

# #Medicines Matter



Medicines  
**Australia**

Better health  
through research  
and innovation

## Annual Report 2020-21

Room for the Patient View

## Acknowledgement of country

We acknowledge the traditional custodians of the lands on which we research and work, and we pay our respects to the Elders past, present and future. We recognise and respect their cultural heritage, beliefs and continuous relationship with the land.

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# About Medicines Australia

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our Members discover, develop and manufacture prescription medicine products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia.

## Our vision

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

## Our 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.

## Our Strategic Blueprint 2021-2026

The work of Medicines Australia is underpinned by a refreshed 5-year Strategic Blueprint, which was developed with the Board during 2020-2021. Following an intensive special working group, the Blueprint focuses on four key pillars that drive our work.

# Strategic Blueprint

2021-2026



## Role

Medicines Australia leads the research-based pharmaceutical industry of Australia. Our members discover, develop and manufacture prescription, pharmaceutical products, biotherapeutic products 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.



## 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.

# The Chair's Report

## Advocating for stronger patient involvement

On behalf of the Medicines Australia Board, I am pleased to introduce our Annual Report addressing Medicines Australia's activities and achievements during the 2020-2021 financial year.

COVID-19 has permanently changed the way we work, increasing our agility and demonstrating our ability to act quickly and decisively to achieve outcomes. Medicines Australia has risen to the challenge. The world has become used to new language such as 'zoom', and 'you're on mute'. Some words have been overused or conjure previously unknown images, such as 'unprecedented' and 'snap lockdown'. But most significantly, Australians have become more health literate than ever before and the contribution of good health to the economy is no longer in any doubt.

This year, Medicines Australia has truly demonstrated our vision of making a real difference to the health of all Australians. I was honoured and inspired to work with such a talented and committed Medicines Australia Board and Executive. Together, we achieved considerable outcomes, despite continuing to live through the pandemic, manage a new COVID-19 strain and cope with countless lockdowns.

Thanks to the tireless efforts of our Members, we saw unparalleled research collaborations that led to the arrival of registered, safe, and effective cutting-edge vaccines in Australia and enormous progress in identifying innovative treatments for

COVID-19. This extraordinary effort from the sector reminds us all why we are here and the critical role of our industry across the world. The pandemic has accelerated interest in innovative therapies and the pharmaceutical industry has responded impressively.

During the year, Medicines Australia and its Members worked closely with all partners across the healthcare system, locally and globally to advance progress in our fight against COVID-19 plus ensure Australians have access to necessary diagnostics, vaccines, and treatments. It has been an exemplary effort from all involved and I feel privileged to witness such an achievement.

### Strategic Agreement negotiations

Throughout the year the Board has been working through complex negotiations with the Minister for Health and Aged Care and his Department for a new five-year Strategic Agreement.

The first part of this partnership work was achieved in the October 2020 Federal Budget when the Government announced the removal of the offset policy and the establishment of the New Medicines Funding Guarantee (NMFG). Together this will deliver new funding each year for the listing of new medicines on the PBS and is expected to deliver at least \$2.8 billion dollars of new funding over the forward estimates.

The second part of the negotiation, to consider issues of strategic importance to the industry and the Government, was completed by June 2021 and announced shortly after the end of financial year. The new five-year Agreement sets the stage for fundamental changes to the Australian health system. I wish to extend my heartfelt gratitude to all those involved in these discussions. The attentiveness and responsiveness of the team plus a future-focused policy outlook will result in tangible benefits for patients and certainty for our industry through to June 2027.

Commitment to this detailed negotiation firmly demonstrates the Government and industry's shared goal of accelerating access to innovative medicines and new technologies and ensuring patient voices are heard earlier in the review and funding processes.

I would like to thank the Minister for Health and Aged Care, the Hon Greg Hunt MP, for his continuing, close personal engagement, support and commitment to patients and the provision of innovative medicines. We will continue to work with Government and relevant stakeholders to ensure patients will be able to access new medicines and therapies when they need them.

The demand for and significant role of innovative medicines, biotherapeutics and new technologies has never been more apparent than in the massive response to the House of Representatives Inquiry into 'approval processes for new drugs and novel medical technologies', led by Trent Zimmerman MP and Dr Mike Freeland MP. The extraordinary response from the community, patient groups, clinicians and the industry has put patients firmly in the spotlight. There has been a long-needed recognition that patients wait too long to access subsidised treatments in Australia and the system needs to be modernised to not only accommodate the innovations of today but also the innovations of tomorrow. Medicines Australia has made significant contributions to this inquiry and strengthened the voice of patients through our patient focused Parliamentary events and through our negotiations for a new Strategic Agreement.

Furthermore, the Minister for Health and Aged Care's announcement in June of the commencement of the National Medicines Policy Review this year has reinforced the importance of sound policies to ensure new medicines can get to patients as soon as possible, without unnecessary delays.

I wish to take the opportunity to extend my thanks to Medicines Australia CEO, Elizabeth de Somer, and her staff for their tireless efforts over the past year. Liz has lifted the profile of Medicines Australia in the media, has instituted a reform process to transform the organisation into an efficient and effective modern organisation and has retained a sense of humour throughout. The Board, leadership team and staff have benefited greatly from her sound judgment and deep expertise, and I look forward to another year of working together.

In conclusion, I wish to express my deep appreciation to the Members for their continued support this past year. The Board have excelled as a cohesive and thoughtful team throughout the many challenges of the year and delivered against agreed principles that are designed to secure better outcomes for Members. The Medicines Australia staff have demonstrated great resilience and collaborative ways of working which I have no doubt puts Medicines Australia in a strong position to deliver on the ambition and objectives of the industry.



**Dr Anna Lavelle**

GAICD, FTSE  
Medicines Australia Board Chair



# The CEO's report

Supporting staff, Members and the Australian community

As I write this year's CEO Report, I reflect that much like the year before, this year has had its challenges. I am proud to say that despite these obstacles, Medicines Australia has shown its strength by seizing opportunities and drawing energy and drive from our purpose and our Members, to make a real difference to the health of Australians and ensuring they have access to world-class medicines when they need them. This Annual Report is a marker in our history that will be remembered for many years to come.

I am incredibly proud and inspired by the Medicines Australia staff and our Members and thank them for their unwavering commitment to the organisation as we have continued to navigate through lockdowns and the COVID-19 crisis. Our industry's contribution to the Australian community is significant and Medicines Australia and its Members have acted decisively.

## Combating the COVID-19 crisis

The COVID-19 pandemic has been a devastating physical, mental and economic crisis felt around the world, deeply impacting many people, including our colleagues, families and friends.

Throughout the year Medicines Australia has continued to consolidate our partnerships with patient advocacy groups, peak bodies and healthcare organisations to support patients. As a founding member of the Continuity of Care Collaboration (CCC) we have concentrated our efforts on providing consumers with the support and information they need to navigate the social, health and economic challenges of the pandemic. The award-winning and highly successful campaign, #DontWaitMate, shared an important message following mounting concerns that Australians are not maintaining their regular doctor visits for existing chronic conditions or new symptoms due to fears of contracting COVID-19 or burdening the health system.

Medicines Australia's commitment to medicines supplies and our work with the Government to mitigate medicine shortages is a highlight of the year. Medicines Australia sought and was granted authorisation by the ACCC to coordinate with Generic Biosimilar Medicines Association (GBMA) and the Therapeutic Goods Administration (TGA) in identifying and addressing shortages in the supply of prescription medicines. This collaboration ensured there were no critical shortages of medicines, that are essential to patient health, due to the pandemic, including medicines used to treat patients suffering from the symptoms of COVID-19. This collaboration also enabled the TGA to work with hospital pharmacists in developing a reliable modelling tool to more accurately forecast medicines demand in hospitals and reduce unnecessary stockpiling behaviour.

## Strategic Blueprint 2021-2026

Our new Strategic Blueprint was introduced this year and provides Medicines Australia with a clear map that will steer us towards our future goals. The Strategic Blueprint will make sure we can continue to thrive and best support our Members as they pursue new innovation-driven opportunities.

The Blueprint 2021-2026 focuses on four priority pillars: Invest in Australia, Invest in Science, Partner in Health, and No Australian Patient Left Behind. These four pillars are founded on upholding the highest ethical standards.

A super working group meeting of Members in early 2021 supported the development of the initial 12–18 month implementation plan which is well underway. The completion of a new Strategic Agreement and Government's commitment to investment in the PBS are early achievements.



## Connections and communications

Listening to feedback from our Members, we have moved towards smarter ways of connecting and communicating. In November 2020, the Members Portal was launched – a secure one-stop-shop that holds public, industry and working group information that is accessible anywhere, any time. It has dramatically improved our communication by creating a consolidated resource hub, chat platforms, Membership directories, spaces for subject matter experts and working groups and modern ways of communicating, such as video updates.

