



Medicines
Australia

Better health
through research
and innovation

Annual Report 2021-22

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.





2021-22 snapshot

Key highlights for Medicines Australia and its members include:

Worked with our growing membership of 43 companies who represent the innovative medicines industry of Australia.

Set the scene for major reform by securing an independent review of Australia's Health Technology Assessment (HTA) system – the first of its kind in 30 years.

Minimised the risk of medicine supply issues by working across industry and the health sector to implement management programs where possible.

Secured commitment to develop a new Enhanced Consumer Engagement process which will incorporate consumer and patient perspectives earlier in the Pharmaceutical Benefits Advisory Committee (PBAC) process when assessing a new medicine for listing on the Pharmaceutical Benefits Scheme (PBS).



Promoted the medicine industry's priorities and negotiated on key issues with parliamentarians and Government.



Signed an historic five-year Strategic Agreement with the Australian Government, centered on earlier patient involvement in the availability of new medicines in Australia and delivering greater certainty for industry and Government.



Committed to deliver \$1.9 billion in savings for Government over the five years of the Strategic Agreement to be reinvested only in the PBS.

Secured the New Medicines Funding Guarantee that will provide dedicated funding, replenished each year, for the listing of new medicines on the PBS, expected to be at least \$2.8 billion over the four years to 2027.



Set up the framework for the first national Horizon Scanning Forum, to promote greater understanding of new medicines and help to assess the future opportunity for patients, and impacts on Government systems and processes.

Advocated throughout the National Medicines Policy (NMP) Review to strengthen its framework for patient access to affordable medicines, as well as support a viable vibrant medicines industry in Australia.

Provided expert advice to agencies such as the Australian Parliament, the Department of Health (including the TGA and PBAC), the Department of Prime Minister and Cabinet, the Department of Industry and Science, the Australian Commission on Safety and Quality in Health Care (ACSQHC), Treasury Ambassadors and international partners.




Generated video content and social media campaigns for the Strategic Agreement and Federal Election, generating more than 5,000 video views.

A record number of 1,520 students enrolled in one or more of the subjects in the Continuing Education Program demonstrating the value to our members. We awarded 24 individual star students for the 2020 and 2021 years.

Provided informative education sessions for over 300 people on the Medicines Australia Code of Conduct through online information sessions and delivered 11 bespoke educational seminars.


Worked with Federal and State Governments to improve Australia's clinical trials environment by creating a nationally harmonised system.

Generated over 800 pieces of media online, in print and radio – up 296% from the previous year. Fifty-five media releases generated an additional 10,397 page views to the Medicines Australia website.

Recommended a lower discount rate applied to medicines and vaccines to recognise the value of preventative treatments and cures – and speed up access to them.



Continued on our journey of organisational transformation and won two awards for workplace culture.

Partnered with Rare Cancers Australia to launch the new Medicines Access Portal (MAP) – an exciting initiative to better link clinicians and their cancer patients to special oncology access treatment programs.

Connected with hundreds of patient advocacy organisation representatives in our work to continue to build collaborative, working relationships with the Australian patient community.



Through it all, maintained our sense of purpose and drive to see an improvement in the time patients wait to access innovative medicines, vaccines and therapies.



Generated 23,507 engagements on LinkedIn and 1,499 engagements on Twitter. Continued to grow our social media platforms with 9,954 followers on LinkedIn and 2,938 followers on Twitter.

The Chair's Report

On behalf of the Medicines Australia Board, I am pleased to present the Annual Report for the 2020-21 financial year.

This year's Annual Report highlights some of Medicines Australia's achievements, challenges and how we worked to progress our objective - to set up Australia's health system for needed reform. We now look towards the future, which includes shaping policy and working together to ensure Australia remains a champion of innovation that supports fast access to innovative medicines, vaccines and treatments.

Within this context, there is no doubt the COVID-19 pandemic will have lasting consequences for our nation, our economy and our community. The innovative pharmaceutical industry continues to work together in delivering vaccines and treatments to Australia as we move into the next phase of the pandemic.

