Annual Report

2019-2020



Better health through research and innovation

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Our Key **Directives**



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

Ensuring Australians have universal, affordable and fast access to treatments that keep pace with advancements in medicine by working with government, health sector and patient organisations to design and implement the right policy settings.

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

- for Australia.
- they need them through:
 - and treatment
 - the community.



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

2. Ensure new medicines are universally available to Australians when

• Ensuring efficient assessment and evaluation methods to reflect ongoing developments in research, diagnostics

• Ensuring funding mechanisms can adapt to meet the needs of, and deliver value to, government, patients and

Chair's Report

On behalf of the Medicines Australia Board I am pleased to introduce our Annual Report addressing Medicines Australia's activities and achievements during 2019-2020.

There are numerous superlatives that could be used to describe this year, particularly since the rise of the global COVID-19 pandemic in early 2020. Terms with negative overtones such as 'unprecedented', 'challenging time', 'quarantine' and 'social distancing' have become commonplace in our language. However, in Medicines Australia's response to the challenges presented by COVID-19 we have rarely seen such unity of purpose and collaboration between Members, the Board, the Executive and governments, Federal and States. The Board, Executive and Members have worked together with determination and focus to respond quickly and effectively to the demands from multiple guarters caused by the pandemic. I am very proud to have led such a talented Board and organisation as Chair, during this extraordinary year.

Although our response to the COVID-19 pandemic has been top of mind for the Board and CEO this year, there has also been substantial progress towards achieving our strategic objectives. You will see in this report significant projects that have been progressed by the CEO and her team, including outreach to our key stakeholders with a focus on consumers and patients. A number of significant submissions that speak clearly about the issues important to Member companies with regard to public policy development. Also change that has been adopted regarding our Code as well as internal changes to improve efficiency and effectiveness.

Strategic Agreement

Towards the end of 2019/20, the Government started to signal its interest in transitioning from the current Strategic Agreement with Medicines Australia, which expires in mid-2022, to a future Agreement. As the financial demands of responding to COVID-19 for the Government increased and the budget position became clearer, the necessity of planning for the post-pandemic future also became clearer. A sub-group of Directors have worked throughout the year on our strategy for achieving the best possible future for the industry so Members can continue to deliver innovative medicines and therapies to Australians when they need them. As we prepare this report on the 2019-2020 year, a framework for the next strategic agreement has been agreed with the Government and I look forward to reporting on achieving the outcome in next year's report.

Whilst Medicines Australia has invested considerable effort preparing for the future, we are also focussed on ensuring the commitments articulated in the current Strategic Agreement are delivered. We have continued to prosecute these through the Access to Medicines Working Group (AMWG), which I co-chair with the Department of Health Deputy Secretary. Stage 1 of the PBS process improvements have commenced, and we are monitoring how these improve efficiency of achieving PBS reimbursement and deliver faster access to innovative medicines for the community. Change for the better takes time and careful consideration and Member Companies should feel certain that this approach is never out of view for the board or the executive.

NMP Review

Building on strategic insights from the Advisory Council, Medicines Australia advocated for a review of the National Medicines Policy in 2017. This was again requested in our 2019 pre-election manifesto and Budget submission. The Minister for Health, Greg Hunt committed to a Review in November 2019, to commence in March 2020. Since this announcement, Medicines Australia has been working on helping to shape the Terms of Reference (TOR) for the Review to ensure the Review delivers tangible benefits for the community served by the NMP. In early 2020 it was expected that the NMP Review would commence in March and be completed by August 2020. However, the COVID-19 pandemic has meant that this work has been rescheduled by the Department of Health to 2021. Although the NMP Review TOR have not been released and submissions have not been called for, the Review remains a priority for Medicines Australia and we are well prepared for when the Review is finally initiated.

Our Members

Medicines Australia's strategic outcomes can only be achieved with the collective 'brain power' provided by all our Members working together. I wish to acknowledge and thank Member Companies who support the Board and Executive's efforts by committing their staff to work on specific industry projects and working groups. You will find a listing of all the working group Members in this report, but there are many others who also contribute beyond the formal groups to whom I am also very grateful and acknowledge their contributions. CEO Elizabeth de Somer has demonstrated great leadership, managing the many challenges of an effective organisation. On behalf of the Board and Members I congratulate Liz on her achievements this year, particularly representing the industry on multiple fronts to ensure Australians continue to have access to the medicines they need during the pandemic. Liz has worked diligently to present Member's issues in an authentic and professional manner, gaining access to decision makers and building a powerful narrative. I also thank the Medicines Australia team who have shown their commitment to delivering the best outcomes for Members and significantly improving our stakeholder engagement this year, particularly our engagement with patients, consumers and carers.

Governance

The Board is responsible for establishing and maintaining good governance and this year that included a review of the Constitution of Medicines Australia Limited. The Constitution was thoroughly revised and updated following a consultative process with Members, lead by Deputy Chair, Melissa McGregor. The new Constitution explicitly recognises that Members are engaged in developing biotherapeutic products and vaccines as well as prescription medicines and has also clearly recognised the value of having independent Directors on the Board. I am pleased to report that Members unanimously agreed to adopt the new Constitution at the AGM in October 2019. Another significant achievement this year was the unanimous adoption by Members of the new Medicines Australia Code of Conduct in November 2019. The new Code of Conduct is principlesbased, which Members have welcomed. The new edition builds on Medicines Australia's longstanding benchmarks for ethical conduct while reflecting a modern and innovative approach to stakeholder education and communications. The 19th edition of the Code of Conduct came into force in March 2020.

Board renewal

In October 2019 we welcomed five new Directors elected by Members to the Board: Ms Leah Goodman (Merck Healthcare), Ms Christi Kelsey (GSK), Mr Stuart Knight (Roche Products), Mr Neil MacGregor (Bristol-Myers Squibb) and James McDonnell (Vifor Pharma).

In October 2019 two long standing Directors resigned from the Board: the former Chair, Mr Wes Cook, (Boehringer Ingelheim) and Ms Kirsten O'Doherty (AbbVie). Both Wes and Kirsten have made outstanding contributions to Medicines Australia and I thank them on behalf of the Board and Members for their leadership.

The deputy Chair, Ms Melissa McGregor (Pfizer Australia), resigned from the Board in February 2020 following her appointment to lead Pfizer's Western European hospital business. Melissa made a significant contribution to the Board and our Association. Following the election, the new board unanimously appointed Liz Chatwin (AstraZeneca) as the new Deputy Chair.

I wish to acknowledge the notable contributions of retiring Directors Mr Brad Edwards appointed as MD Takeda and Ms My Linh Kha (Amgen) who was appointed to lead Amgen in China.

Thank you to my fellow Directors, both current and recently retired, for your service to Medicines Australia and collegiality as directors.

The year ahead

Although the year ahead will, no doubt, be equally as challenging as 2019-2020 as we negotiate a new Strategic Agreement with the Government and emerge into the post-COVID-19 future, the board and executive envisage an exciting set of opportunities for us to shape into a bright future for the industry. The Directors and I look forward to continuing our work with Members in achieving optimal health outcomes for Australians.

Thank you to all our Medicines Australia Members for your ongoing advice and support.



Dr Anna Lavelle

Medicines Australia Independent Chair

CEO's Report

The 2019-2020 year has been an extraordinary one. The stability of the political agenda provided early optimism, as the Hon. Greg Hunt MP retained the Health portfolio following the Scott Morrison led Government winning the unwinnable 2019 election. Progress continued on prosecuting our strategic agenda, with confidence that there was considerable parliamentary support for timely access to new medicines, modernising the National Medicines Policy and enhancing the clinical trials environment, amongst other things.

Medicines Australia's Strategic Objectives, outlined in the Strategic Blueprint, were made available on the public and Member website and highlighted the key priorities for the organisation on behalf of the industry. This was underpinned by an ambitious operational plan, developed in collaboration with Members and working groups through consultation and workshops, refined by the Executive, and endorsed by the Board in July 2019. A core focus of the 2019 operational plan was to reinforce the industry's thought leadership on the broader health, social and economic value of innovative medicines, including through our communications campaign, 'Medicines Matter'. This involved building stronger ties with third-party voices including Health Consumer Organisations (HCOs), HealthCare Practitioner (HCP) professional bodies and other industry associations, as well as boosting engagement with Parliamentarians and strengthening relationships across the breadth of government departments. The priorities also focussed on planning for a future Strategic Agreement, ensuring implementation of the election commitments, and securing ongoing funding and Government commitment to the PBS, for example through the Budget process.

2019-2020 was also the year to consolidate the organisational capability and performance framework and undertake a review of the Medicines Australia business and value proposition for Members and broader stakeholders.