Another exciting development was a refreshed public website and includes helpful resources and information for our stakeholders and the public. The updated website, coupled with increased social media activity, has strengthened awareness and engagement with the public and grown our digital footprint.

Looking forward, we will continue to build and refine these digital platforms.

## Ongoing organisational transformation

Within Medicines Australia the organisational transformation has further strengthened the leadership breadth and depth, expanding communications and modernising business processes and systems to meet the challenges of the rapidly changing environment.

Medicines Australia has continued to evolve to ensure our business model is fit for purpose and serves the needs of our Members and the Australian public. Operational systems have been reviewed resulting in the implementation of simplified, contemporary processes and practices to support the great work of our staff, especially those who are working remotely.

Our staff are Medicines Australia's most valuable asset and our greatest supporters. We have implemented several improvements to recognise the contribution of staff, further grow skills and capabilities and provide improved career opportunities to retain our talent.

Efficiency in corporate operations has reversed operating deficits and enhanced resourcing of policy and communications. A surplus has been delivered on the investment reserve share market performance, more than recovering any lost

ground of 2019-20, providing greater certainty to be able to resource short term, specialist capability where required to promote industry positions such as the National Medicines Policy Review and implementation of the Strategic Agreement.

Medicines Australia, our Members, and the people we work with and for, have countered many hurdles and risen to the challenge. I wish to thank the Medicines Australia Chair, Dr Anna Lavelle, and the Board for their wisdom, professionalism and guidance. I would also like to thank my leadership team and staff for a tremendous effort during what has been an incredibly demanding year. I feel privileged and extremely proud to be part of this team.

In closing, I also wish to thank our Members for choosing to support us. We are indebted to you for all that you have done and continue to do for all Australians.



**Elizabeth de Somer**

Medicines Australia CEO

# 2020-21 Board of Directors

Thank you to the 2020-21 Board of Directors for your dedication and exemplary efforts.



**Dr Anna Lavelle**  
Chair  
Medicines Australia Independent  
Director



**Liz Chatwin**  
Deputy Chair  
Country President Australia & New  
Zealand  
AstraZeneca Pty Ltd



**Michael Azrak**  
VP and Managing Director,  
Australia and New Zealand  
Merck Sharp & Dohme  
(Australia) Pty Limited



**Leah Goodman**  
General Manager Biopharma /  
Managing Director for Australia &  
New Zealand  
Merck Healthcare Pty Ltd



**Bruce Goodwin**  
Selected Board Director



**Christi Kelsey**  
VP and General Manager  
GlaxoSmithKline Australia



**Anne Harris**  
Managing Director,  
Pfizer Australia and New Zealand  
Internal Medicine Lead, Developed Asia  
Pfizer Australia



**Stuart Knight**  
Managing Director  
Roche Products Limited



**Neil MacGregor**  
Managing Director  
Bristol-Myers Squibb Australia



**Chris Stemple**  
Vice President and General Manager  
Australia and New Zealand  
Abbvie Pty Ltd



**James McDonnell**  
VP and General Manager  
Vifor Pharma Australia



**Shannon Sullivan**  
Vice President & Managing Director  
Australia and New Zealand  
Amgen Australia Pty Ltd

# 2020-21

Medicines Australia works with our Members to place the patient at the centre of the collaboration between government, clinicians, and industry. Through this collaboration, Medicines Australia aims to ensure that no Australian patient is left behind in gaining rapid access to innovative treatments, biotherapeutics and vaccines and the benefits that innovative therapies bring to the individual, the community and the economy.

The COVID-19 pandemic has proven the irrefutable link between good health and economic prosperity. We believe that encouraging investment in Australia will ensure a high value innovative sector, a robust medicine supply chain, and healthy Australians who can contribute to their full potential.

Diseases and illnesses can rapidly change, and our health system must be able to keep pace and evolve. Investing in science to advance new medicines and innovative therapies to meet new health challenges is critical. Strengthening Australia's attractiveness as a destination for clinical trials and cutting-edge research and development is part of that important investment.

We must also ensure that the Pharmaceutical Benefits Scheme (PBS), which underpins our healthcare system, can grow to invest in innovations of today and those of the future.

Medicines Australia strongly believe that no matter your background, location, age or gender, all Australians should benefit from world-leading healthcare and have access to medicines when they need them. Our society and our economy benefit from having a healthy population. Medicines Australia works with stakeholders and our partners to inform, educate and raise awareness from a strong evidence base.

The following report highlights the 2020-21 focus on partnerships, encouraging strong stakeholder engagement, listening to patient perspectives and analysing evidence to lead discussions and develop sound policies to achieve our common goals. All the efforts of Medicines Australia could not be realised without the commitment and contributions of our Members.

# Parliamentary Engagement PharmAus

PharmAus is an annual event that brings together Members of Parliament, parliamentary staff and government department officials with patient advocacy groups and representatives from across the health and pharmaceutical industry, as well as media commentators. The event provides a platform to share ideas and identify opportunities for improved collaboration to improve public health policy.

Medicines Australia hosted two PharmAus events during 2020-21 as the COVID-19 pandemic required flexibility in the format and timing of the events to cater to the needs of our community and stakeholders.

## PharmAus20 Digital Forum: A health-led economic recovery

COVID-19 disrupted our way of life dramatically and changed the way we consider all facets of our health. PharmAus20 focused on the changing environment as we look toward a health-led economic recovery and the future of medicines.

The impact of COVID-19 not only provided the theme but also set the parameters for PharmAus2020. The event was converted from a face-to-face gathering to a digital one, spread over four sessions, starting on 27 August and concluding on 17 September 2020.

Over 200 participants joined each session, including patients, industry leaders, Government, academia and the community. The Hon Greg Hunt MP, Minister for Health and Aged Care, and the Hon Chris Bowen MP, the then Shadow Minister for Health addressed the forums, as well as CEOs, chairs, and industry leaders.

The overarching theme, based on the incredible response to COVID-19, generated great interest. Many speakers reflected with admiration on the level of collaboration, commitment, and communication that was generated with great speed in responding to the pandemic. It was widely acknowledged that this approach to collaboration should be taken forward into future settings and continue the partnerships created by a common global objective.

Distinguished speakers from the international industry, Thomas Cueni, Director General of IFPMA, Nathalie Moll, Director General of EFPIA and Dr Richard Torbett, CEO of ABPI, highlighted the close collaborations contributing to the expeditious development of innovative vaccines and treatments across the world and emphasised the impact of the policies in the international environment that may affect Australia and vice versa.

You can read a [full summary report on our website](#).



Minister Hunt addresses attendees at the PharmAus20 Digital Forum



## PharmAus21 - “Room for the Patient View”

At a time when health was firmly in the spotlight as the engine room of Australia’s economy, PharmAus21 again brought patient advocacy groups together with Members of Parliament, policy makers, and representatives from across the health industry to examine the issues that impact all Australians. This forum centred more closely on the importance of ensuring there is ‘room for the patients’ view’.

In a hybrid event, ‘Room for the Patient View’ saw 128 people attend Parliament House Great Hall in-person with 129 joining virtually via livestream and the interactive Q&A platform. The Minister for Health and Aged Care, the Hon Greg Hunt MP and Shadow Minister for Health and Ageing, the Hon Mark Butler MP attended in-person and addressed the forum.

Master of Ceremonies, Tracey Spicer AM, facilitated this important conversation. David Lockwood, a NeuroEndocrine cancer patient, and Kaitlyn Sapier, a Multiple Sclerosis patient, were two inspiring patient speakers who took attendees through their journey of diagnosis to treatment of their disease. A following panel included two further patients, Nicole Cooper, a bowel cancer patient and Jessica Bean, a cystic fibrosis patient, who shared their stories. Specialist clinician Professor Andrew Spencer from Monash University joined Dr Mike Freeland MP and Medicines Australia CEO Elizabeth de Somer for the panel discussion, which focused on what needs to change to speed up patients access to innovative treatments.

Understanding what matters to patients in the health system was extensively explored, including how best to incorporate the patient view in the regulatory and reimbursement processes, and how we can work together to improve timely access to new and innovative treatments.

You can read a [full summary report on our website](#).



Photos: Top left: Brad Edwards and Paula Dry, bottom left: NeuroEndocrine group and patients, top right: James McDonnell and Professor Andrew Spencer, bottom right: networking in the foyer.

## The House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia

The House of Representatives Inquiry has been an important focus for Medicines Australia and our Members since it was announced in August 2020.

The Inquiry saw over 200 submissions made over several months from patients, clinicians, industry and a host of interested stakeholders, demonstrating the importance of this inquiry to the community. The committee held numerous public hearings between September 2020 and July 2021.

Medicines Australia provided a comprehensive submission and supplementary submission to the Inquiry and appeared as witnesses to the inquiry on 26 March 2021.

Medicines Australia's submission and subsequent discussions have remained steadfast, focusing on four key areas for reform.

1. Improving timeliness of access to new medicines through Australia's regulatory and reimbursement processes.
2. Optimising research and development, including clinical trials.
3. Elevating the role of the consumer in medicines access.
4. Considering the global context to the regulatory and reimbursement environment.