Access to these lifesaving and life-changing COVID-19 vaccines and treatments have been and will continue to be a key aspect of our nation's recovery and future wellbeing. The time is now to put into place crucial, overdue reforms to ensure Australians have rapid access to not only COVID-19 vaccines and treatments, but all innovative medicines.

Strategic Agreement secured

After months of extensive and complex negotiations, Medicines Australia and the Federal Government signed a new Strategic Agreement. This Agreement sets out a five-year, hardworking plan that centres on significant reforms to speed up access to new and innovative medicines, give patients a greater voice and provides business certainty for our essential industry.

The Agreement received bipartisan support, and this set us in good stead with the change of Government in May 2022 and opening of the 47th

Parliament. The Agreement must go hand-in-hand with action – by Government and industry – to ensure the intent becomes a reality and results in patients getting access to the most innovative medicines which address poorly met or unmet medical need.

Solidarity for bold change

The new Strategic Agreement came into effect from 1 July 2022 and in preparation for this date, Medicines Australia marshalled resources from many groups to prepare for its implementation. The Strategic Agreement contains several initiatives that will introduce bold reform into Australia's health system, including the much-anticipated HTA Review of policy and processes.

I have been impressed by the enormous amount of energy and effort from the membership who are invested in setting the scene for change. A substantial amount of well-considered work has been produced by the membership – which could not have been done without close collaboration with key stakeholders including clinicians, health experts, government officials and patient groups. This partnership approach and the relationships the membership has built, will be crucial in the future when making the case for courageous change.

Conclusion

The pharmaceutical industry has an outstanding track record of delivering real innovation to patients. I will continue in my role as Chair with a genuine commitment to work with all stakeholders to overcome hurdles to ensure Australians can access the life changing benefits that result from this critical, research-based, innovative industry.

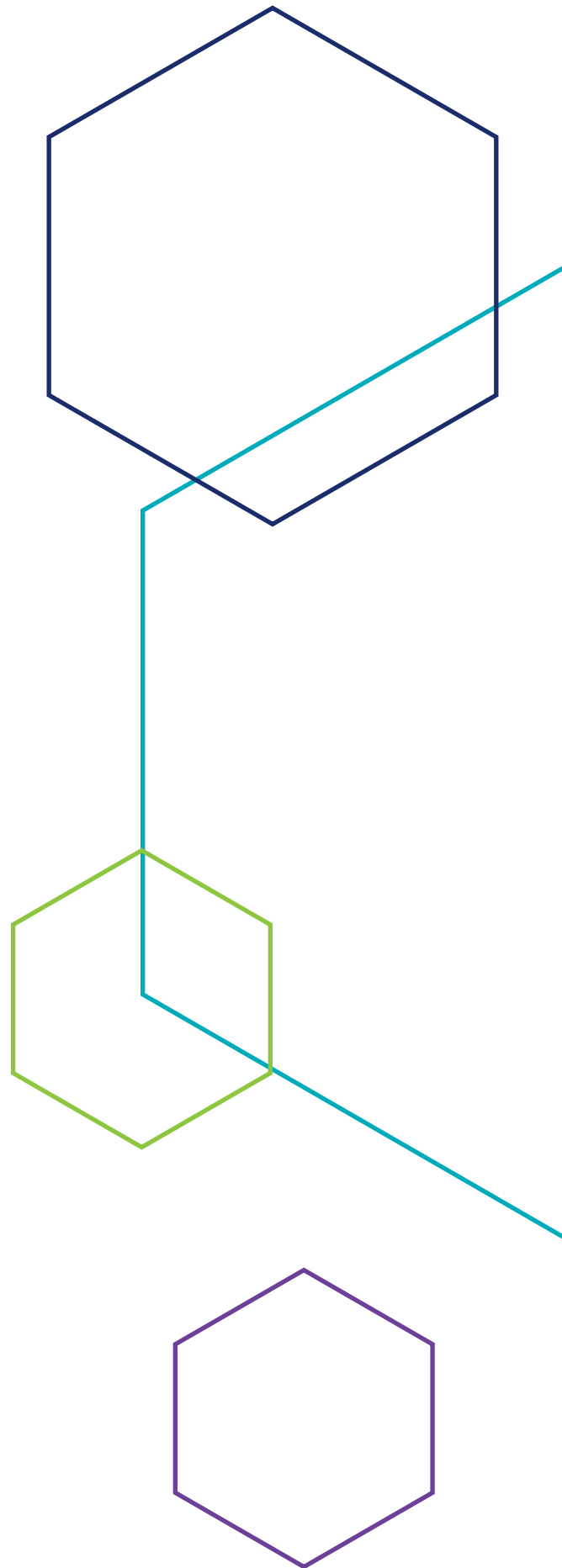
Thank you to our dedicated Medicines Australia staff under the sound leadership of CEO Elizabeth de Somer. Your tireless efforts and strong relationships with key stakeholders have ensured we can deliver -critical outcomes for innovation and for patients. I know the motivation for the team and the members is a dedication to achieving outcomes for patients.