Election Commitments

In the lead up to the 2019 Federal election, Medicines Australia had advocated and received bipartisan support for five key strategic opportunities. Confirmed in a letter from the Federal Director of the Liberal Party, the Government is committed to 1.) Improve the PBS listing processes. 2.) Continue Strategic Agreements with the industry, through Medicines Australia. 3.) Review the National Medicines Policy (NMP) to ensure it is fit for purpose for future medical innovation. 4.) Work with Medicines Australia to harmonise governance and improve the clinical trials environment, and 5.) Work with Medicines Australia to ensure research and development (R&D) is underpinned by a strong and reliable system of intellectual property protection to enable access to clinical trials and ultimately, patients' access to innovative medicines.

Medicines Australia focussed internal and Member resources to these key areas, being sure to consider domestic and international considerations in developing options and associated work plans. The Research and Development Task Force (RDTF) focussed on developing a proposal for harmonisation of governance and regulatory systems across the States and Territories, whilst Members also convened to establish the framework for our submission to the National Medicines Policy Review.

The Global Innovation Policy Centre (GIPC) from the US Chamber of Commerce and colleagues from the Pharmaceutical Research and Manufacturers of America (PhRMA) association visited Australia in September 2019 for a full program of advocacy on Australia's limitations in its Intellectual Property regime. The GIPC supported Medicines Australia's calls for improved patent notification, extended data exclusivity and removal of the damages claims policy, in order for Australia to appropriately recognise and encourage access to innovative medicines for Australian patients.

Budget Strategy 2019-2020

In the second half of 2019, Medicines Australia determined that our forthcoming submission to the Federal Budget, scheduled to be delivered in May 2020, should make a single request to remove the Government's offset policy for listing new medicines on the PBS. Extensive Member consultation informed the approach and the goal to lodge our pre-Budget submission by the end of the year was achieved, with the submission being made in December 2019.

Significant specialist media and stakeholder reporting since 2017 had established that whilst so ever an offset policy remained in place, coupled with PBAC constraints, the PBS would be unable to continue to meet the needs and expectations of the community.

A collaborative partnership between Government and industry over the past decade has resulted in a sustainable PBS for Government through the introduction of structural and enduring pricing policies that generate continuous savings. Alongside these savings, the introduction (and continuation) of the offset policy in the wake of the global financial crisis has led to a structural decline in the PBS, with flat growth and decreasing net PBS expenditure as a proportion of national GDP.

Our submission made a strong case for the Government to continue to meet its commitment to list all medicines recommended for PBS listing and remove the offset policy for new listings. Thereby, strengthening the ability of Government to provide significant health and economic benefits that the PBS delivers to Australians through access to new medicines.

To support our Budget submission, Medicines Australia and Members conducted a comprehensive advocacy and education program with key Ministers and Shadow Ministers, key departments, key government backbenchers and HCOs. This continued well into 2020, even when it was clear that the Budget, expected in May, would be delayed until October.

Strategic Priorities

As expected, the priorities continued to focus on the PBS listing process and realisation of the current Strategic Agreement; preparation for the National Medicines Policy Review; options for Clinical Trials harmonisation; support for Research and Development through the R&D Tax Incentive, and ensuring damaging legislative amendments were not introduced; improvements to Intellectual Property though support for improved patent notification; and ensuring a compelling communications and stakeholder engagement plan to demonstrate the value of medicines. Medicines Australia continued to prosecute the implementation of the terms of the Strategic Agreement (Agreement) signed in 2017, through extensive sub-committee work of the Access to Medicines Working Group (AMWG). This included implementation and consolidation of stage 1 of the Streamlined Pathways; development and establishment of the Medicines Status Website; and collaboration on forward looking metrics to evaluate the outcomes of the pathways implementation and the goals to reduce listing times and resubmissions.

The Joint Oversight Committee met in accordance with the Agreement to monitor the implementation of the terms. The Department of Health indicated that the savings foreshadowed in the Agreement were not being met, however, Medicines Australia reiterated that given the Agreement had not yet run its course, and more savings are accumulating, this outcome cannot be assumed.

The Public Affairs team strengthened Medicines Australia's information and education campaign around Medicines Matter and increased our activities on social media to raise awareness of the important contribution of medicines and the medicines industry. This became particularly poignant as the crises of 2019-2020 unfolded.

Crisis Response

Bushfires: During the latter part of the year, through December 2019 and January 2020, Australia was consumed by a catastrophic bushfire season. Medicines Australia and our Members worked tirelessly to ensure that the community's access to medicines was uninterrupted and made significant financial and inkind donations to affected communities. The Medicines Shortages Working Party (MSWP), a multi-stakeholder group comprising government and industry peak bodies across the medicines supply chain, was reconvened to address issues arising in supply chain management and communications during the bushfires.

Medicines Australia provided Members and stakeholders with timely and relevant information and supported coordination and collaboration with Government and others. We also supported measures with Government and the pharmacy sector to ensure access to medicines for Australian patients during this difficult period.

COVID-19: By the end of January, as Australia was still coping with impact of the bushfires, a novel coronavirus was sweeping the globe. The COVID-19 virus outbreak was recognised as having pandemic potential and in February was declared a pandemic by Australia's Prime Minister, the Hon. Scott Morrison MP. Medicines Australia pivoted rapidly to prepare for supply chain management and crisis response. The MSWP also focussed attention on medicines supply and formed the platform for Medicines Australia to quickly draw continuity of supply issues to the government's attention.

The Medicines Australia Crisis Response Team (CRT) included the Executive, Members and selected expert advisors to coordinate issues and develop appropriate options and communications.

Meeting weekly, the CRT developed a strong communications platform to keep Medicines Australia Members informed of local and global activities. Medicines Australia implemented weekly surveys to establish areas of significant concern. Medicines Australia also strengthened close ties with relevant Government Ministers, departments and other peak representatives. Weekly email updates were provided to Government and stakeholders for early identification of issues and to provide rapid response and options for resolving matters.

We communicated emerging freight issues, as passenger planes were halted and inbound medicines supplies were disrupted; and worked with Government to establish border and freight support mechanisms. We worked with our Member companies to determine other disruptions to medicines supplies arising internationally, that may impact on Australia's supply chain resilience.

Medicines Australia further ramped up our media presence to provide sound and relevant advice on medicines supplies to the community and the industry response to the pandemic. This included the unprecedented global cooperation to rapidly develop diagnostics, treatments and vaccines to fight the COVID-19 virus.

Furthermore, we partnered with patients, consumer organisations and other peak bodies to ensure that Australians maintained their continuity of care. The Continuity of Care Collaboration was formed, as many Australians were restricted to their homes and worrying trends of delayed diagnoses and poorly managed chronic health care started to emerge.

Organisational Value Proposition and Transformation

The second half of 2019 also heralded Medicines Australia's reimagined vision for the organisation. Following deep consultation with Members and other stakeholders Medicines Australia has earmarked 2020 to embark on a period of organisational transformation. The focus of this transformation is to ensure that the

industry peak body is fit for the future to represent a sector that is at the forefront of medical and technical innovation. With so much dependence on innovation and the lessons of COVID-19 highlighting the importance of research, science and an agile and responsive pharmaceutical industry to deliver solutions to global problems, there is a fantastic opportunity to ensure that the industry in Australia is ready to meet the growing needs of our society and the broader health community. The defining report, commissioned by the CEO and developed by Bendelta in 2019, highlighted considerable opportunities across the organisational structure, working group management and potential reinvigorated membership models. A proposal to commence a program of transformation was put to the Board in early 2020 and we have commenced the first stages of talent identification for capability and capacity growth, with the broader transformational goals to be achieved in the coming year.

Collaboration: My final observation is that collaboration is the key word for 2019-2020, both International and locally. Highlights of our collaborative successes include working with PhRMA and the GIPC on intellectual property; partnering with AusBiotech and Research Australia to support the R&D Tax Incentive; Partnering with Members and MTPConnect on Antimicrobial Resistance and the Genomics Alliance, facilitating collaboration between Medicines Australia and the Zero Childhood Cancer Initiative; facilitating an industry NACCHO roundtable; participating in the Bellberry led (and Oncology Industry Taskforce supported) workshop on the challenges of valuing combination therapies in HTA; contributing to the Science Meets Parliament program with Science Technology Australia (STA); contribution to the Blood Cancer Taskforce and development of the Blood Cancer Strategy; Joining International Heads of Associations at the IFPMA conference in Geneva; opening the 2019 Prime Awards ceremony; and Partnering with AusBiotech to deliver the Women in Life Sciences Luncheon; and many, many more.

Constructive collaboration, coordinated cooperation with common goals, leads to better outcomes for all. An extraordinary year; disruptive for sure, occasionally terrifying, but at all times fulfilling when patients continue to have access to the world leading medicines they need, when and where they need them.