Read Medicines Australia's [submission](#) and [supplementary submission](#).

# Medicines Australia in the community

## Corporate Social Responsibility Initiatives

Medicines Australia continues to support the Shalom Gamarada Indigenous Residential Scholarship Program that was established in 2009 to help in closing the gap between Aboriginal and Torres Strait Islander people with other Australians through higher education and by increasing the number of Indigenous healthcare professionals.

Medicines Australia has sponsored two students studying medicine at UNSW this financial year which brings the total to \$487,600 in funding for Shalom Gamarada. This year we saw one of our sponsored students, India Kinsey (pictured), graduate with a Bachelor of Medical Studies/ Doctor of Medicines.



“Thank you to Shalom college for making this place a home, for supporting me through some challenging years and for genuinely caring. Thank you to my scholarship provider Medicines Australia for making an immense difference in my life.”

- Dr India Kinsey.

We continue to sponsor a further two students: Jorge Hormovas who is a fourth-year medical student and Anne Dillon who is a first-year medical student. Their student profiles can be found on our [website](#).



Professor Kelvin Kong (centre), ENT surgeon, ASMR medallist and Worimi man meets Jorge Hormovas (right), who's in his fourth year of medicine at UNSW Medicine & Health and a Ngarabal man. At the National Press Club of Australia with CEO Elizabeth de Somer (left).

Professor Kong regularly works in remote communities and spoke about breaking the cycle of health disadvantage for First Nations people.

Read more about Medicines Australia's Corporate Social Responsibility commitment on our [website](#).



# Patients

## Continuity of Care Collaboration (CCC)

The Continuity of Care Collaboration is a first of its kind collaboration comprising over 40 Peak Bodies, Industry and Healthcare Organisations. The CCC has come together to highlight the importance of all people in Australia continuing to access healthcare during the COVID-19 pandemic to ensure optimal long-term health. Medicines Australia is a founding member of the CCC.

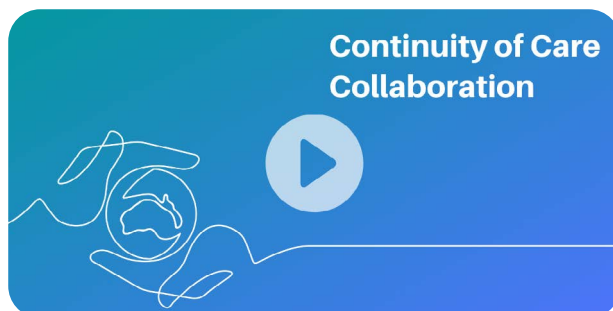
CCC activities have generated an estimated media reach of 258 million and around 1 million via social media.

The CCC launched the #DontWaitMate campaign that encourages people to continue with their health management during the COVID-19 pandemic. This campaign received the PRIME 2021 Finalist Award 'Best Public Health Initiative' and was supported by many political stakeholders including the Hon Greg Hunt MP, Minister for Health and Aged Care and the then Shadow Minister for Health, the Hon Chris Bowen MP as well as Dr Mike Freeland MP.

#DontWaitMate was a great success with key politicians and significant personalities sharing the message on social media.



Above: Senator Helen Polley, right: the Hon Greg Hunt MP



Greg Hunt  
@GregHuntMP

The 'Don't Wait Mate' campaign encourages Australians to look after their non-COVID-19 health needs during the pandemic.

Please continue to attend vital healthcare appointments, pathology tests, scans and screenings during COVID-19 restrictions.



Find out more about the Continuity of Care Collaboration at [continuityofcare.org](https://continuityofcare.org).



## 'Navigating COVID-19 & Beyond' program tailored to patient groups.

The COVID-19 crisis has affected everyone. Patient groups, serving as a lifeline to the Australian patient community, experienced added stresses. Many patient groups were concerned that they would be unable to continue providing their support services, education and awareness campaigns, and information to patients particularly with declining income and limited fundraising opportunities.

The Medicines Australia Consumer Advocacy Working Group (CAWG) engaged with over 100 patient groups throughout the year ranging in scale and complexity, and with different operating and financial characteristics. In October 2020 the CAWG surveyed the patient community to understand their pressures and determine how best the industry could provide meaningful and appropriate assistance to ensure Australian patients would not be left without community support.

The highest priorities for patient groups were fundraising and financial management during

COVID-19. Medicines Australia partnered with subject matter experts to develop the 'Navigating COVID-19 & Beyond' program, a series of tailored, interactive webcasts and workshops to help patient groups plan through this challenging time. Resources are available on [our website](#).

The program has helped patient groups set up stronger infrastructures and sustainable business systems to continue their great work for patients.

Following the success of these webcasts, patient groups have expressed an interest in other similar series or programs.

Medicines Australia and nine of its members contributed \$117,500 towards this program.

AstraZeneca

Bayer

Bristol Myers Squibb

IPSEN  
Innovation for patient care

Janssen  
A Johnson & Johnson company

Lilly

Merck

MSD

Novo Nordisk

Pfizer

Roche

SANOFI



## Building community understanding: patients impacted by COVID-19

The COVID-19 pandemic has been a concerning time for many Australians and in particular, patients who are living with serious or ongoing health concerns. When COVID-19 first hit Australia, Medicines Australia partnered with patient groups and Members, to alleviate fears, dispel misinformation and provide transparent and consistent information to patients and the community.



## Clinical trials

During the height of the pandemic in 2020, Australia saw notable disruption to clinical trials as trial sites sought to avoid patients' unnecessary exposure to the COVID-19 virus. Medicines Australia held a webinar specifically for the patient community about clinical trials which outlined how the disruptions also prompted rapid response from pharmaceutical companies and Government to address these challenges and implement fast adoption of remote patient monitoring and expansion in the use of tele-trials.

This educational information session built understanding among patients and reassurance to patients that their safety remains paramount.



## Medicine Supply Chain

Panic buying and stockpiling of medicines, coupled by media reports of medicines shortages added to patients' concerns during 2020-21. Medicines Australia hosted a roundtable for patient groups that included guest speakers from the Consumer Health Forum (CHF) and the Therapeutic Goods Administration (TGA).

This roundtable provided an overview on the supply chain in Australia to inform patient groups about the complexity of the supply chain dynamics during COVID-19 and it reassured the patient community that the industry is working closely with the Government to mitigate any shortages. Medicines Australia was able to confirm that there were no shortages directly related to the pandemic and although supply chains are under pressure, Australia was managing the situation well. An outcome of the discussion led to improved communications from the TGA and further work to mitigate potential medicines shortages into the future.



## First Nations patients

Medicines Australia's objective to ensure that no Australian patient is left behind includes our First Nations peoples.

Medicines Australia recognises that partnerships are needed to close the gap and ensure that all Aboriginal and Torres Strait Islander peoples have access to health services that are equitable and accessible.

In partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO), Medicines Australia is working to ensure that Aboriginal and Torres Strait Islander peoples are provided the opportunity to be actively involved in the decision-making and policy improvements for the timely access to medicines and treatments.

To support this work, a first ever joint committee was formed between NACCHO and Medicines Australia, with a key focus on improving medicines access and health outcomes for Aboriginal and Torres Strait Islander peoples.

Discussions are initially focused on exploring ways of working together, such as strengthening the medicines sector's cultural responsiveness, addressing health literacy, improving Aboriginal and Torres Strait Islander representation in the sector, addressing medicines access and affordability, and considering remote and regional access. The group is also considering how reforms in health policy, legislation and Health Technology Assessment (HTA) processes may improve the needs of Aboriginal and Torres Strait Islander peoples.

**"Up until now, there has not been a formal coordinated way for Aboriginal Community Controlled Health Organisations (ACCHOs) to engage with industry. The creation of this Committee will help streamline this process and effectively support medicines-related measures that improve health outcomes for Aboriginal and Torres Strait Islander clients and communities."**

**NACCHO CEO Pat Turner**

## International Women's Day

The Patient Voice Initiative (PVI) partnered with Medicines Australia on International Women's Day and hosted a webinar '*Choose to Challenge*' with a panel of resilient women to explore their experiences of accessing healthcare and how they think we can all 'choose to challenge' healthcare in Australia to better meet the needs of women and all patients.

Navigating a health diagnosis comes with immense challenges for a patient and their loved ones. For women in particular, many of these challenges remain unseen - balancing family life amidst medical treatment, juggling inequities in the workforce and income in addition to a health system that does not always meet the diverse needs of women.

This event is one of the ways throughout the year that Medicines Australia partnered with PVI and the great work they do for patients.





# Medicines Australia in the community

## Pharma Australia Inclusion Group

The 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 and rewarded.

PAIG is committed to establishing the pharmaceutical industry as a known leader in inclusion. While the pharmaceutical industry is leading other industries in practices that support inclusion, there is still more work to be done.