I acknowledge and thank the Medicines Australia Board Directors – both current and outgoing – for their energy, efforts and insights over the past 12 months. I am grateful for their support and dedication that reflect Medicines Australia's mission of driving policy outcomes in partnership with government, health sector organisations and the community. The Board have contributed generously, and I thank them.



Dr Anna Lavelle
GAICD, FTSE

**Medicines Australia
Board Chair**



CEO's report

Medicines Australia's vision is to make a real difference to the health of Australians by ensuring they have access to world-class medicines when they need them. This year I have seen our organisation and our membership deliver on this vision through the most demanding times.

COVID-19

The continuation of the COVID-19 pandemic requires flexibility, resilience, and innovation. This year, as well as vaccines, we saw our industry deliver new antiviral treatments for people at higher risk of severe COVID-19. Rapid access to these new advances, coupled with a range of cutting-edge vaccines, has been crucial in protecting the vulnerable, easing the strain on our health system, reducing deaths and supporting the recovery of our economy. Our Members are dedicated to delivering innovative medicines, vaccines, and treatments not only for COVID-19 but other diseases and illnesses.

Australia has a high vaccination rate, but this privilege is not experienced by everyone across the world. Many poorer nations – including our closest neighbour, Papua New Guinea – still experience dangerously low vaccination rates against COVID-19. Medicines Australia worked with other health experts to call on the then-Prime Minister to make a Budget commitment to speed up the global vaccination effort. The Government pledged an additional \$85 million along with an extra 10 million vaccine doses through COVAX. This advocacy work was complemented by a social media campaign where Medicines Australia ran calling for renewed efforts in this area.

The effects of the pandemic continue to be felt across our manufacturing and supply chains. Throughout the year, Medicines Australia – in partnership with the Generic and Biosimilars Medicines Association (GBMA) – worked with the Australian Government to minimise and manage

critical medicine shortages. Shortages can occur for several reasons and Medicines Australia continue to work with prescribers, pharmacists, wholesalers and the other parts of the supply chain to minimise impacts on patients.

Another impact of the pandemic has been the concerning drop in regular health check-ups and pathology testing. Reporting shows Australians are still working to catch-up on these often-crucial medical appointments. Throughout the year, Medicines Australia continued its contribution to the Continuity of Care Collaboration (CCC) that uses social media campaigns to encourage people to re-engage with routine health checks.

Setting the scene for reform

The signing of a new five-year Strategic Agreement with the Government on 6 September 2021 was a significant milestone which, for the first time, introduced measures to enhance earlier engagement from patients in reimbursement decisions. The Agreement also aims to provide policy predictability and business certainty for the industry.