Elizabeth de Somer

Medicines Australia Chief Executive Officer

2019-2020 **Board of Directors**

Current Board of Directors



Dr Anna Lavelle Medicines Australia Independent Chair. Independent Director.



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



Ms Liz Chatwin Deputy Chair (from March 2020) & Country President, AstraZeneca Pty Ltd

Australia & New Zealand



Ms Leah Goodman * Managing Director Merck Healthcare Australia & New Zealand



Mr Bruce Goodwin Managing Director Janssen Australia & New Zealand



Ms Christi Kelsey * Vice President & General Manager GlaxoSmithKline Australia Pty Ltd



Mr Stuart Knight * General Manager, Pharma, Roche Products Pty Ltd



Mr Christopher Stemple Vice President & General Manager (from March 2020) AbbVie Pty Ltd Australia & New Zealand





Mr Wes Cook Managing Director Boehringer Ingelheim Pty Ltd Australia & New Zealand Ceased 24 October 2019



Mr Brad Edwards General Manager Takeda Pharmaceuticals Australia & New Zealand Ceased 24 October 2019



Ms Melissa McGregor Deputy Chair & Managing Director, Pfizer Australia Pty Ltd Resigned 29 February 2019

Medicines Australia Leadership Team





Sophie Hibburd

Director Ethics & Compliance (from August 2019)



Mr Neil MacGregor * Managing Director Bristol-Myers Squibb Australia & New Zealand



Mr James McDonnell * Vice President & General Manager Vifor Pharma Pty Ltd Australia & New Zealand





Elizabeth de

Somer

Chief Executive

Officer





* Elected 24 October 2019



Ms My Linh Kha

Managing Director Amgen Australia & New Zealand Resigned 25 September 2019



Ms Kirsten O'Doherty Vice President & General Manager AbbVie Pty Ltd Australia & New Zealand Ceased 24 October 2019





Jamie Snashall Director, Public Affairs



Dr Vicki Gardiner Director, Policy and Research (to February 2020)

Medicines Australia Membership

AS AT 30 JUNE 2020

		Class 1		
MENARINI	abbvie	AMGEN	Astellas	AstraZeneca
BAYER R R	Biogen	Boehringer Ingelheim	ر ^{ال} Bristol Myers Squibb	Celgene
		GILEAD		
Eisai	Lilly	Advancing Therapeutics. Improving Lives.	gsk	PSEN Innovation for patient care
Janssen Martine Pitteren filteren	Merck		<mark>ம்</mark> novartis	novo nordisk
Pfizer	Roche	SANOFI	Takeda	urt
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	Class
Bio Ceuticals ⁻	
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PRINCETON	PROSPECTION





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Government Relations Working Group (GWG)

The GWG had an extremely busy year with briefing newly arrived MPs in Parliament and revamping work to be done virtually as a result of COVID. Major priorities and activities in 2019-2020 included:



Development of a GWG strategy house and operations plan to guide our work.

Public Affairs Highlights

Parliamentary Friends of Medicines

On 30 June 2020 Medicines Australia held its annual Parliamentary Friends of Medicines event which saw Elizabeth de Somer join Professor Raina Macintyre from the Kirby Institute, and Dr Rob Grenfell from the CSIRO to discuss pandemics and vaccine development. We were joined by specialists from several Member companies on their latest activities in the COVID-19 vaccines and therapies space.

Parliamentary Staffer Drinks

Medicines Australia hosted end of year drinks for staffers in November 2019 for the Coalition and the ALP. These informal events provide the CEO, Director Public Affairs, the Medicines Australia Executive, and several of our Member companies with the opportunity to engage with parliamentary staffers in a casual setting and better understand the challenges they are currently facing in the rapidly changing political environment. These insights assist us in customising our engagement approach with the parliament to maximise the impact of future meetings, and identify new opportunities to educate political stakeholders about our industry and the broader value of medicines.





Delivering issues briefs
on the industry to all
MPs and Senators.



Supporting the Medicines Australia Budget submission with advocacy to key ministers and backbenchers.



Amplification of Medicines Australia messaging on industry's response to the COVID-19 pandemic.



Assisting in the delivery of Member events with ministers and shadow ministers as guest speakers.



Meeting approximately fortnightly since April and securing guest speakers for most of those meetings.



For those GR people who are not on GWG, we have developed a buddy system to brief them alongside occasional 'open mic' GWG meetings.

Strategic Communications & Election Messaging

PharmAus19

PharmAus19 is Medicines Australia's third annual Policy Symposium and Industry Showcase. Attended by pharmaceutical industry experts, health experts, academics, consumers, policy makers and parliamentarians, PharmAus19 provided a forum for open dialogue on priorities and innovation in the pharmaceuticals environment and explore the implications and opportunities of this rapidly evolving sector.

Over the course of the Symposium, 17 speakers, including the Federal Minister for Health, the Shadow Minister for Health, Leader of the Greens and keynote speaker Professor Frank Lichtenberg offered their perspectives on why medicines matter-to patients, to communities, to the economy and to government. Participants heard from key stakeholders with a breadth of expertise in a day of presentations and panels that explored the key issues in the pharmaceutical sector and beyond. At the Innovation Showcase, Medicines Australia Member companies and partners provided parliamentarians and other key stakeholders with an interactive opportunity to learn more about the sector and the indispensable role it plays for all Australians.

The four key themes that emerged from the discussions were:

- 1. Patients must be at the centre of all health care decisions—from decisions of care through to involvement in policy and regulatory decision making.
- 2. The upcoming review of the National Medicines Policy offers a significant opportunity for change. We need to take this opportunity to engage with the National Medicines Policy review to ensure the Policy is fit for the 21st century.
- 3. The pharmaceutical industry is facing—and embracing—rapid change. From technological developments to advances in personalised care, the medicines landscape is evolving, and we must be responsive and adaptive.
- Compelling economic arguments support investment in innovative medicines. Medicines support economic growth through extending lives, reducing morbidity, reducing hospital costs, creating jobs, furthering the export industry and boosting productivity. Each of these themes was explored in each discussion of why medicines matter—to patients, community and government.

PharmAus19 summary report can be viewed at https://medicinesaustralia.com.au/wp-content/ uploads/sites/52/2019/10/PharmAus19summary-report.pdf

Strategic Communication Messaging and Framework

Throughout the past year, Medicines Australia amended our strategic messaging to draw the threads of our evidence base together to create a compelling narrative for industry during COVID-19 and on the road to a health-led economic recovery.

Members were encouraged to adopt and integrate this messaging into their own communications and advocacy framework. The messaging framework is supported by key evidence cards. Further work will be undertaken to ensure that the messaging is amplified by our key stakeholders.





Communication Issues Group

Medicines Australia established a Communications Issues Group in early 2020 to assist us to enhance our membership capability to speak with one voice; amplify our strategic communications activities; and identify ways in which we can disseminate our messaging throughout our membership.



Stakeholder Relations

A key strategic driver for the industry this year is a renewed emphasis on forming relationships with patient groups. In support of this, we have increased the frequency of the e-newsletter **update** for Health Consumer Organisations (HCOs) during the pandemic to advise them on relevant COVID-19 related information. We also revamped the **community section** of the Medicines Australia website to include up to date reliable information with helpful resources and tools relevant for HCOs. This has been crystalised during this period of crisis, and we have worked hard to strengthen these networks.

In May 2020, Medicines Australia hosted a Consumer Roundtable on medicines and vaccines supply chain issues with HCOs after hearing concerns that patients could not access their medicines. The aim of this roundtable was to gain insights around the understanding of the medicines supply chain and consequently, due to COVID-19, where there were identified challenges and issues in ensuring minimal disruption to patient access. This was supported by the Department of Health, and the office of the Minister for Health. It was jointly facilitated by the Consumers' Health Forum (CHF) and included participation from the TGA. Through this roundtable discussion, Medicines Australia has identified three recommendations that are short- to medium-term in nature including more effective communication about advanced warning of stock-outs; support and utilise Government's e-health program long-term and ensure that any substitution of a medicine be carefully considered at the physician level.

The Continuity of Care Collaboration (CCC) is another way we have supported HCOs during the pandemic. Medicines Australia is a founding partner of the CCC, a communication collaboration that is made up of over 40 organisations of Peak Bodies, Industry and Healthcare Organisations coming together to stress the importance for people to continue monitoring their health status and conditions to ensure optimal long term health outcomes are achieved. The CCC represents the broad healthcare ecosystem and is the first ever such collaboration.

To continue this support, the Medicines Australia Consumer Advocacy Working Group (CAWG) sought feedback from HCOs about what was important to them in terms of managing their organisation's capability and capacity during COVID-19 so they could continue providing essential services to patients and consumers. Key areas were identified as highest priorities (e.g. fundraising, financial management) and Medicines Australia partnered with key leaders within these areas to develop the **Navigating COVID-19 and Beyond Program** - a series of tailored, interactive webcasts and workshops to help HCOs navigate this challenging time.