Inclusion is the foundation of equity and impacts all aspects of an organisation. Building inclusive workplaces is key to strengthening talent attraction and retention, as well as creating conditions that bring out the best in all people. PAIG has established a two-year program of activities focused on inclusion which covers:

- Mental Health and Wellbeing
- Building a culture of inclusion and reconciliation
- Age and Generations
- LGBTQI+
- Gender equity

Throughout 2021, the COVID-19 pandemic has continued to challenge the PAIG program and the traditional face-to-face learning format. However, in partnership with Willis Towers Watson, the PAIG executive team successfully adapted

workshops to accommodate hybrid/flexible working and minimise the impact of 'meeting fatigue' across the industry.

The response from Medicines Australia companies to the PAIG program has been truly inspiring with all companies placing the upmost importance on employee welfare and mental wellbeing. The program is both a learning opportunity and a benchmarking tool. Members have had the opportunity to share initiatives and case studies of work they have implemented in key inclusion areas and subject matter experts have also provided insights that has helped to increase awareness and understanding of key issues for inclusion such as reconciliation and support of First Nations people and support for LGBTQI+ colleagues.

PAIG has continued to serve as a good news story for member companies and in 2021 the program has increased media activities and social media presence, collaborating closely with member companies to amplify case studies and engagement via content across these channels.

The PAIG committee has also commissioned a new White Paper that will be delivered in late 2021, which will delve into the future state of inclusive workplaces. As we move into 2022, PAIG will leverage insights from the White Paper and member company consultation to continue to evolve and find new ways to ensure that the industry is an inclusive and diverse workplace, with conditions that bring out the best in all people.



Some of the PAIG members meet in 2020

# Federal Budget

This Annual report covers two Federal Budgets as the Federal Government delayed the 2020-21 Budget to October while managing and responding to COVID-19.

## 2020-21 Budget – October 2020

### New Medicines Funding Guarantee

Medicines Australia's 2020-21 pre-budget submission highlighted that over a decade of constructive partnership with Government has delivered enduring savings measures such that the offset policy for listing new medicines was no longer necessary. In fact, the PBS needs new investment to ensure timely access to new medicines for Australian patients.

In response, the Government announced in the October 2020 Federal Budget the removal of the offset policy for PBS listings and the establishment of the New Medicines Funding Guarantee (NMFG).

Medicines Australia welcomed the Federal Government's landmark step to introduce a guaranteed PBS new medicines funding commitment, heralding a new chapter of greater certainty for Australian patients in accessing new, innovative medicines.

The NMFG is a significant investment in Australia and will deliver new funding each year for the listing of the new medicines on the PBS, with at least \$2.8 billion in new, uncapped funding expected to be committed over the next four years.

Following these exciting announcements, Medicines Australia hosted briefings for Members to break down the outcomes and discuss next steps.

### Budget Week 2020

Medicines Australia attended the Budget announcement dinner at Australian Parliament House, followed by a comprehensive breakfast briefing the next day with Members.

Medicines Australia, in partnership with The Australian Institute of Policy and Science (AIPS), hosted two significant Health Post Budget Briefings with the Minister for Health and Aged Care, the Hon Greg Hunt MP and the then Shadow Minister for Health, the Hon Chris Bowen MP. These events brought together industry, government and patient groups and other healthcare stakeholders.

Other key events following the Budget announcement included attending the Treasurer's address at the National Press Club and the Opposition Budget reply.

Medicines Australia's role in joining and engaging with stakeholders at these significant events strengthens our position as a key partner in health.

## 2021-22 Budget – May 2021

Medicines Australia continues to partner with the Australian Government to ensure that Australia's healthcare system can keep pace with advances in scientific discovery to deliver lifesaving and life-changing medicines, therapies, and vaccines to Australian patients in 2021 and beyond.

Medicines Australia's 2021-22 pre-budget recommendations supported this goal by requesting the Government:

1. Implement the New Medicines Funding Guarantee (NMFG)
2. Demonstrate the removal of cost offsets for new listings
3. Finalise a new Strategic Agreement
4. Secure harmonised clinical trial governance
5. Implement the Review of the National Medicines Policy (NMP)
6. Convene a ministerial roundtable to discuss challenges of international reference pricing

Medicines Australia was therefore pleased that the Minister for Health and Aged Care, the Hon Greg Hunt MP, confirmed expenditure on the PBS funded by the NMFG, and demonstrating the removal of the offset policy.



Since the Budget, in June, Minister Hunt also confirmed the commencement of the NMP Review, commencing from August 2021.

Minister Hunt has further announced that the Australian Commission on Safety and Quality in Health Care will lead the development of requirements and specifications for a [National One Stop Shop for clinical trials and human research approvals](#) (One Stop Shop) and the National Clinical Trials Front Door. This includes the establishment of a Health and Medical Research Advisory Group, chaired by Professor Ian Chubb and including Medicines Australia as a member.

Finally, the Strategic Agreement was finalised and announced shortly after the end of the Financial Year.

Pre-budget submission [here](#)

CEO video [here](#)

## Budget Week 2021

### Post-Budget Analysis 2021

The post-budget breakfast briefing 2021 included 90 Members and featured the expert insights from influential stakeholders: Glenys Beauchamp PSM, Nick Campbell, Jody Fassina, and Medicines Australia Chair, Dr Anna Lavelle.

The briefing included analysis of the investment in Australia and our healthcare system in the Budget announcements, including the NMFG, funding for onshore mRNA vaccine manufacturing capability in Australia, additional funding for the COVID-19 response, and the patent box proposal.

A range of Budget related events strengthened the industry voice and positioned Medicines Australia and Members with government influencers via Federal Budget night dinners at Parliament House and post-Budget gatherings. It was a pleasure to be able to host face-to-face events in this brief window of the pandemic.

Medicines Australia also continued our partnership with AIPS to host two significant Health Post Budget Briefings with the Minister

for Health and Aged Care, the Hon Greg Hunt MP and the Shadow Minister for Health and Ageing, the Hon Mark Butler MP. These events brought together industry, government and patient groups and other healthcare stakeholders.

138 attendees in Canberra and 140 in Sydney.



Q&A session at post-budget breakfast

### VaxAus 2021 Roundtable

The first ever VaxAus brought together vaccine developers and manufacturing companies for a roundtable. Key outcomes included exploring potential reform of the vaccines reimbursement process in Australia and aligning policy options for vaccine advocacy.



Attendees at the first VaxAus Roundtable event

# Broader government engagement

## Strategic Agreement negotiations

Delivering timely access to much-needed vaccines and innovative treatments for Australians is a priority for the Government, Medicines Australia, industry and patients. To accomplish this, we must create opportunities that enable appropriate investment in Australia.

Medicines Australia worked closely with the Minister for Health and Aged Care and his Department during 2020 to develop a new 5-year Strategic Agreement to commence at the expiry of the current Agreement in July 2022, to deliver greater long-term certainty for both industry and Government.

The COVID-19 pandemic also highlighted the need to prepare for the post pandemic economic recovery and proactively strengthen our partnership with Government to deliver secure and timely access to medicines for patients.

A framework for revised statutory pricing policy settings was finalised in the October 2020 Federal Budget alongside Government's commitment to remove the requirement for cost offsets and the initiation of the New Medicines Funding Guarantee (NMFG). This framework provided the foundation for broader discussions of strategic importance to finalise a new Strategic Agreement. These discussions commenced immediately after the October 2020 budget announcement and were completed in June 2021.

The new Strategic Agreement signifies a strong collaboration between Government, industry and patients. The new Strategic Agreement will also ensure Australia's Health Technology Assessment (HTA) system evolves to keep pace with rapid advances in science and technologies and reflect international best practice.

## Response to COVID – TGA Medicines Shortages Working Party (MSWP)

During the height of the pandemic, Medicines Australia and its Members rose to the forefront as key players in the fight against COVID-19. Part of this work was the TGA Medicines Shortages Working Party (MSWP), which is comprised of representatives from Medicines Australia, the Generic Biosimilar Medicines Association (GBMA), pharmacy and wholesaler peak bodies, health professional groups, state and territory health authorities and is chaired by the Federal Department of Health.

During 2020, the MSWP met weekly to discuss and respond to COVID-19 medicines shortages and supply issues.

Working party Members continue to discuss issues impacting the supply of medicines and work together to ensure the medicine supply chain is maintained and shortages are managed or mitigated during the current health emergency.

## Response to COVID-19 – ACCC Authorisation for the supply of medicines

Medicines Australia and GBMA continue to work with the TGA to identify potential supply issues that may require coordination under the ACCC authorisation.

Under the ACCC authorisation Medicines Australia, reports fortnightly to the ACCC on any activities under the conduct of the authorisation. We regularly engage with the TGA to discuss potential and/or emerging supply concerns of essential medicines, including those necessary for the treatment of COVID-19 patients, and to ensure measures are in place to mitigate any medicines shortages or supply chain issues.