Savings of \$1.9 billion from late life-cycle statutory price-reductions will be reinvested in the PBS to make way for the latest innovative medicines, vaccines and treatments. This, plus the commitment of at least \$2.8 billion dollars from the New Medicines Funding Guarantee (NMFG) ensures that \$5 billion dollars is available to list innovative medicines on the PBS.

The Agreement heralds an opportunity to bring about bold change to improve health outcomes for all Australians. The first-of-its-kind Health Technology Assessment (HTA) Review aims to reduce the time it takes for Australians to access innovative medicines and ensure Australia is prepared to deliver next generation innovations just over the horizon. Efficiencies introduced during the pandemic should set the objectives for speeding up access to innovative vaccines, and treatments for all diseases.

Reform of Australia's HTA system is long overdue, and many stakeholders have been calling for change. We look forward to working with Government and other experts across the health landscape to make sure all voices are heard and considered. This and other complementary work, such as the review of the National Medicines Policy, will modernise our systems for today and into the future.

Collaborative connections

Setting up and nurturing strong, collaborative relationships with key stakeholders is crucial to our success. After the outcome of the Federal Election, Medicines Australia made it a priority to engage with the new Albanese Ministry and we continue to build important relationships, including with the new Minister for Health and Aged Care, the Hon. Mark Butler MP and his expanded team in the Health Portfolio. This early engagement could not have been possible without the strong relationship we built with Minister Butler, during his time in Opposition, and I am grateful for the opportunity to continue to work with him and his team.

A key initiative that saw impressive and effective stakeholder collaboration was during the review of the National Medicines Policy (NMP). It was the first time the NMP had been reviewed in over 20 years with feedback sought from patient groups, health bodies and industry. The Government hoped to complete the NMP Review before the Federal Election, but as the date approached, it became clear that stakeholders needed more time to provide considered feedback on the new draft.

Stakeholders presented one united voice calling on the then-Minister for Health to pause the NMP Review until after the Election. The then-Government heeded this call and extended the finalisation of the NMP to allow for proper debate and discussion. The NMP Review reanimated in August 2022 with a revised draft that better

reflected stakeholder feedback and allowed for targeted consultation to make sure all voices were heard and listened to.

One significant achievement this year has been the establishment of the Medicines Access Portal (MAP) – a joint project with Rare Cancers Australia. The MAP is a single, secure online portal for pharmaceutical companies to inform Australian medical practitioners of the existence of special access programs available to cancer patients. The MAP could not have been developed without the financial contributions from Medicines Australia's Oncology Industry Taskforce (OIT) and led by Rare Cancers Australia with guidance from the TGA. We look forward to officially launching this soon.

Looking forward

When I reflect on the near-15 years I have been part of this organisation, it is evident how much Medicines Australia, its membership and the health environment has evolved over that time. Going forward, in consultation with the Board, Medicines Australia is setting up strategies and management plans to reinvigorate and strengthen engagement with the membership and stakeholders, to empower and embolden real change that benefits all Australians.

I extend my appreciation to the Chair, Dr Anna Lavelle, and the Board for their efforts this year, particularly on the Strategic Agreement. I look forward to continuing to work collaboratively to ensure Medicines Australia's continued success.

The past year has provided a solid platform on which to build, but many challenges lie ahead. I am proud to lead a team of professional staff who have consistently shown resilience and adeptness across multiple cycles of adversity and opportunity. Each member of staff contributes to a thriving workplace, and it was pleasing to see this recognised with two awards for Best Workplace and Change Champions for 2022. The next 12 months will be another busy year, and I'm confident we have the right team in place to deliver outcomes for Members and to realise our vision to make a real difference to the health of Australians.