Consumer Advocacy Working Group

During COVID-19 the **Consumer Advocacy Working Group** (CAWG) met virtually on a weekly basis and invited different HCO leads to attend each meeting to ensure the group continued to augment the patient voice and for industry to understand the challenges facing the HCO sector. The CAWG established the Navigating COVID-19 and Beyond program, a capacity building program of practical webcasts and workshops to support HCOs navigate through this crisis and on the road to recovery.

One of the key objectives of the CAWG looking forward will be to work in collaboration with key stakeholders and evolve the Working Together Guide, a framework outlining how industry and HCOs can engage to achieve best outcomes for health consumers, carers and families.



Medicines Australia presents Navigating COVID-19 and Beyond

#ContinuityofCare #Collaboration

Medicines Access Portal (MAP)

The Oncology Industry Taskforce (OIT) is a subgroup of Medicines Australia and has generously provided funding of \$60,000 (inc GST) to support the development of the MOGA/HSANZ Medicine Access Portal (MAP). The MAP will be a secure, national online portal for pharmaceutical companies to inform clinicians of the existence of compassionate/early access program options for cancer patients. These programs will provide pathways for patients with life-threatening conditions or serious disease to gain access to treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. https://www.fda.gov/newsevents/expanded-access/expanded-accesskeywords-definitions-and-resources.

Medicines Australia is proud to have funded the build of this great project that will aid clinicians and patients to achieve access to much needed medicines they need, when they need them, especially for those clinicians living in regional areas of Australia that are unaware of such programs and as a result, patients may miss out on medicines they could have had access to and may never be prescribed depending on the course of their illness and resultant treatment.

The MAP is scheduled to go live in December 2020.

Policy Highlights

Strategic Objective

Ensure new medicines are universally available to Australians when they need them through:

- Ensuring efficient assessment and evaluation methods 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

Medicines Policy highlights

The Strategic Agreement implementation progress

This year, Medicines Australia continued to work with the Department of Health (the Department) on the implementation of measures arising from the Strategic Agreement, with some major milestones achieved.

July 2019 saw the start of Stage 1 of PBS improvements which introduced higher quality pre-submission meetings; four pricing pathways, including a case manager for the most complex medicines; earlier availability of other company's deed; and an agreed set of metrics which will be published on a regular basis.

The aim of the Stage 1 improvements is to reduce time to PBS listing by two months.

Work has begun on Stage 2 PBS improvements which will deliver four solution-focussed

resubmission pathways, in order to meet the Strategic Agreement target of a 50% reduction in resubmission churn.

The Strategic Agreement acknowledges the introduction of active ingredient prescribing (or prescribing by international non-proprietary name), and e-prescribing that will enable prescriptions to be sent directly from prescribers. The first electronic script was dispensed in May 2020, while the arrangements for implementing active ingredient prescribing ensure that prescriber choice is preserved. The brand name will be allowed where the prescriber deems it clinically necessary.

Medicines Australia successfully secured a phased approach to cost recovery arrangements introduced as part of the Strategic Agreement, with 50% of the new fee applying from July 2019.

Much of the work on the Strategic Agreement has been conducted through Working Groups under the umbrella of the Access to Medicines Working Group. These working groups have been meeting regularly throughout the year to continue progressing important improvements to the pre and post PBAC listing processes.

COVID-19

As the COVID-19 crisis escalated in Australia in March, Medicines Australia acted swiftly and effectively to support governments, healthcare professionals, patients, the scientific community and our employees on numerous levels.

Our intent has been to do whatever is required to support Australia through these challenging times.

Our focus has been to:

- 1. Deploy scientific expertise and capabilities in the fight against COVID-19 to uncover the urgently needed measures to protect and treat the community.
- 2. Maintain the supply of essential medicines and vaccines to patients who need them—in our hospitals and the community, by working collaboratively with Government, healthcare professionals and consumer organisations to manage and pre-empt healthcare delivery needs as they emerge.
- 3. Recognise and actively support Australia's healthcare professional community working on the frontline and the patients they serve.

As an industry, we recognised the critical role we must play, both in the urgent response to the COVID-19 crisis, but also in the recovery of Australia—ensuring our community manages their health effectively.

COVID-19 has reinforced the importance and value of science and innovation—our core competencies. It has also generated new efficiencies and positive outcomes resulting from the rapid implementation of advancements in health delivery to healthcare professionals and patients (telehealth mechanisms, at home care, home delivery). Medicines Australia also built five Critical Medicine Supply Priorities to support the ongoing and responsible management of Australia's vital medicines supplies and reinforce and extend medicine supply strategies for the immediate short-term:

- 1. Discourage Stockpiling or Panic Buying. This caused unnecessary surges and spikes in demand for medicine supplies—which could result in pharmacy stock-outs if large orders are fulfilled.
- 2. Encourage adherence to Monthly Quantities Prescribed and Dispensed during COVID-19. It was important for medicines to be prescribed in quantities that cover a patient's immediate needs, as we responded to the COVID-19 crisis.
- 3. Prioritise the Movement and Distribution of Medicines. The movement of medicines into the country and distribution around our nation needed to be prioritised.
- Provide Clear Public Information on the Medicines Shortage Lists and Protocols to Manage Shortages.
- 5. Encourage Patient Interactions with their Doctor and Pharmacist. We knew patients were feeling anxious and we actively encouraged them to interact with their doctor and pharmacist to discuss their concerns with any of their medicines. Telehealth provided a safe way for patients to keep connected with their healthcare professional which reduced their anxiety and helped them to maintain their regular health routines.
- Medicines Australia actively prosecuted these priorities through a number of key activities:
- Formation of Crisis Response Team, which consisted of several representatives from Medicines Australia, our Members, and subject matter experts. It convened daily for several months in order to tackle the issues this crisis presented us with.

- Distribution of a daily survey (later a weekly survey) of Members. This survey sought the membership's issues with the global and local supply chain, pharmacy and wholesaler demand increases, impacts on new and existing clinical trials, and staff assistance options provided by the Members.
- Taking a leading role in managing the potential for medicines shortages by seeking ACCC authorisation to permit discussions with the Generic and Biosimilars and Medicines Association and the implementation of strategies that support the continued supply of essential medicines and associated supplies to Australians, including those urgently needed for the treatment of COVID-19.

This authorisation reflected the critical need to stabilise and manage the supply of medicines which had seen unprecedented demand resulting from the COVID-19 pandemic.

Actively participated in the key Government forums to manage the supply of medicines:

Chaired by the TGA, the Medicines Shortages Working Party began meeting weekly during the COVID-19 crisis to discuss the supply of medicines both in the hospital and general community settings. The working party provided a good forum to exchange information on medicines supply issue and address challenges relating to:

- public communications about medicines shortages
- demand forecast modelling of critical medicines required to treat COVID-19 patients in hospitals, including Intensive Care Units
- international and domestic distribution supply chain problems
- localised shortages at the pharmacy level
- medicine stockpiling.

Medicines Australia also participated in the Medicines Shortages Subgroup, chaired by GBMA, whose smaller membership

(Medicines Australia, GBMA, NPSA and DHL) allowed for more focused discussions on international and domestic distribution channels.

It actively collaborated with other • international peak bodies: with COVID-19 providing a global challenge that required a global solution, Medicines Australia worked to enhance international and domestic regulatory agility and advocated for common approaches to assessments and approvals of COVID-19 treatments and vaccines.

This involved working closely through IFPMA, and alongside PhRMA, JPMA, EFPIA and ABPI, to facilitate discussions with senior regulatory officials at the International Coalition of Medicines Regulatory Authorities (ICRMA) and the World Health Organisation (WHO).

 Medicines Australia also developed a submission to the Joint Standing Committee on Foreign Affairs, Defence and Trade's 'Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade'. Our submission highlighted some key opportunities that will be critical in the recovery of the Australian economy. This included recommending a focus on innovation and an eco-system of medical research and development partnerships that translate discoveries into commercial products, increase supply chain efficiencies and open the door to more advanced manufacturing.

National Medicines Policy review

Review of the National Medicines Policy was one of the Government's election commitments. The review was foreshadowed to commence in early 2020.

Medicines Australia conducted an industry roundtable to gather expert Member input and build consensus on key issues of focus for the Review, including the terms of reference and overarching objectives. There was broad

consensus within the industry that the policy should be patient centric and future proofed to accommodate rapidly changing technologies.

The government committed to the establishment of a pre-NMP Review working group comprised of consumers, clinicians and industry, to consider the scope of the review, the formation of the NMP taskforce and the terms of reference. This was held in January 2020 before the COVID pandemic delayed further progress on the Review.