## Supply chain

Throughout 2020 and 2021 Medicines Australia has actively participated in a multi-stakeholder Supply Chain Roundtable led by the Department of Industry. The roundtable provides a forum to raise sectoral and cross sectoral supply chain challenges where Government support may assist in resolving them. For example, to resolve trade and export restrictions that interrupt medicines supply.

Medicines Australia has periodically surveyed

Members to establish potential supply chain concerns to raise at the roundtable. Challenges with air and sea freight are an ongoing discussion.

Members have benefitted from the introduction of the International Freight Assistance Mechanism (IFAM), however, freight disruptions have become the norm during the pandemic.

Medicines Australia continues to work closely with our Members and stakeholders to ensure that the supply of medicines is continuous and not disrupted where possible.



CEO Elizabeth de Somer was interviewed by Sky News in March 2021 and spoke about European vaccine nationalism, sovereign manufacturing, supply chain and flu vaccines.

## Deepening partnership with broader Federal Government departments

This year, Medicines Australia has broadened and deepened our partnership and engagement across government departments such as the Department of Foreign Affairs and Trade, Treasury, Finance, Prime Minister & Cabinet and Home Affairs on issues including domestic manufacturing, supply chains, trade agreements and critical infrastructure.

Medicines Australia has a strong government relations focus which continues to ensure issues, challenges and opportunities are top-of-mind for policy makers. This will ensure future decisions are made with consideration for how they will directly impact Medicines Australia, its Membership and patients.



## Research and Development Task Force (RDTF)

The RDTF is co-sponsored by Medicines Australia, AusBiotech and the Medical Technology Association of Australia (MTAA).

The key objective is to strengthen the Task Force's position as a trusted partner of governments and industry, and the national harmonisation of clinical trials

During the pandemic, the RDTF completed significant work on updating the Clinical Trials Research Agreement templates for tele-trials.

Medicines Australia and the RDTF have been working with the Department of Health on activities to harmonise clinical trials regulation in Australia, which are also supported by the Minister for Health and Aged Care, the Hon Greg Hunt MP.

Clinical trials in Australia are a significant enabler for faster access to innovative treatments for patients and make an important contribution to the economy but we require a consistent, national approach to remain competitive.

The Australian Commission on Safety and Quality in Health Care announced national consultations to scope the requirements for a national health and medical research approvals platform – a National One Stop Shop. Consultations will commence from July 2021.

This much anticipated consultation will present an opportunity to achieve a national, interconnected, rapid and streamlined pathway for attracting clinical trials to our shores.

## Medicines Australia in the community

### Patient Voice Initiative

Medicines Australia continues to partner with Patient Voice Initiative (PVI). PVI is a collaboration between patients (or health consumers), researchers and industry working towards improving the patient voice in the Australian health system.

Throughout 2020-21, PVI continue to advocate for the inclusion of the patient perspective in the structure and operation of Australia's health system; all aspects of patient care in Australia and the development, approval and funding of medical technologies.





# Data and Evidence

## Medicines Matter

In late 2020, Medicines Australia released its [Medicines Matter: Australia's Access to Medicines 2014-2019 Report](#).

The Medicines Matter Report involves a detailed and specific methodology, built by IQVIA, that standardises timelines for medicines registration (market authorisation) and also reimbursement across a variety of healthcare systems within comparable OECD countries including Australia.

The methodology is used to evaluate access to

innovative medicines across the selected OECD countries. By providing a benchmark against other countries, this report reveals the strengths and areas of improvement in Australia's system.

Access to medicines requires further focus and improvement which cannot be achieved without strong partners in health and Government.

**Medicines  
Matter**  
An investment for a  
healthier tomorrow



## Facts book

In early 2021, Medicines Australia released the fifth edition of its Facts Book. The Facts Book provides vital industry information and statistics on government investment in health, Pharmaceutical Benefits Advisory Committee (PBAC) statistics, research and development, clinical trials, patent numbers, manufacturing, exports, as well as the breakdown of employment and industry growth.

The Facts Book is available on our website and is regularly used by Members and media to add an extra layer of depth and context when speaking about topics such as clinical trials, overseas investment, manufacturing or value of the biopharmaceutical industry.



Download  
Facts Book



## Days of significance

Medicines Australia continued to support patient causes. Here are a selection of the highlights from 2020-21.

### NAIDOC Week with Jorge

It's important to highlight and celebrate the fantastic benefits of increasing representation of First Nations people in health and medicine. During NAIDOC Week, Medicines Australia interviewed Jorge Hormovas, a Ngarabal man and fourth year medical student at UNSW.



### Purple day for Epilepsy

On behalf of Medicines Australia, Petrina Keogh, Manager of Stakeholder Relations, attended Epilepsy Action Australia's Purple Day Events in March and witnessed the Sydney Opera House light up purple to raise awareness for 250,000 Australia's living with epilepsy.



### Bowel Cancer Awareness



Medicines Australia staff supported Bowel Cancer Awareness with social media posts.

### Kosi Challenge 2021

The Kosi Challenge is Rare Cancers Australia biggest annual fundraiser and is supported by Medicines Australia and many of our Members. Now in its 9th year, the event welcomes participants from around Australia who climb Mt Kosciuszko to raise much needed funds for cancer patients. The 2021 Kosi Challenge has been the biggest ever seen and patients will directly benefit.





# Submissions

Medicines Australia has continued to work with Members and the Australian Government and Parliament to improve healthcare benefits for Australians through timely access to medicines. Over the course of the past year, Medicines Australia has made 12 submissions related to access and pricing, 4 submissions on broad medicines policy and 12 submissions on regulatory affairs and TGA.

## Submissions made in 2020-21

### [Senate Select Committee on COVID-19 – September 2020](#)

Medicines Australia made a submission to the Senate Select Committee which outlined how our Members deployed scientific expertise and capabilities to help the fight against COVID-19. It also described how Medicines Australia's Members maintained the supply of essential medicines and vaccines to patients, and how they supported the community working on the front line.

Medicines Australia recommended that government work with the private sector and identify opportunities to enhance industry capabilities.

### [House of Representatives Standing Committee on Health, Aged Care and Sport: Inquiry into approval process for new drugs and novel medical technologies in Australia – November 2020](#)

Medicines Australia made a submission to the inquiry in November 2020. Medicines Australia outlined a number of important recommendations calling for review and reform in the timeliness of access to new medicines, research and development, including clinical trials, and the role of the consumer in medicines access.

Medicines Australia also attended a hearing with the committee in March to present the positions outlined in the submission and to answer questions from the committee.

You can read Medicines Australia [initial submission](#) and [supplementary submission](#) on the Parliament of Australia website.

## Other Submissions

### [Medicines Australia submission to the Public Consultation – Revised Procedure Guidance – Public Summary Documents – September 2020](#)

### [Medicines Australia submission to the Public Consultation – Revised Procedure Guidance – Initial Submission Categories and Single Submission Date – September 2020](#)

### [Medicines Australia submission to the Public Consultation – Revised Procedure Guidance – Resubmission pathways – September 2020](#)

In these three submissions, Medicines Australia outlined their support for important changes, but also outlined remaining concerns. This included concerns about clinical data redaction criteria, concerns about the single submission date delaying access, and clarification as to the approach required to resolve the issues associated with 'Positive Recommendations' and 'Deferrals' that involve changes that cannot be met by the sponsor.

### [Submission – Treasury Laws Amendment \(Research and Development Tax Incentive\) Bill 2019 – September 2020](#)

In this submission Medicines Australia outlined that the Bill weakens the Research and Development Tax Incentive and will risk Australia losing its international competitiveness at a time where competition with regional and emerging players is increasing.

### [Medicines Australia Submission – Department of Health Lung Cancer Screening consultation – September 2020](#)

In this submission Medicines Australia recommended that the Government move to innovate evaluation and payment models which focus on the value of therapy to individual patients, to improve and simplify access to quality diagnostics. Medicines Australia also recommended that Government work with stakeholders to create incentivising policies for precision medicine, and that health professionals and patients are provided with education on lung cancer to enhance public awareness and reduce stigma.

### [Submission – Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade – September 2020](#)

In this submission Medicines Australia outlined the global nature of the pharmaceutical industry and put forward recommendations to strengthen regional and global cooperation, investigate various forums of international health related agreements, and provide a resilient national framework to achieve these objectives.

### [Submission – Inquiry into supporting Australia's exports and attracting investment – September 2020](#)

In this submission, Medicines Australia outlined the opportunity to boost the profile of Australia industry internationally, encouraging foreign investment and trade, thus growing economic growth and prosperity.

### [Submission from Medicines Australia to the Department of Home Affairs: Protecting Critical Infrastructure and Systems of National Significance: Exposure Draft Security Legislation Amendment \(Critical Infrastructure\) Bill 2020 – January 2021](#)

In this submission to the Department of Home Affairs, Medicines Australia outlined its broad support for efforts to strengthen Australia's security and economic resilience, but cautioned any introduction of measures that impede the ability of companies to continue usual business operations.