Elizabeth de Somer

Medicines Australia CEO

2021-22 Board of Directors

Thank you to the 2021-22 Board of Directors for your dedication and exemplary efforts. The Board who served between 1 July 2021 - 30 June 2022 includes:



Dr Anna Lavelle
Chair
Medicines Australia
Independent Director



Chris Stemple
Deputy Chair
Vice President and General
Manager Australia and New
Zealand, Abbvie Pty Ltd



Adam Roach
Vice President, Head of
Commercial, APAC, BeiGene
AUS Pty Ltd



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



Ashraf Al-Ouf
General Manager,
Bayer Australia Limited



Bruce Goodwin
Selected Board Director



James McDonnell
VP and General Manager,
Vifor Pharma Australia



Neil MacGregor
Managing Director,
Bristol-Myers Squibb Australia



Patrick Desbiens
Senior Vice President & General
Manager ANZ,
GSK Australia Pty Ltd



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



Stuart Knight
Managing Director,
Roche Products Limited

The following directors resigned during the year as they ceased their positions as member company corporate representatives (MDs) and took up other roles within their international group or industry.



Christi Kelsey
VP and General Manager,
GlaxoSmithKline Australia
Resigned effective
1 December 2021.



Kylie Bromley
Managing Director, Australia &
New Zealand, Biogen
Resigned effective 1 June 2022.



Leah Goodman
General Manager Biopharma /
Managing Director for Australia
& New Zealand,
Merck Healthcare Pty Ltd
Resigned effective
31 December 2021.



Liz Chatwin
Country President Australia &
New Zealand,
AstraZeneca Pty Ltd
Resigned effective
3 February 2022.



Michael Azrak
Vice President and Managing
Director, MSD Australia
& New Zealand
Resigned effective
18 October 2021.



United efforts to champion faster access to innovative medicines

New Strategic Agreement

On 6 September 2021, Medicines Australia secured a 5-year Strategic Agreement with the Federal Government, centred on earlier patient involvement and influence in the availability of new medicines in Australia.

The new Agreement sets out a hardworking, five-year plan that heralds a new era by securing stronger patient involvement in critical processes and ensuring Australia keeps pace with access to rapidly transforming medical advancements developed around the world.

In a major step forward, the Agreement ensures patients will become fundamental contributors to the first independent review of Australia's Health Technology Assessment (HTA) system in nearly 30 years. The HTA system evaluates new medicines and technologies before they are made available in Australia.

“The Strategic Agreement will establish an important platform where patients are a priority focus in creating faster access to lifesaving medicines and treatments.”

Dr Anna Lavelle, Chair of Medicines Australia.

The Agreement is underpinned by a shared commitment and responsibility to:

- deliver greater longer-term certainty for patients, industry and the government
- provide timely access to new medicines
- ensure patients have improved involvement in decision making for medicines access
- address the changing international environment
- ensure Australia is a global priority for the launch of new and innovative medical treatments
- modernise processes to keep pace with advancing science and innovative technologies
- continuously improve HTA processes, informed by the House of Representatives Inquiry into approval processes for new drugs and novel medical technologies, and the review of the National Medicines Policy.



Find out more about the Strategic Agreement by visiting www.medicinesaustralia.com.au/policy/strategic-agreement-2022-2027

Independent HTA Reform

A united approach to reform Australia's HTA system so that it evolves to keep pace with advancements in medical technologies and delivers faster access to new medicines for patients.

As part of Medicine Australia's five-year Strategic Agreement with the Federal Government there will be an independent review of Australia's HTA system – the first of its kind in nearly 30 years.

HTA reform will ensure Australia's HTA system evolves to keep pace with advancements in medical technologies and delivers faster access to new medicines for patients.

What is a HTA and why is it important?

- The purpose of HTA is to provide necessary information to understand the benefits and comparative value of health technologies and procedures. HTA assists and informs government funding decisions.
- HTA is commonly applied to pharmaceuticals including vaccines, diagnostic tests, medical devices and other public health interventions.
- The main bodies involved include the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC). Some state hospitals also do HTAs.
- The key questions HTA aims to answer for each new health technology in comparison to alternative interventions are:
 - Does it improve health outcomes for a population of patients?
 - Is it cost effective compared to the existing treatment it will replace?