Frank Lichtenberg Report and Visit to Australia

In late 2019 Professor Frank Lichtenberg released his paper: The impact of pharmaceutical innovation on premature mortality and hospitalization in Australia, 1998-2018. This paper highlighted how the development and use of new medicines in Australia contributed to long-term economic growth in Australia through increased workforce participation and productivity.

Professor Lichtenberg's paper highlighted the importance of pharmaceutical innovation in reducing mortality, reducing the number of days Australians spend in hospital, and were cost effective. This paper was meaningful to Medicines Australia Members, as it demonstrated the crucial role the pharmaceutical industry plays in Australia in helping Australians stay healthy and contributing to economic participation.

Accompanying the release of this paper Professor enhancing patient health and providing Lichtenberg travelled to Australia as the keynote access to medicines. speaker of Medicines Australia's PharmAus conference. Professor Lichtenberg also did a tour Medicines Australia will remain connected to this of Australia meeting with numerous Government important project and looks forward to remaining and Opposition representatives at the Federal and involved in the Blood Cancer Taskforce as it moves State level, as well as appearing at a number of from a development phase into implementation. events to discuss the outcomes of his paper.

Blood Cancer: National Action Plan

Medicines Australia was proud to assist the Leukemia Foundation to develop the National Action Plan for Blood Cancer. In 2019, the Leukaemia Foundation developed the landmark State of the Nation: Blood Cancer in Australia report. The report was the first to look at blood cancers collectively rather than as individual diseases, highlighted the true scale and impact of blood cancer in Australia and identified the challenges faced by people living with blood cancer and their families.

In response to this report, the Federal Government committed to the establishment of a Blood Cancer Taskforce and the development of Australia's first National Strategic Action Plan for Blood Cancer. The report was finalised in June 2020 and will be formally launched in September 2020.

Medicines Australia CEO Ms Elizabeth de Somer represented industry Members on the Blood Cancer Taskforce, while Medicines Australia staff and Members provided input into the working groups. Collectively, the Medicines Australia team advocated for the action plan to recognise

- The need for timely access to, and reimbursement of, novel therapies and diagnostics
- The value of precision medicine to patients and the health system
- The important role of clinical trials in

Developed and piloted over three years, the COSA tele-trials project has demonstrated its proof of concept, including that it can be scaled up nationally for all tele-trials. There are already many patients participating in tele-trials across Australia, including in Queensland, NSW, ACT, Victoria and South Australia.

In February 2020, the COSA Steering Committee—of which Medicines Australia is a Member—agreed to set an ambitious voluntary target of tele-trials being part of 30% of all clinical trials in Australia by 2025. Medicines Australia continues to spread awareness of the tele-trials model and we encourage all industry and public institutions, including Medicines Australia's own Members, to consider tele-trials as a viable option when looking to conduct new clinical trials.

Clinical Trials: Impact and Quality (CT:IQ)

Medicines Australia has been a funding partner of CT:IQ since it was founded in 2018 by The George Institute for Global Health, Bellberry Limited, the Australian Clinical Trials Alliance (ACTA) and the National Health and Medical Research Council. CT:IQ acts as platform for stakeholder

Industry Policy highlights

2019-2020 Bridge Program

Medicines Australia has continued its support for the Bridge program, which 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.

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. Adapting the program to COVID-19 provided new challenges but the seamless transition to web-based symposiums has meant the continued delivery of this highly successful program.

Clinical Trials

Medicines Australia has prioritised its advocacy efforts on Clinical Trials in Australia by working with governments, industry and patient groups to improve the overall clinical trials environment. **Medicines Australia has strongly advocated for:**

- the harmonisation of state and territory differences in clinical trial ethics, governance and process requirements
- enhancing Australia's reputation as an attractive research destination
- more government support for, and industry take-up of, tele-trials.

Research and Development Task Force (R&DTF)

The R&DTF is co-sponsored by Medicines Australia, AusBiotech and the Medical Technology Association of Australia (MTAA). Co-chaired by Medicines Australia Members GSK and Roche, the R&DTF consists of research and development experts, particularly in clinical trials, and offers a unique industry perspective to stakeholders across Federal and State Governments as well as the broader health and research and development sector.

The R&DTF has been a trusted partner for governments and industry stakeholders, particularly throughout the pandemic. In response to the effects of COVID-19 on the clinical trials sector, the R&DTF released the Joint Position Statement Supporting Clinical Trials During the COVID-19 Pandemic. This statement provides guidance to stakeholders on issues such as patient recruitment, clinical trial site safety and expectations on ethics committee so that sponsors could continue their clinical trials.

Clinical Oncology Society of Australia (COSA) Tele-Trials Project

Medicines Australia was proud to continue its support for the development of the Australasian Tele-Trial Model, including as part of the funding consortium. The model has been developed by the Clinical Oncology Society of Australia (COSA) Rural and Regional Group in consultation with clinical trial sponsors, clinicians, health administrators and regulatory bodies. While the model was initially designed to increase access to clinical trials for people with cancer living in rural and remote locations, it became apparent that the model was applicable for all clinical trials. This has become particularly significant and achievable through the rapid uptake of telehealth, which will further facilitate clinical trial activity across rural and remote locations.



voices to come together to develop solutions to the roadblocks and inefficiencies that impede the value and conduct of clinical trials in Australia. The membership has expanded and now includes over 45 organisations across the sector including MTAA, MTPConnect, NHMRC, PBAC, MSAC, TGA as well as representation from, industry, academia, sites, phase I units, HRECs, interest groups and consumers, all focused on improving the clinical trial sector collectively.

In the last financial year, four clinical trial improvement projects were launched:

- **Project 1:** Consumer Involvement & Engagement Platform
- **Project 2:** eConsent in Clinical Trials
- **Project 3:** Early Phase Best Practice— Checklist
- **Project 4:** Optimising Clinical Trial Recruitment

Research and Development Tax Incentive

Medicines Australia led an alliance of peak bodies that developed a joint response to the Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019.

The alliance included Research Australia, AusBiotech, Medical Technology Association of Australia (MTAA), the BioMelbourne Network, the Association of Australian Medical Research Institutes (AAMRI) and Life Sciences Queensland (LSQ).

The alliance strongly advocated against the Bill and called for it to be withdrawn as it would undermine innovative medical research and development in Australia.

On 29 June 2020, Medicines Australia appeared before the Senate Economics Committee at a public hearing to represent Members' interests on the Bill. We took this opportunity to further advocate on the additionality and spillover effects that industry research and development brings to Australia.

International Trade, including **Intellectual Property**

International trade issues continue to dominate the globally complex environment in which Medicines Australia's Members work. In response to these increased demands, Medicines Australia stood up a temporary International Trade Issues Group (ITIG) to tackle these ongoing issues. The ITIG jointly developed Medicines Australia's submission to the Joint Standing Committee on Trade and Investment Growth inquiry on 'Supporting Australia's export and investment opportunities'.

Medicines Australia's advocacy focused on the need to:

- strengthen intellectual property
- enhance skilled migration opportunities

- harmonise national the clinical trials environment
- . increase regulatory cooperation and alignment

The Committee's subsequent report, Trade transformation: Supporting Australia's export and investment opportunities, focused heavily on medicines and made a raft of positive recommendations in support of the pharmaceutical industry. The report acknowledged the potential for leveraging Australia's competitive advantages in the innovative health sector, particularly in attracting great research and development investment and export opportunities that it could deliver for the Australian economy.

Working Group Activities

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.

It is co-chaired by the Chair of Medicines Australia and the Deputy Secretary of the Department of Health and met twice during the year. During the year, the Medicines Australia Board decided to have higher level representation on this group with the addition of two Board Members to the AMWG.

As part of its remit, the AMWG also works collaboratively to overcome barriers to the implementation of the Strategic Agreement.

Four AMWG sub-groups, that meet more regularly are dedicated to delivering the key AMWG priorities. 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 every 3-4 weeks during 2019-2020 to progress the tasks identified in the Strategic Agreement associated with PBS Process Improvements, the aim of which is to improve transparency, efficiency and timeliness of the medicines listing process.

Stage 1 of the changes began in July 2019, and Other issues being considered by the subgroup aims to deliver a reduction in the time from PBAC include the Consumer Medicines Status Website, the Health Products Portal and Public Summary recommendation to listing by an average of 2 months by reducing time taken to finalise deeds of Document(PSD) transparency issues. The agreement; restrictions and listing requirements to Department of Health has proposed process and content changes to Public Summary Documents publication by July 2020. (PSDs), which it believes will increase efficiencies Stage 2 is scheduled to begin in January 2021. through standardising PSD redactions and increasing transparency in PBAC decision making. Medicines Australia representatives on the The key changes will take effect in the next financial year.

SPS also hosted two educational webinars for Members, in addition to the information sessions run by the Department of Health to outline the changes.