### [Medicines Australia Pre-Budget Submission 2021-2022 - March 2021](#)

In the 2021-2022 pre-budget submission Medicines Australia recommended that the government fully implement the 2020 Budget commitments, fully implement the 2019 election commitments, and convene a Ministerial Roundtable with industry in the first half of 2021 to discuss the challenges international reference pricing poses to Australian patients.

### [TGA consultation on repurposing – April 2021](#)

In this submission Medicines Australia noted support for investigating mechanisms, and conducting risk/benefit assessments for new indications for prescription medicines to facilitate appropriate access to medicines for patients in the context of repurposing.



[Submission to the Productivity Commission report into vulnerable supply chains- May 2021](#)  
[House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval process for new drugs and novel medical technologies in Australia](#)

Medicines Australia provided an overview to the Productivity Commission of the medicines supply chain in Australia, showing how it had remained resilient during the COVID-19 pandemic in 2020, while also acknowledging that Australia had not be as severely affected as other countries at the time. Medicines Australia recommended greater government and industry collaboration.

[Building a more robust medicines supply chain: Proposals to help prevent, mitigate and manage medicine shortages – Submission to TGA consultation – May 2021](#)

Medicines Australia provided response to the TGA consultation, noting that this should be read alongside the Productivity Commission submission. Medicines Australia welcomed the options outlined by the TGA, but noted more work needed to be undertaken.

[PBS Cost Recovery Implementation Statement for Stage 2 PBS Improvements for 2021](#)

Medicines Australia provided response to the revised cost recovery arrangements to support implementation of Stage 2 process improvements. This includes changes to initial submission categories (including introduction of a single submission date) and the introduction of resubmission pathways for submissions not recommended by the PBAC.

[PBS Cost Recovery Implementation Statement for 2021-22 Financial Year](#)

Medicines Australia provided the annual response to the cost recovery arrangements for the 2021-22 financial year.

[National Opioid Analgesic Stewardship Program](#)

Medicines Australia consulted on the use of opioid analgesics in emergency departments, perioperative and surgical services. This consultation will be used to inform the development of a National Opioid Analgesic Stewardship Program.

[Opioid Dependence Treatment Program Terms of Reference](#)

Medicines Australia provided support on the public consultation on the draft Terms of Reference to the Post-market Review of the Opiate Dependence Treatment Program (ODTP PMR) medicines acknowledging this was first opportunity for stakeholders to provide input to the ODTP PMR with the full review to commence thereafter.

[Efficient Funding of Chemotherapy \(EFC\) Review](#)

Arising from the 2020-21 Budget, the Government announced a review of the current Efficient Funding of Chemotherapy (EFC) program. This review looked at the impact and continuing suitability of the current EFC program and associated practices within the supply chain to ensure continuing access to medicines under this program.

Medicines Australia and Members of the Oncology Industry Taskforce worked together to outline how the EFC program has not remained fit-for-purpose for today's oncology medicines and should be adjusted to ensure the EFC program supports a future-proof reimbursement system. The provision of services by oncology stakeholders must be recognised by a standardised fee-for-service that reflects the value of a service and distinguishes the cost of medicine from service provision.



# Ethics and Compliance

Medicines Australia and its Members are committed to ensuring our conduct is of the highest ethical standard, and that the environment we provide access to our medicines is sustainable and fair. This is demonstrated through high levels of compliance with the [Code of Conduct](#), and alignment with global standards of ethical conduct.

Ethics and Compliance activities in 2020-21 focused on the ongoing implementation of Edition 19 of the Code of Conduct. Since coming into effect in March 2020, the principles-based Code has supported industry in appropriately contributing to the health narrative and meeting the information needs of our audiences. The inclusion of new permissions that facilitate the

scientific exchange of vital information with healthcare professionals underscores the quality use of medicines and has a positive impact on Australian patients.

In supporting industry through the unpredictability of COVID-19, the Code of Conduct provided flexibility in transitioning away from traditional engagements to supporting our healthcare professional colleagues virtually. The new [Code Resource Toolkit](#) allows Medicines Australia to provide clear advice promptly and with agility, heightening compliance with the Code. Through the Toolkit, Medicines Australia has shared templates and briefing notes that are factual and relevant to the practical application of the Code.

## Complaints, Appeals and Monitoring

### Complaints handling

Medicines Australia considered 4 complaints in 2020-2021, with all complaints finalised before the end of the financial year.

Complaint	Subject Company	Complainant	Outcome
1159	Member Company	Member Company	Breach
1160	Member Company	Member Company	Breach (appeal not upheld)
1161	Member Company	Member Company	Breach
1162	Member Company	Member Company	Breach (appeal upheld)

Full details of all complaints are published on the Medicines Australia [website](#).

## 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 [www.disclosureaustralia.com.au](http://www.disclosureaustralia.com.au). Data has been reported onto the system since August 2019, with over 30,000 searches performed during that time. During the 2020-21 financial year, payments and transfers of value reports were published in August 2020 and February 2021.

### Third Party Meeting and Symposium Sponsorship Reports

Medicines Australia Members 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 2020 showed that there were 804 events sponsored by 29 Members in the period 1 November 2019 – 30 April 2020. On 30 April 2021, Members published reports for the period May 2020 – October 2020, which reported on 655 events sponsored by 26 Member companies in that six month period.

The impact of COVID-19 is evident in the reduced number of events sponsored in the financial year as many events were cancelled or transitioned to virtual platforms.

## Health Consumer Organisation Support Reports

In June 2021 Medicines Australia published the eighth annual reports of Member Companies' financial support for Health Consumer Organisations (HCO). Members supported 224 different HCOs across Australia in calendar year 2020, ranging from national consumer organisations to small local groups, relating to 315 different projects or events to the total value of \$7,417,333 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 more than 30 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](#).

# Organisational transformation

Medicines Australia must continue to evolve to ensure our business model is fit for purpose and serves the needs of our Members and the Australian public.

## Significant deliverables

In addition to a number of smaller, internally focused outcomes, the Executive have delivered the following:

- Delivered the Strategic Blueprint 2021-2026 to focus on four priority pillars over 5 years: Invest in Australia, Invest in Science, Partner in Health, and No Australian Patient Left Behind.
  - » These four pillars are underscored by the foundational platform of ensuring that our industry conduct remains of the highest ethical standard.
  - » Outcomes and actions for these pillars are being operationalised through greater partnership with our stakeholders.
- Launch of a new Members Portal in November 2020 – a secure one-stop-shop for all Members which holds public, industry and working group information.
- A refreshed public website was launched in November 2020 which includes resources and information for our stakeholders and the public.
- A staff-driven People Committee was announced in June 2021 and will be established in the new Financial Year.
- Operational systems were reviewed in February 2021 resulting in the implementation of simplified, contemporary processes and practices to support transparent tracking and reporting.
- A comprehensive Data Strategy was developed in June 2021, to ensure that the right data is being made available at the right time to support Members and the Strategic Blueprint.

## Future deliverables

Future phases of the transformation project will include internal and external priorities that will deliver value for Medicines Australia Members.

Key deliverables which are currently in progress for the new Financial Year include:

- Review existing Working Groups structures and representation to ensure the best industry minds and effort are harnessed to contribute towards industry goals set out in the Strategic Blueprint.
- Review Membership classifications to ensure the right representation across the industry for future needs.
- Staff coaching and support to build cohesiveness and non-technical work skills and establish greater career development opportunities.
- Enhanced engagement with non-Members to highlight the value proposition of having a voice at the table in the rapidly evolving medicines and health dialogue with governments and industry partners.





# Working with our Members

Medicines Australia acknowledges the incredible contribution that our Members make to collaborating with the Medicines Australia Executive. The achievements in this Annual report could not have been made without your commitment and contributions. Your support is remarkable.

## Chief Executive Group (CEG)

Chief Executive Group (CEG) assists Medicines Australia to deliver against the Board strategic priorities, to achieve a predictable and positive environment registration and reimbursement of medicines in Australia, and to lead and maintain industry consensus and unity.

Members of CEG during 2020-21 were:

Anne-Maree Englund (Co-Chair)	Medicines Australia
Nicola Richards (Co-Chair)	Merck Sharpe and Dohme Pty Ltd
Alan Paul	GlaxoSmithKline Australia Pty Ltd
Ben Hopkins	Takeda Pharmaceuticals Australia Pty Ltd
Ian Black	Roche Products Pty Ltd
Jodie Thomas	Novo Nordisk Pharmaceuticals Pty Ltd
Julie Ellis	A. Menarini Australia Pty Ltd
Kieran Schneemann	AstraZeneca Pty Ltd
Louise Graham	Pfizer Australia Pty Ltd
Paul Lindsay	Merck Healthcare Pty Ltd
Penny George	Sanofi-aventis Australia Pty Ltd
Stuart Englund	Janssen-Cilag Pty Ltd
Wade McMonagle	AbbVie Pty Ltd

## Standing Working Groups

### Health Economics Working Group (HEWG)

Health Economics Working Group (HEWG) provide advice and support on areas of health economic and market access trends, issues and initiatives which may impact on the pharmaceutical industry and timely access to innovative prescription medicines and vaccines for all Australian patients.