The aims of independent HTA reform are:

1. Reduce time to access for Australian patients, so that they can access new health technologies as early as possible.
2. Increase the attractiveness of Australia as a first-launch country for new medicines.
3. Ensure Australia's assessment processes keep pace with rapid advances in science and health technology.

4. What needs to be improved?
5. Patients must be at the centre of the process, so that reimbursement decisions consider the impact and benefits of medicines from their perspective.
6. New evaluation and funding pathways for innovative medicines and treatments are needed to ensure the value of innovation is recognised, and to ensure efficient ways of assessing treatments and therapies that do not fit neatly into the existing system (such as cell and gene therapies and precision medicines).
7. Time to access must be improved. Currently PBAC assessments take on average 33-35 weeks after a medicine has been approved by the TGA. This is far below international standards and increases the waiting time for patients.

These improvements are consistent with a 2020 [House of Representatives Inquiry](#) which considered the approval processes for new drugs and novel medical technologies in Australia. The full list of recommendations can be found on the [Parliament of Australia website](#).

HTA reform timeline

HTA reform is due to start in July 2022¹ and conclude in June 2023, with recommendations to be implemented by July 2024.

Who will benefit

- Australians will continue to benefit from access to affordable breakthrough, innovative medicines as early as possible.
- The medicines industry will benefit from stability and certainty for investment in new medicines and assessment processes that remain world class and keep pace with rapid advances in medicine enabling them to be marketed and funded in Australia as they emerge.
- The Australian economy will benefit from improved health outcomes, and continued investment in research and innovation.

¹ Due to the Federal Election in 2022, the start of HTA reform has been delayed.

Enhanced Consumer Engagement

As part of the Strategic Agreement, a new Enhanced Consumer Engagement process will be developed that will incorporate consumer and patient perspectives earlier in the Pharmaceutical Benefits Advisory Committee (PBAC) process when assessing a new medicine for listing on the Pharmaceutical Benefits Scheme (PBS).

The ability to have earlier involvement in this process will allow consumers and patients to highlight the value of new medicines to them beyond the monetary cost. This new process will be co-designed with consumers, patients, clinicians, the medicines industry, and other health professionals in the first year of the agreement.

The new Enhanced Consumer Engagement process will reflect the issues arising from new technologies and medicine innovations, particularly those patients with high unmet needs. It will consider patient-defined needs at the start of the PBAC process, rather than towards the end, which will drive further efficiencies in access to medicines.

Horizon Scanning Forum

As part of the Strategic Agreement, an annual Horizon Scanning Forum, will be run by Medicines Australia from 2022 and will promote greater understanding and insight into the new medicines, vaccines and technologies coming through development pipelines to facilitate faster access for patients in Australia.

The forum will include consumer and patient representatives and their valuable perspectives to ensure their insights inform any recommendations.

The Medicines Australia Horizon Scanning Forum will feature presentations on major therapeutic advances as well as broader discussions about horizon scanning, how it is currently applied in Australia and abroad and how it can advance planning for these potentially disruptive therapies.

The event is scheduled towards the end of 2022 and aims to promote collaboration and further discussion of how to create a nationally coordinated horizon scanning system that can accelerate access to innovation.

Funding the PBS

Working together, the Australian Government's commitment in 2020 to the New Medicines Funding Guarantee provides at least \$2.8 billion dollars over the first four years, and savings of approximately \$1.9 billion from the new Strategic Agreement, will be fully re-invested in the PBS, ensuring at least \$5 billion of uncapped new investment is available for Australians to have the earliest possible access to innovative medicines.

Earlier access through conditional listings

Currently under the Therapeutic Goods Administration (TGA), certain promising new medicines are fast tracked, where the TGA assess that the benefit of early availability of the medicine outweighs the risk of waiting while additional data is collected. This is referred to as a "provisional registration". This means that some prescription medicines that provide a major therapeutic advancement for Australians could come to the market up to two years sooner than in the current framework.

Under the new Strategic Agreement, revised conditional listing and funding arrangements will deliver new medicines to patients even earlier and faster, building on the TGA's fast-track registration processes. The Government and Medicines Australia will work together on the arrangements during the term of the Agreement.