Comparator Selection Subgroup

The Comparator Selection Subgroup works on the incidence and nature of choice of comparators in relation to submissions made to the PBAC.

AMWG comparator selection meetings through 2019-2020 focused on better understanding the Department/PBAC and Medicines Australia's perspectives on this topic.

The key initiative being taken forward in the short term is the development and dissemination of educational material to improve understanding of the PBAC's decision making specific to the selection of the lowest cost comparator (LCC), and the evidentiary requirements to avoid being linked to LCC.

AMWG & GMWG Transparency Subgroup

The AMWG Transparency Subgroup has joint membership with Members of the Generic Medicines Working Group (GMWG) represented by the Generic and Biosimilar Medicines Association (GBMA).

This subgroup has been considering the impact of policies that affect both the innovative and generic industry Members. It has been the home for all discussions and negotiations on cost recovery in the lead up to the new fees and charging structure for Stage 1 PBS improvements that began on 1 July 2019.

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 of the Strategic Agreement.

In terms of biosimilar uptake drivers, further work is needed to understand whether the uptake drivers are working or making sure that barriers to their implementation are removed.

A large focus for the Biosimilars Policy subgroup has been on the introduction of active ingredient (INN) prescribing and electronic prescribing. The first electronic script was dispensed in May 2020.

Chief Executive Group

The Chief Executive Group is comprised of a Member of each of the Medicines Australia working groups and aims to provide advice to the CEO and the Executive on translating Medicines Australia's strategic objectives into an operational plan. It is a key contributor to Medicines Australia's objective of building unity and consensus on key challenges facing the industry and is integral to the work of the organisation to achieve the industry's strategic priorities.

The CEG took a leading role in developing the organisation's 2020-2021 operational plan and liaising with working groups to deliver on the operational plan and ensure we are well prepared for the rapidly evolving environment, the post-COVID recovery, Federal Budget discussions, and preparation for the next Strategic Agreement.

Health Economics Working Group

Medicines Australia Health Economics Working Group (HEWG) provides advice and support on matters relating to HTA policy and best practice health systems to improve time to reimbursement and access for patients. It also undertakes discrete project for the Medicines Australia Executive as required that align with the organisation's strategic priorities.

In the last year, the HEWG has shared learning opportunities and identified issues and potential solution for Medicines Australia to raise with the Department of Health on HTA policy and processes (e.g. PBS Post Market Reviews, Streamlined Pathway processes etc). The HEWG met 7 times in 2019-2020 and the group's key focus moving into 2020/2021 will be to contribute to the implementation of the next Strategic Agreement between Medicines Australia and the Australian Government specifically regarding market access, pricing, and reimbursement, and continuing its role in providing clear advice and support on areas of health economics and market access trends.

Policy Scanning Working Group

The Policy Scanning Working Group meets at least four times per year, and its purpose is to provide advice and support relating to international policy trends, issues and initiatives which may impact on the pharmaceutical industry. The group scans global best practice and provides advice to the Medicines Australia Executive on comparisons in international HTA systems and international pricing policies.

The Policy Scanning Working Group met in January 2020 to discuss the priority projects the group would execute to meet the group's objectives, and to further aid Medicines Australia's Strategic Objectives. The group's key focus has been to prepare industry for the National Medicines Policy Review, and this includes doing extensive research into significant areas of importance to industry, and hosting an industry stakeholder roundtable, gathering feedback and insights from key industry representatives.

Additionally, the Policy Scanning Working Group has highlighted other areas of focus which will be priorities for the group. This includes developing a cell and gene therapy paper with an international focus, an international pricing policies document, and a public sector roundtable.

Regulatory Affairs Working Group

Medicines Australia and the Regulatory Affairs Working Group (RAWG) have continued to work on streamlining and easing the regulatory burden for industry.

Key highlights on the regulatory front included:

Health Minister Hunt approving a new CMI template and Medicines Australia securing a five-year implementation period, from 1 January 2021 to 30 December 2025. The new CMI format is shorter, better laid-out and features a one-page summary that succinctly provides people with the most critical information relating to the safe and effective use of their medicines

- The Government proposing transparency improvements relating to prescription medicines under evaluation for listing on the Australian Register for Therapeutic Goods
- Working with the TGA to identify opportunities for enhancing the prescription medicines registration process and variations workflows that reduce the burden on industry and government
- Securing temporary flexibility from the TGA in the implementation of TGO91, related to medicine labelling, to support manufacturing operations whilst industry is focused on the continuity of supply during COVID-19.

Medicines Australia has also provided responses to many TGA consultations throughout the year as a part of our engagement and collaboration with TGA.

The Pharma Australia Inclusion Group (PAIG)

Pharma Australia Inclusion Group (PAIG) is a special interest group of Medicines Australia. The primary objective of PAIG is to help build a more inclusive industry where all people are equally valued, rewarded and thrive. Formerly known as Pharma Australia Gender Equity (PAGE), it was decided the group would broaden its remit through 2020 and 2021 to focus on workplace diversity and inclusion.

Inclusive workplaces are key to strengthening talent attraction and retention; and creating conditions that bring out the best in all people. PAIG is committed to establishing the pharmaceutical industry as a known leader in diversity and inclusion and identified the following priority areas for the 2020-2021 program.

- Mental Health and Wellbeing
- Building a culture of inclusion

- LGBTQI+ Community
- Age/Generational gap

Like many other projects, PAIG had to contend with considerable change and uncertainty in 2020. The COVID-19 pandemic forced the pharmaceutical industry to evolve how we work and interact with colleagues.

The PAIG program included a new format of virtual workshops which incorporated Member case studies and external experts as keynote speakers. A suite of online materials including podcasts from leading experts in workplace diversity and reading materials were also made available for Member companies via the online Medicines Australia PAIG portal.

PAIG also underwent considerable change in leadership in 2020. New Steering Committee Members Chris Stemple (AbbVie), Liz de Somer (Medicines Australia) and Anne Harris (Pfizer) joined PAIG co-founder Kathy Connell (Johnson & Johnson), following the departure of co-founders Melissa McGregor (Pfizer) and Kirsten O'Doherty (AbbVie).

Lee Davelaar (Pfizer) and Fiona Sheppard (Johnson & Johnson) also succeeded Kate Richards (Abbvie) and Fabienne Conet (Biogen) as PAIG co-chairs and began working with a new delivery partner Willis Towers Watson on the 2020-2021 program.

PAIG continued to be an avenue through which the medicines industry could work together, learn and model best practice in 2020. PAIG will continue to adapt and evolve in 2021 to suit the changing needs of Member companies and reflect the latest workplaces practices to ensure the industry is an inclusive and progressive place to work.

Submissions

Medicines Australia has continued to work with Member companies and the Australian Government to improve healthcare benefits for Australians through timely access to medicines. Medicines Australia made multiple submissions into the review process and participated in consultation processes together with other key stakeholders in the health sector. Over the course of the past year, Medicines Australia has made 12 submissions related to access and pricing, 4 submissions to the Senate Committee on broad medicines policy and 12 submissions on regulatory affairs and TGA.

Submissions made in 2019-2020:

Access and Pricing

- Medicines Australia Summary of comments re: moving all existing and future Special Pricing Agreement deeds of agreement to monthly invoicing (June 2020)
- Medicines Australia and Members' response to the proposed new policy on rescinding Pharmaceutical Benefits Advisory Committee positive recommendations (June 2020)
- Medicines Australia's submission to the final report of the Chronic Plaque Psoriasis Cost-Effectiveness Review (June 2020)
- Medicines Australia submission to the Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP 1 July 2020–30 June 2021 (June 2020)
- Medicines Australia Submission to TGA Scope of Regulated Software (May 2020)
- Medicines Australia's Response to Public Summary Documents (PSD) Process (April 2020)

- Medicines Australia submission to the Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP 1 July 2020–30 June 2021 (March 2020)
- Medicines Australia submission to the Public Consultation—Revised Procedure Guidance—Resubmission Pathways (December 2019)
- Medicines Australia submission to the Public Consultation—Revised Procedure Guidance— Initial Submission Categories and Single Submission Date (December 2019)
- Medicines Australia submission to the Public Consultation—Revised Procedure Guidance— Public Summary Documents (December 2019)
- Medicines Australia submission to the Australian Government consultation on Data Sharing and Release—Legislative Reforms (October 2019)
- Medicines Australia submission on the Public consultation on standardised redaction of Public Summary Documents (September 2019)

Broad Medicines Policy

- Medicines Australia submission to the Senate Select Committee on COVID-19 (May 2020)
- Medicines Australia OIT Cancer submission (March 2020)
- Medicines Australia submission to the Senate Standing Committee on Economics— Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019 (March 2020)

