  
David Thomson ..... AbbVie (now Amgen)  
Elizabeth de Somer ..... Medicines Australia  
Jamshed Ahmen ..... Novo Nordisk  
Jodie Wilson ..... AbbVie  
Josh Bowen ..... Roche Products  
Kate Webb ..... Takeda  
Louise Graham ..... Pfizer  
Lee Davelaar ..... Pfizer Australia  
Matthew Little ..... AbbVie  
Mark Schulz ..... Novartis  
Paul Lindsay ..... Merck Serono  
Penny George ..... Sanofi-aventis  
Peter Germanos ..... Boehringer Ingelheim  
Peter Murphy ..... Novartis  
Peter Vermeer ..... Eli Lilly Australia  
Rowan O’Brien .. Novo Nordisk Pharmaceuticals  
Roger Falconer-Flint ..... AstaZeneca  
Sara Pantzer ..... Amgen  
Stacey Bolto ..... Novartis  
Stephen Richardson ..... Sanofi-aventis  
Stuart Englund ..... Janssen-Cilag  
Tim Dow ..... Ipsen  
Todd Stephenson ..... Janssen-Cilag  
Vicki Gardiner ..... Medicines Australia

**Intellectual Property Issues Group (IP Issues Group)**

Amy Moore ..... AbbVie  
Duncan Purvis ..... Janssen-Cilag  
Elizabeth de Somer ..... Medicines Australia  
James Sharkey ..... AstraZeneca  
Kelly Griffiths ..... GlaxoSmithKline  
Sara Pantzer ..... Amgen Australia  
Stuart Englund ..... Janssen-Cilag  
Vanessa Stevens ..... Vifor Pharma  
Vicki Gardiner ..... Medicines Australia

**OTHER GROUPS**

**Research and Development Taskforce (R&DTF)**

Andrew Bowskill ..... Medicines Australia  
Andrea Kunca ..... Medicine Technology Association of Australia  
Anita van de Meer ..... Medtronic  
Candice Fitzgerald ..... Boehringer Ingelheim  
Carrie Bloomfield ..... GlaxoSmithKline  
Catherine Bourgeois ..... Abbott  
David Lloyd ..... Southern Star Research  
David Wilks ..... Bristol-Myers Squibb  
Edwin Ho ..... Medical Technology Association of Australia  
Elizabeth de Somer ..... Medicines Australia  
Falko Thiel ..... Biotronik  
Gemma Eldridge ..... Medpace  
Helen Aunedi ..... Roche  
Jane Kelly ..... CMax  
Lauren Macnaughton ..... Eli Lilly  
Mitch Kirkman ..... Novartis  
Neina Fahey ..... Medical Technology Association of Australia  
Pedro Crisant ..... Servier Laboratories Australia  
Peter Komocki ..... Medicines Australia  
Sara Pantzer ..... Amgen  
Shanny Dyer ..... ARCS Australia  
Sharon Charles ..... Mesoblast  
Val Theisz ..... MTAA Secretariat Support  
Vicki Gardiner ..... Medicines Australia

# Members' Events

## 2018 Annual General Meeting

The 2018 Annual General meeting was held on Friday 26 October 2018 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.

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 medicines industry.

## Board Meetings

Medicines Australia convened a number of Board meetings during the 2018-2019 financial year:

|                        |                         |
|------------------------|-------------------------|
| 18 July 2018 .....     | Board Strategic Retreat |
| 19 July 2018 .....     | Board meeting           |
| 26 October 2018 .....  | Board Meeting           |
| 12 December 2018 ..... | Board Meeting           |
| 20 February 2019 ..... | Board Meeting           |
| 2 April 2019 .....     | Board Meeting           |

## PAGE Gender Equity Workshop

The Special Interest Group Pharma Australia Gender Equity (PAGE) was formed in 2017 with the goal of strengthening the industry's

approach to developing talent by ensuring all people have equal opportunities to advance and be rewarded.

In conjunction with Mercer, an industry wide senior leadership workshop was held in July 2018 to build a change agenda that would support the industry to lead Australian workplaces on gender equality.

The key priorities areas identified and agreed upon at the workshop were gender pay equity, mainstreaming flexible working for everyone and supporting parental leave. These priorities formed the focus for PAGE in 2018-2019 to support the pharmaceutical industry and meet demands of the future of work.

In December 2018, PAGE held a breakfast briefing to share an overview of the work completed by PAGE to date and plans for 2019. During the briefing, the then PAGE co-chairs, Kimberly Elliott (AstraZeneca) and Maria Allart (Janssen) gave an overview of PAGE's objectives and plans for the future, and Yolanda Beattie from Mercer presented gender equity research conducted across the Pharmaceutical industry in Australia.

The session concluded with a panel discussion covering the origins of the PAGE initiative, challenges and opportunities for gender equity in the pharma industry, and a leaders' perspective on the initiatives that have made the biggest difference to gender equity for men and women at work.

In 2019 PAGE has implemented its active program, led by the current co-chairs Kate Richards (AbbVie) and Fabienne Connet (Biogen), holding a two-day "Flex Ready" flagship workshop in early April and a "Guiding principles and pay equity workshop" in May. On 4 July, PAGE launched the '[Creating an industry where everyone thrives](#)' White Paper Report, which outlines the successes and future challenges for pharma in achieving gender equity and creating an environment where all people can thrive.

While pharma is leading other industries in policies and practices that support gender equity, there is still work to be done. By mainstreaming flexible working, improving parental leave for all and reducing existing pay gaps, PAGE driving meaningful change across the industry.

## Women in Life Sciences Luncheon NSW

On Friday 8 March 2019, Medicines Australia joined forces with AusBiotech to host the NSW Women in Life Sciences Luncheon on International Women's Day. The theme this year was 'An Hour to Empower', which featured an action-oriented speaking programme to encourage, support and empower women in the sector.

## Super Working Group

On Thursday 11 April 2019, the Medicines Australia Super Working Group meeting took place at the Pfizer offices in Sydney. In attendance were Medicines Australia Members

including those from the following working groups: HEWG, RAWG, GWG, MAVIG, and Future of the Code.

The purpose of the annual Super Working Group meeting is to facilitate collaboration between the specialist technical and strategic thinkers in our membership that are drawn together in discrete working groups. This enormous wealth of expertise and experience is great to bring together to ensure the focus and activities of the individual groups can be harnessed to better deliver on the Strategic Objectives of the organisation. This group were asked to provide input to the Board Strategic Retreat and the future vision of the industry in the current political and policy environment.

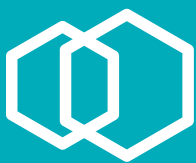
## Issues that were discussed during the day included:

- Alignment with values of the next Government
- The Medicines Australia strategic blueprint
- What are the asks of industry?
- What are the priorities for industry?
- What are the asks of Government?

Also discussed was the status of the progress against the implementation of the current Strategic Agreement following a recent Transformational HTA workshop with the Chief Executive Group. The day resulted in considerable insight and discussion points.



Women in Life Sciences Luncheon NSW



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