Members of HEWG as at 30 June 2021:

Jodie Wilson (Co-Chair)	AbbVie Pty Ltd
Vincent Tran (Co-Chair)	Medicines Australia
Greg Cook	Bristol-Myers Squibb Australia Pty Ltd
Louise Graham	Pfizer Australia Pty Ltd
Lucas Tocchini	Novartis Australia Pty Ltd
Megan Bohensky	Merck Sharpe and Dohme Pty Ltd
Michael Haberl	GlaxoSmithKline Australia Pty Ltd
Paul Alexander	Roche Products Pty Ltd
Peter Germanos	Boehringer Ingelheim Pty Ltd
Sarah Bridge	Bayer Australia Ltd
Vanessa Stevens	Vifor Pharma Pty Ltd

### Policy Scanning Working Group (PSWG)

Policy Scanning Working Group (PSWG) provide advice and support relating to international policy trends, issues and initiatives which may impact on the pharmaceutical industry and timely access to innovative prescription medicines for all Australian patients.

Members of PSWG as at 30 June 2021:

Mark Stewart (Co-Chair)	Medicines Australia
Stuart Englund (Co-Chair)	Janssen-Cilag Pty Ltd
Andrew Thirlwell	Pfizer Australia Pty Ltd
Darin Kottege	Merck Sharpe and Dohme Pty Ltd
David Thomson	Amgen Australia Pty Ltd
Gillian Sharratt	AbbVie Pty Ltd
Guillaume Herry	Biointelect Pty Ltd
Martin Snoke	Roche Products Pty Ltd
Sophie Schultz	Takeda Pharmaceuticals Australia Pty Ltd
Stacey Bolto	Novartis Australia Pty Ltd

## Consumer Advocacy Working Group (CAWG)

The aim of the Consumer Advocacy Working Group (CAWG) is an inclusive, collaborative forum of industry Members to connect best practice, emerging issues and activities of mutual interest with the patient community.

Members of CAWG as at 30 June 2021:

Petrina Keogh (Co-Chair)	Medicines Australia
Andi Bennett	Novartis Pharmaceuticals Australia Pty Ltd
Cathy Sertori	AstraZeneca Pty Ltd
Hayley Andersen	Bristol-Myers Squibb Australia Pty Ltd
Jamie Nicholson	Roche Products Pty Ltd
Katherine Tocchini	Novo Nordisk Pharmaceuticals Pty Ltd-Australia
Leigh Simmonds	Pfizer Australia Pty Ltd
Lisa Julian	Eli Lilly Australia Pty Ltd
Zarli French	Merck Sharpe and Dohme Pty Ltd

## Government Working Group (GWG)

Government Working Group (GWG) provide advice and support on areas of government relations, issues and initiatives which may impact on the pharmaceutical industry and timely access to innovative prescription medicines and vaccines for all Australian patients.

Members of GWG as at 30 June 2021:

Amy Moore (Co-Chair)	AbbVie Pty Ltd
Jamie Snashall (Co-Chair)	Medicines Australia
Ben Gommers	Merck Sharpe and Dohme Pty Ltd
Fiona Tigar	Biogen Australia Pty Ltd
James McAdam	Bristol-Myers Squibb Australia Pty Ltd
Josh Bihary	Pfizer Australia Pty Ltd
Kieran Schneemann	AstraZeneca Pty Ltd
Meriana Baxter	Amgen Australia Pty Ltd
Penny George	Sanofi-aventis Australia Pty Ltd
Stacey Bolto	Novartis Pharmaceuticals Australia Pty Ltd
Todd Stephenson	Janssen-Cilag Pty Ltd

## Regulatory Affairs Working Group (RAWG)

Regulatory Affairs Working Group (RAWG) provide advice and support on areas of sustainable regulatory trends, issues and initiatives which may impact on the pharmaceutical industry and timely access to innovative prescription medicines for all Australian patients.

Members of RAWG as at 30 June 2021:

Helen Critchley (Co-Chair)	Sanofi-aventis Australia Pty Ltd
Peter Komocki (Co-Chair)	Medicines Australia
Ailsa Surman	Amgen Australia Pty Ltd
Brian Hewitt	Amgen Australia Pty Ltd
Carolyn Tucek-Szabo	GlaxoSmithKline Australia Pty Ltd
George Lillis	Novartis Pharmaceuticals Australia Pty Ltd
Kirpal Kaur	Bristol-Myers Squibb Australia Pty Ltd
Linda Ponkshe	Janssen-Cilag Pty Ltd
Maria Dionyssopoulos	Commercial Eyes Pty Ltd
Mary Flannery	Bayer Australia Ltd
Michael Parker	AstraZeneca Pty Ltd

## Medicines Australia Vaccination Industry Group (MAVIG)

Medicines Australia Vaccination Industry Group (MAVIG) is an issues group comprising nominated Members of MA member companies. MAVIG manage the ongoing and emerging issues related to the registration and funding of vaccines and to enhance processes and policies supporting a strong evidence-based vaccines sector.

Members of MAVIG as at 30 June 2021:

Anne-Maree Englund (Co-Chair)	Medicines Australia
Paul Hester (Co-Chair)	Merck Sharpe and Dohme Pty Ltd
Birgit Beisner	GlaxoSmithKlein Australia Pty Ltd
Crissa Kyriazis	Biointelect Pty Ltd
Danica Prodanovic	Biointelect Pty Ltd
David Pullar	GlaxoSmithKlein Australia Pty Ltd
Dylan Jones	Merck Sharpe and Dohme Pty Ltd
Louise Graham	Pfizer Australia Pty Ltd
Marcello Blanch	Janssen-Cilag Pty Ltd
Michael Parker	AstraZeneca Pty Ltd
Pierre Niles	Pfizer Australia Pty Ltd
Sarah Lindeman	Sanofi-aventis Australia Pty Ltd
Valda Struwig	Pfizer Australia Pty Ltd
Vanessa Xavier	Sanofi-aventis Australia Pty Ltd



## Communication Issues Working Group (CIWG)

Communication Issues Working Group (CIWG) is a communications issues group that is made up of communications, public relations, marketing and media specialists from MA member companies and chaired by the MA Manager for Media and Communications. CIWG Members actively contribute to communication frameworks, strategies, campaigns and marketing collateral that contribute to the delivery of Medicines Australia's Strategic Blueprint.

Members of CIWG as at 30 June 2021:

Chrystianna Moran (Co-Chair)	Medicines Australia
Tanya Holloway (Co-Chair)	Merck Sharpe and Dohme Pty Ltd
Alison Melville	Bristol-Myers Squibb Australia Pty Ltd
Angela Hill	GlaxoSmithKline Australia Pty Ltd
Camilla Jury	Novartis Pharmaceuticals Australia Pty Ltd
Claire Russell	Amgen Australia Pty Ltd
Helen Han	Pfizer Australia Pty Ltd
Kate Richards	AbbVie Pty Ltd
Kristin Trace-MacLaren	GlaxoSmithKline Australia Pty Ltd
Maeve Eilki	Janssen-Cilag Pty Ltd
Melissa Millard	AstraZeneca Pty Ltd
Michelle D'Heureux	Bayer Australia Ltd
Rebekah Cassidy	Sanofi-aventis Australia Pty Ltd
Sam Pearson	AbbVie Pty Ltd
Stephanie Johnston	Roche Products Pty Ltd

## Oncology Industry Taskforce (OIT)

Medicines Australia has a dedicated group, the Oncology Industry Taskforce (OIT) that was formed in 2012 to catalyse an informed public debate about accessing new medicines generally, and new cancer medicines in particular, and to work collaboratively with Government, clinicians, and patients to address the challenge of access to cancer medicines

Members of OIT as at 30 June 2021:

Megan Bohensky (Co-Chair)	Merck Sharpe and Dohme Pty Ltd
Todd Stephenson (Co-Chair)	Janssen-Cilag Pty Ltd
Amy Moore	AbbVie Pty Ltd
Andrea Kunca	Roche Products Pty Ltd
Andrew Thirlwell	Pfizer Australia Pty Ltd
Angela Lai	Eli Lilly Australia Pty Ltd
Anne-Maree Englund	Medicines Australia
Catherine Vaughan	Novartis Pharmaceuticals Australia Pty Ltd
Dani Thut	Bayer Australia Ltd
Darin Kottege	Merck Sharpe and Dohme Pty Ltd
David Cain	Astellas Pharma Australia Pty Ltd
David Thomson	Amgen Australia Pty Ltd
Elise Kelly	Pfizer Australia Pty Ltd
James McAdam	Bristol-Myers Squibb Australia Pty Ltd
Jan Lewis	AbbVie Pty Ltd
Katrina Vanin	GlaxoSmithKline Australia Pty Ltd
Kerrie McDonald	AstraZeneca Pty Ltd
Kieran Schneeman	AstraZeneca Pty Ltd
Kylie Earle	Sanofi-aventis Australia Pty Ltd
Laura Issa	AbbVie Pty Ltd
Liliana Chavez	Novartis Pharmaceuticals Australia Pty Ltd
Matt Douglas	Bristol-Myers Squibb Australia Pty Ltd
Matthias Brunner	Roche Products Pty Limited
Meg Simmonds	AstraZeneca Pty Ltd
Meriana Baxter	Amgen Australia Pty Ltd
Natalie Betts	Roche Products Pty Ltd
Nicki Conway	Eli Lilly Australia Pty Ltd
Paul Lindsay	Merck Healthcare Pty Ltd
Petrina Keogh	Medicines Australia
Pinky Dharmshaktu	Merck Healthcare Pty Ltd
Rebecca Stratford	AstraZeneca Pty Ltd
Sally Ryan	Pfizer Australia Pty Ltd
Sophie Schultz	Takeda Pharmaceuticals Australia Pty Ltd
Stephen Richardson	Sanofi-aventis Australia Pty Ltd

# Corporate Governance

## Advisory Council

The Advisory Council supports the Medicine Australia Board's role in shaping strategy and maintaining appropriate continuity of direction. The Advisory Council provides advice on trends and issues impacting industry.

Members of the Advisory Council during 2020-21 were:

Anna Lavelle (Chair)	Chair of the Board, Medicines Australia
Andrew Carter	Managing Director, Commercial Eyes Pty Ltd
Belinda Wood	Senior Director Government Affairs ANZ, Gilead Sciences
David Norton	Formerly Chair, Global Pharmaceuticals, Johnson & Johnson
Greg Allen	Finance Manager, Epworth Freemasons Hospital
Ian Chubb	Formerly Chief Scientist of Australia
Jane Hill	CEO, Ovarian Cancer Australia
Jeff Harmer	Managing Director, Australia and New Zealand School of Govt (ANZSOG)
Kelly Constable	CEO, AULUS Partners
Leigh Farrell	Executive Advisor, Certara C-Suite

## Appointment of Board of Directors

Medicines Australia's constitution prescribes the composition of and appointment of directors of the Board. The number of directors must be between five and 13, consisting of between two and 10 Member directors (from classes 1, 2 or 3, including at least two from small to medium sized entities). Vacancies arising for Member directors lead to invitations for nominations from Member Representatives 90 days before the AGM and, if necessary, an election the results of which are notified at the AGM. One independent selected director and up to two additional selected directors may be appointed by the Board. Directors are appointed for three years.

## Board charter

Responsibilities and activities of the Board are covered in detail in the Board Charter. The Charter sets out the responsibilities and role of the Board, the Chairperson, the CEO and the Company Secretary and addresses all aspects of Board appointments, activity and performance. Directors have the right of access to all company information and to the company's Executive and, subject to prior consultation with the Chairperson, may seek independent professional advice at the company's expense. The Board meets in-person at least five times during the year, and additionally via teleconference or through consideration of out-of-session papers as required.

## Conflicts of interest

Directors declare at each Board meeting any changes to their statement of interests, which are prepared annually affirming that they have no specific interests that will impact on their ability as a director and that any potential or perceived conflicts of interest will be declared to the Board.

## Competition law

Directors acknowledge at each meeting the requirements of competition and consumer law and ensure that no individual company commercial or pricing issues are discussed.

## Legal compliance

Both the Performance and Governance Committee and the Finance, Risk and Audit Committee are charged with different aspects of monitoring assurance systems. The Company Secretary is responsible for corporate legislative compliance and risk management, reporting to both committees, which in turn provide advice and recommendations to the Board. The responsibilities of the committees are set out in their respective charters. Membership comprises at least three Directors. The committees meet at least twice each year. Auditors are provided notice of general meetings of Members and are invited to present to the Finance, Risk and Audit Committee when annual financial statements are considered.

## Financial policies and procedures

Comprehensive practices are established and included in the company's policy manual. The Board approves annual budget and the Finance, Risk and Audit Committee review current financial statements at each meeting and present and discuss the operating position with the Board. The management of the investment portfolio is governed within a specific investment policy by an external specialist provider.

## Risk management

The management of company risks is a specific responsibility of the Finance, Risk and Audit Committee. The Executive and staff review and assess risk frequently in terms of business environment, work health and safety, financial sustainability, internal control, program delivery and reputation. Internal audit reviews are undertaken periodically at the direction of the Audit and Risk Management Committee.

## Member consultation and communications

The Board aims to ensure that all Members are informed of all major developments affecting the company through consultation, Board buddies, working groups and the Members Portal. The Board encourages full participation of Members at the AGM. Full participation is also encouraged at a general meeting held by the company in June each year at which the Annual Operating Plan is presented, and core subscription levels are formally agreed on by Members for the upcoming financial year.

## Values

Medicines Australia's values are excellence, integrity, passion and collaboration. Leaders are required to model and staff demonstrate in the performance of their duties and interactions with each other, Members, patient groups and stakeholders. The requirement to comply with these ethical standards is communicated to all employees. Directors and employees are expected to always strive to enhance the reputation and performance of the company.



## Outcomes focus and performance improvement

### Board performance evaluation

The Board is committed to the ongoing development of both individual directors and the Board as a whole and undertakes an evaluation annually.

### Company performance evaluation

The Strategic Blueprint guides the company's priorities and the new Blueprint contains Member perception audits. The performance of the CEO is evaluated on an annual basis by the Chairperson, P&G Chair, N&R Chair with recommendations to the Board.

### Staff performance evaluation

Each staff member is employed under an employment contract that specifically calls for an annual performance agreement against which performance is measured by the staff member's manager.

## Fair and responsible remuneration

### Directors

Member directors are not remunerated. The remuneration payable to selected directors is assessed by the N&R Committee with recommendations to the Board.

### Executive and staff

The remuneration of all Executives is reviewed annually by the CEO in the context of performance outcomes with recommendations to the N&R committee. Executives make recommendations regarding staff remuneration within classification bands and moderate all staff assessed performance with recommendations to the CEO.

# Medicines Australia Team

Please note this is a list of staff who were employed during 2020-21.



**Elizabeth de Somer**  
Chief Executive Officer



**Anne-Maree Englund**  
Head of Strategic Policy  
Implementation



**Jamie Snashall**  
Head of Government Relations



**Jas Kaur**  
Head of Communications &  
Stakeholder Engagement



**Sophie Hibburd**  
Director Ethics & Compliance



**Tony Marks**  
Head of Operations & Company  
Secretary



**Anonnya Chowdhury**  
Policy Officer



**Brent Weston**  
Finance Officer



**Chrystianna Moran**  
Manager, Media and Communications



**David Newman**  
ICT Manager



**Gerry Rossiter**  
Executive Officer to the CEO and  
Chair



**Kaity Harris**  
Member Communications and Events  
Coordinator



**Mark Stewart**  
Manager, Data Research & Policy



**Peter Komocki**  
Manager, Industry and Regulatory  
Policy



**Petrina Keogh**  
Manager, Stakeholder Relations



**Vincent Tran**  
Manager, Access & Funding

# Medicines Australia Membership as at 30 June 2021

## Class 1



## Class 2



## Class 3



## Class 4



NEW

NEW

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# Glossary

ABPI – Association of the British Pharmaceutical Industry

CAWG – Consumer Advocacy Working Group

CCC – Continuity of Care Collaboration

CEG – Chief Executive Group

CIWG – Communications Issues Working Group

DoH – Department of Health

EFC – Efficient Funding of Chemotherapy

EFPIA – European Federation of Pharmaceutical Industries and Associations

GWG – Government Working Group

HEWG – Health Economics Working Group

HCO – Health Consumer Organisation

HTA – Health Technology Assessment

IFPMA – International Federation of Pharmaceutical Manufacturers & Associations

INGENA – Industry Genomics Network Alliance

MA – Medicines Australia

MAVIG – Medicines Australia Vaccination Industry Group

MTAA – Medical Technology Association of Australia

NACCHO – National Aboriginal Community Controlled Health Organisation

NMFG – New Medicines Funding Guarantee

NMP – National Medicines Policy

OECD – Organisation for Economic Co-operation and Development

PAIG – Pharma Australia Inclusion Group

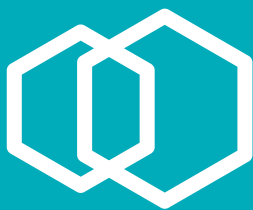
PBS – Pharmaceutical Benefits Scheme

PSWG – Policy Scanning Working Group

PVI – Patient Voice Initiative

RAWG – Regulatory Affairs Working Group

TGA – Therapeutic Goods Administration



Medicines  
**Australia**

Better health  
through research  
and innovation

[www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)