- Medicines Australia Submission—
 Department of Health Lung Cancer
 Screening consultation (February 2020)
- Medicines Australia submission to the National Action Plan for Blood Cancer (October 2019)
- Medicines Australia submission to the Senate Economic Legislation Committee on Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019 (November 2019)
- Medicines Australia submission to the Joint Standing Committee on Trade and Investment Growth Inquiry on supporting Australia's exports and attracting investment (October 2019)

Regulatory Affairs and the TGA

- TGA consultation on patent-related transparency measures (June 2020; not released publicly)
- Medicines Australia Submission to TGA
 Scope of Regulated Software (May 2020)
- Medicines Australia submission on the TGA consultation on export of therapeutic goods from Australia (February 2020)
- Consultation on adoption of European Union guidelines in Australia (February 2020)
- Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade (June 2020)
- Medicines Australia submission to the proposed changes to the medical device Essential Principles for safety and performance (October 2019)

- Medicines Australia submission to the proposed clarification of the regulatory requirements for medical device systems and procedure packs (October 2019)
- Medicines Australia submission to the TGA consultation on modification of an existing provisional registration (October 2019)
- Medicines Australia submission to TGA consultation on increased online access to ingredient information (October 2019)
- Medicines Australia submission to the TGA targeted consultation on generic medicines reforms (October 2019)
- TGA's consultation on a voluntary standard for the use of 2D data matrix bar codes. Medicines Australia's response to TGA's consultation can be found **here**.

Code of Conduct

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 2019-2020 focused on the launch of Edition the Code of Conduct. After a thorough review, Edition 19 was adopted by Members in November 2019 and became effective on 30 March 2020.

In response to Member feedback, Edition 19 has transitioned from detailed and prescriptive advice to a principles-based Code. In doing so, the Medicines Australia Code of Conduct reflects the maturity of our industry and provides a strong framework for risk-based decision making and innovation in our industry.



Complaints, Appeals & Monitoring

Complaints handling

Medicines Australia considered 4 complaints in 2019-2020, with all complaints finalised before the end of the financial year. The number of complaints received by Medicines Australia remains has remained low this year.

Complaint: 1154

Subject Company: Medicines Australia Member Company

Complainant: Medicines Australia Member Company

Outcome: Breach

Complaint: 1155

Subject Company: Pharmaceutical Company

Complainant: Healthcare Professional

Outcome: Advice provided to the TGA

Complaint: 1156

Subject Company: Medicines Australia Member Company

Complainant: Medicines Australia Member Company

Outcome: Breach

As shown in the table above, one matter was heard by the Code of Conduct Committee and advice provided to the Therapeutic Goods Administration for consideration. No further information will be provided about this matter.



Complaint: 1157
Subject Company: Medicines Australia Member Company
Complainant: Medicines Australia Member Company
Outcome: Breach (appeal not upheld)
Complaint: 1158
Subject Company: Medicines Australia Member Company
Complainant: Healthcare Professional
Outcome: Breach

Transparency Reporting

Central Reporting System

Medicines Australia launched the Central Reporting System to publish payments and transfers of value reporting on 29 August 2019. The system can be accessed at **disclosureaustralia.com.au**. Data has been reported onto the system in August 2019 and February 2020, with over 10,000 searches performed during that time.

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 2019 showed that there were 1,301 events sponsored by 32 Member companies in the period 1 November 2018—30 April 2019. On 30 April 2020, Member Companies published reports for the period May 2019—October 2019, which reported on 1,769 events sponsored by 29 Member companies in that six month period.

Health Consumer Organisation Support Reports

In June 2020 Medicines Australia published the sixth annual reports of Member Companies' financial support for Health Consumer Organisations (HCOs). Member companies supported 224 different HCOs across Australia in calendar year 2019, ranging from national consumer organisations to small local groups, relating to 355 different projects or events to the total value of \$7,319,335 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.

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 2019 were presented in March 2020.

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 Taft Owen from Boehringer Ingelheim, and Carmen Loh from AstraZeneca.

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 Natasha Bakshi from Gilead.

CEP Achievement Award

CEP Achievement Award winners are the students who achieve the 10 highest aggregate marks, and the recipients for 2019 are:

- Bernd Merkle Biogen
- Taft Owen Boehringer Ingelheim
- Mostafa Basiouny AstraZeneca
- Kainaaz Choksey AstraZeneca
- Natasha Williams Hahn Healthcare
- Jessica Mikhail Worked at Boehringer at the time of course, currently at Novotech
- Matthew Payne Boehringer Ingelheim
- Yen Sim (Rachel Chan) Eli Lilly
- Yao Yang Zhang Servier
- Sophie Taylo Actelion

Medicines Australia In The Community

CSR Activities

As part of Medicines Australia's **Corporate Social Responsibility** commitment, this year has seen an increasingly significant focus on supporting our Indigenous communities with ongoing support for the Purple Truck mobile dialysis clinic. This service is important to Aboriginal patients in remote areas with end stage renal disease as it allows them to return to country and remain connected to elders, family and traditional country and culture.

This financial year, Medicines Australia provided funding to install a wheelchair lifter for the second Purple Truck which brings the total to \$505,000 in funding for the **Purple Truck** since 2009. Medicines Australia continues to support the Shalom Gamarada Indigenous Residential Scholarship Program that was established in 2009 to help in 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 three students studying medicine at UNSW this financial year which brings the total to \$453,600 in funding for the Shalom Gamarada.



Responding to the Bushfire Crisis

Medicines Australia was deeply saddened at the devastation caused by the Australian bushfires and the impact on people and wildlife in affected communities. In response Medicines Australia took a whole-of-business approach to support the bushfire crisis response. Medicines Australia made a financial donation of \$150,000 to support humanitarian efforts:

\$100,000 to the Australian Red Cross Bushfire Disaster Recovery Fund which provided 4,380 Australians (and counting) with grants that helped them meet immediate needs, make repairs, cover out-of-pocket funeral or hospital costs, or re-establish a safe place to live

\$50,000 to Rare Cancers Facemasks4firies campaign that provided volunteer firefighters with a P3 full-face mask fitted with a prefilter, particle filter and gas filter.

Medicines Australia took every step necessary for the continued and uninterrupted supply of our medicines and vaccines to the community, working with our supply chains partners to ensure



that Australians could access essential medicines and consumer healthcare products.



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

Dr Anna Lavelle	Chair
Andrew Carter	Commercial Eyes Pty Ltd
Carol Bennett	Independent
Catherine McGovern	Independent
David Grainger	Biointelect
David Herd	GlaxoSmithKline
	Australia Pty Ltd

Prof. Ian Chubb	Independent
Dr Jeffrey Harmer	Independent
Mark McCrindle	Independent
Nicola Richards	Merck Sharp Dohme Australia Pty Ltd
Elizabeth de Somer	Medicines Australia

Chief Executive Group

Elizabeth de Somer	Co-Chair	Medicines Australia Pty Ltd
Nicola Richards	Co-Chair	Merck Sharp & Dohme (Australia) Pty Ltd
Alan Paul	Member	Ipsen Pty Ltd
Ben Hopkins	Member	Takeda Pharmaceuticals Australia Pty Ltd
lan Black	Member	Roche Products Pty Ltd
Jodie Thomas	Member	Novo Nordisk Pharmaceuticals Pty Ltd
Julie Ellis	Member	A. Menarini Australia Pty Ltd
Kieran Schneemann	Member	AstraZeneca Pty Ltd
Louise Graham	Member	Pfizer Australia Pty Ltd
Paul Lindsay	Member	Merck Healthcare Pty Ltd
Penny George	Member	Sanofi-aventis Australia Pty Ltd
Stuart Englund	Member	Janssen-Cilag Pty Ltd
Wade McMonagle	Member	AbbVie Pty Ltd
Mitch Kirkman	Member	Novartis Australia Pty Ltd

Standing Working Groups

HEWG

PSWG

	Co-Chair
	Co-Chair
	Member
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	Member
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	Member
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AbbVie Pty Ltd
Medicines Australia
Medicines Australia
Pfizer Australia Pty Ltd
Novartis Australia Pty Ltd
Merck Sharp & Dohme (Australia) Pty Ltd
GlaxoSmithKline Australia Pty Ltd
Roche Products Pty Ltd
Boehringer Ingelheim Pty Ltd
Eli Lilly Australia Pty Ltd
Vifor Pharma Pty Ltd
Bristol-Myers Squibb Australia Pty Ltd
Bayer Australia Limited
Amgen Australia Pty Ltd
Roche Products Pty Ltd
AstraZeneca Pty Ltd
Commercial Eyes Pty Ltd

Medicines Australia
Janssen-Cilag Pty Ltd
Novartis Australia Pty Ltd
Merck Sharp & Dohme (Australia) Pty Ltd
AbbVie Pty Ltd
Roche Products Pty Ltd
Amgen Australia Pty Ltd
Biointelect Pty Ltd
Celgene Pty Ltd
GlaxoSmithKline Australia Pty Ltd

CAWG

Co-Chair	Medicines Australia
Co-Chair	Celgene Pty Ltd
Member	AstraZeneca Pty Ltd
Member	Bristol-Myers Squibb Australia Pty Ltd
Member	Roche Products Pty Ltd
Member	Novo Nordisk Pharmaceuticals Pty Ltd
Member	Pfizer Australia Pty Ltd
Member	Eli Lilly Australia Pty Ltd
Member	Merck Sharp & Dohme (Australia) Pty Ltd
Member	Novartis Australia Pty Ltd
Member	Vifor Pharma Pty Ltd
Member	Bayer Australia Limited
	Co-Chair Member Member Member Member Member Member Member Member

GWG

Jamie Snashall	Co-Chair	Medicines Australia
Amy Moore	Co-Chair	AbbVie Pty Ltd
Fiona Tigar	Member	Biogen Australia Pty Ltd
James McAdam	Member	Bristol-Myers Squibb Australia Pty Ltd
Ben Gommers	Member	Merck Sharp & Dohme (Australia) Pty Ltd
Josh Bihary	Member	Pfizer Australia Pty Ltd
Kieran Schneemann	Member	AstraZeneca Pty Ltd
Penny George	Member	Sanofi-aventis Australia Pty Ltd
Stacey Bolto	Member	Novartis Australia Pty Ltd
Todd Stephenson	Member	Janssen-Cilag Pty Ltd
Anna Karelas	Member	Bayer Australia Limited
Paul Lindsay	Member	Merck Healthcare Pty Ltd
Peter Murphy	Member	Novartis Australia Pty Ltd
Sara Pantzer	Member	Amgen Australia Pty Ltd

RAWG

Peter Komocki	Co-Chair
Helen Critchley	Co-Chair
Ailsa Surman	Member
Brian Hewitt	Member
Carolyn Tucek-Szabo	Member
George Lillis	Member
Kirpal Kaur	Member
Linda Ponkshe	Member
Maria Dionyssopoulos	Member
Mary Flannery	Member
Michael Parker	Member
Andrew Notley	Member
Jagdish Ghadge	Member
Mark Rowland	Member
Natalie Touzell	Member
Simon Byrne	Member
Sylvia Roins	Member

MAVIG

Member
Member

Medicines Australia
Amgen Australia Pty Ltd
Pfizer Australia Pty Ltd
GlaxoSmithKline Australia Pty Ltd
Novartis Australia Pty Ltd
Sanofi-aventis Australia Pty Ltd
Bristol-Myers Squibb Australia Pty Ltd
Janssen-Cilag Pty Ltd
Commercial Eyes Pty Ltd
Bayer Australia Limited
AstraZeneca Pty Ltd
Gilead Sciences Pty Ltd
Takeda Pharmaceuticals Australia Pty Ltd
Amgen Australia Pty Ltd
Roche Products Pty Ltd
Celgene Pty Ltd
Novartis Australia Pty Ltd

GlaxoSmithKline Australia Pty Ltd
Pfizer Australia Pty Ltd
Medicines Australia Pty Ltd
GlaxoSmithKline Australia Pty Ltd
Sanofi-aventis Australia Pty Ltd
Pfizer Australia Pty Ltd
Merck Sharp & Dohme (Australia) Pty Ltd
Merck Sharp & Dohme (Australia) Pty Ltd
Sanofi-aventis Australia Pty Ltd
Pfizer Australia Pty Ltd
GlaxoSmithKline Australia Pty Ltd
Amgen Australia Pty Ltd
Sanofi-aventis Australia Pty Ltd

OIT

Amy Moore	Member	AbbVie Pty Ltd
Andrew Thirlwell	Member	Pfizer Australia Pty Ltd
Darin Kottege	Member	Merck Sharp & Dohme (Australia) Pty Ltd
David Pullar	Member	Roche Products Pty Ltd
David Thomson	Member	Amgen Australia Pty Ltd
Elise Kelly	Member	Pfizer Australia Pty Ltd
Elizabeth de Somer	Member	Medicines Australia Pty Ltd
James McAdam	Member	Bristol-Myers Squibb Australia Pty Ltd
Jan Lewis	Member	AbbVie Pty Ltd
Katherine Rocks	Member	Takeda Pharmaceuticals Australia Pty Ltd
Kelly Griffiths	Member	GlaxoSmithKline Australia Pty Ltd
Kieran Schneemann	Member	AstraZeneca Pty Ltd
Kristina Turner	Member	AbbVie Pty Ltd
Kylie Earle	Member	AstraZeneca Pty Ltd
Liliana Chavez	Member	Novartis Australia Pty Ltd
Louise Graham	Member	Pfizer Australia Pty Ltd
Matthew Douglas	Member	Bristol-Myers Squibb Australia Pty Ltd
Matthew Slabbert	Member	Bayer Australia Limited
Megan Bohensky	Member	Merck Sharp & Dohme (Australia) Pty Ltd
Meriana Baxter	Member	Amgen Australia Pty Ltd
Natalie Betts	Member	AstraZeneca Pty Ltd
Nicholette Conway	Member	Eli Lilly Australia Pty Ltd
Paul Lindsay	Member	Merck Healthcare Pty Ltd



OIT continued

Peter Murphy	Member	Novartis Australia Pty Ltd
Pinky Dharmshaktu	Member	Merck Healthcare Pty Ltd
Rachael Anderson	Member	AstraZeneca Pty Ltd
Rebecca Stratford	Member	Novartis Australia Pty Ltd
Rita Corrente	Member	Janssen-Cilag Pty Ltd
Sally Ryan	Member	Pfizer Australia Pty Ltd
Sophie Schultz	Member	Takeda Pharmaceuticals Australia Pty Ltd
Stephan Meier	Member	Eli Lilly Australia Pty Ltd
Stephen Richardson	Member	Sanofi-aventis Australia Pty Ltd
Todd Stephenson	Member	Janssen-Cilag Pty Ltd

Members' Events

Women in Life Sciences Luncheon — 6 March 2020

The NSW Women in Life Sciences Luncheon, cohosted by AusBiotech and Medicines Australia, was held on Friday 6 March 2020 in Sydney. The theme Inspire, Influence, Involve conveyed a movement that is beyond gender, and increasing the number of female leaders in senior positions is a conversation everyone should be a part of.

The 2020 NSW Women in Life Sciences Luncheon celebrated leaders who nurture female ambition, elevate, involve and inspire others to achieve their aspirations, and ultimately influence the new standards and benchmarks in support of more women reaching senior leadership positions.

AGM — 24 October 2019

The appointment of the new Board of Medicines Australia was announced at the association's Annual General Meeting in Sydney on 24 October 2019.

In welcoming new faces to the Board, we must also have departures and Medicines Australia thanks them for their commitment to the sector:

• Medicines Australia acknowledged former Chair, Wes Cook Managing Director of Boehringer Ingelheim, Australia. The current Chair, Dr Lavelle, worked very closely alongside Wes to develop the Strategic Agreement with the Commonwealth in 2017. Industry has benefited greatly from his keen negotiation skills, his passion and his forward thinking.

- Medicines Australia also recognised the commitment of Kirsten O'Doherty, Managing Director of AbbVie. 'It is a testament to her that PAGE (now PAIG) is leading the way on improving industry's diversity, equity, and inclusiveness'.
- Also departing from the Board was Brad Edwards, Managing Director of Shire, who sat for a number of years on the Board and Governance sub-committee.
- My Linh Kha, Managing Director of Amgen, who was appointed to lead Amgen in China.

At the AGM, Medicines Australia Members also unanimously voted in favour of adopting the revised Constitution. The changes incorporated will ensure that the Constitution remains aligned with best practice and consistent with all legislative requirements and also implement further recommendations stemming from the 2016 Governance Review.

Board Meetings

Medicines Australia convened a number of Board meetings during the 2019-2020 financial year:

23 July 2019	Board Strategic Retreat
24 July 2019	Board Meeting
25 September 2019	Board Meeting
24 October 2019	Board Meeting
10 December 2019	Board Strategic Retreat
10 December 2019 11 December 2019	Board Strategic Retreat

In addition, a number of out of session meetings were convened for the Board to make decisions relating to Medicines Australia's COVID-19 response and consider the progress of discussions with the Government related to Medicines Australia's Strategic Agreement.



Super Working Group — Tuesday 25 February 2020

Medicines Australia held its annual energetic meeting with a collection of working groups to discuss strategic objectives and to identify the key operational work plan priorities, challenges and more effective communications throughout the working groups and the wider membership. This super working group meeting also provided a great opportunity to network amongst our peers, share information and induct new working group Members after the renewal of working group memberships late last year.



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