Discount Rate

A discount rate is a mechanism for valuing costs and benefits delivered in the short term versus the longer term. In Australia, medicines that deliver a benefit more quickly are valued more highly than those that deliver a benefit in the future. This is reflected by the discount rate, which accumulates over time: for every year the benefit is delayed, the discount rate is compounded, and the value of the medicine is reduced. Medicines with benefits that take a long time to demonstrate, such as childhood vaccines, are not valued as highly when it comes to reimbursement. The PBAC set the base discount rate at 5% in 1990 and it hasn't changed.

The Strategic Agreement between Medicines Australia and the Commonwealth Government commits to reviewing the PBAC base case discount rate against international health technology assessment (HTA) best practice.

Medicines Australia has made a recommendation to PBAC to lower its discount rate from 5% to 1.5%.

This recommendation is based on a review of international HTA discount rate practice, the impact of high discount rates on access to medicines, and government policies which stress the importance of long-term health, such as Australia's Long-Term National Health Plan. A lower discount rate of 1.5% will recognise the value of long-term future health benefits and:

- prove to the Australian people and the world that our population's future health is valued
- contribute to improving the speed of patient access to new and innovative therapies
- promote PBAC decision making equity
- align with the Commonwealth Government's preventative health agenda.

It is important the new discount rate is applied as soon as possible. The change could be affected by simple adjustment to the PBAC Guidelines.



Scan for more information about Australia's discount rate

Investment and Savings Measures

The Strategic Agreement provides savings measures for Government that will be reinvested in the PBS to make way for new, innovative medicines and treatments.

Some of these investment and savings measures include:

- The **New Medicines Funding Guarantee** which will provide dedicated funding, replenished each year, for the listing of new medicines on the PBS, expected to be at least \$2.8 billion over the first four years.
- \$1.9 billion in savings over the term of the Agreement to be reinvested in the PBS, via various measures such as catch-up price reductions.

Together the savings and the New Medicines Funding Guarantee will provide at least \$5 billion of uncapped investment in medicines, over the term of the Agreement.

National Medicines Policy Review

The National Medicines Policy (NMP) focuses on availability and use medicines, vaccines, and treatments for all Australians. The NMP provides a framework to ensure patient access to affordable medicines, as well as support for a viable medicines industry in Australia.

The NMP was first introduced in 1999 and the NMP Review, which commenced in July 2021, was the first time the NMP has been reviewed since its implementation. Over the past two decades, medicines have changed and so have patient and consumer expectations.

Two of the pillars of the NMP are that all Australians should have timely and affordable access to essential medicines, and that medicines should be prescribed and used appropriately.

Yet the reality is that these goals are not being met for all Australians – such as those in remote and regional communities, or Aboriginal and Torres Strait Islander people.

The commitment to the Review demonstrates the Australian Government's appetite to prepare our health system for the future.

The Morrison Government commenced a review of the NMP in July 2021 and final consultations were held in February 2022, with the plan to finalise the Review before the Federal Election in May 2022.

Medicines Australia and stakeholders – including a considerable number of patient groups – were concerned that the NMP Review was being rushed so it could be completed by the May Election and there had not been enough time for stakeholder feedback and consideration. Stakeholders came together with a united voice and were successful in advocating to have the NMP Review paused until after the Election.

A refreshed, future-focused NMP can provide the framework to enable the best outcomes for Australians living with serious diseases like rare cancers, now and into the future.

Following a united call from stakeholders, the additional consultation time will place the NMP Review on a productive, collaborative path forward.



Watch a short video about the NMP Review or you can read Medicines Australia's submission to the Review by visiting www.medicinesaustralia.com.au/policy/submissions.

Patients

Medicines Access Portal (MAP)

A new online pathway for accessing cancer treatments



Medicines Australia and Rare Cancers Australia worked together to establish the new Medicines Access Portal (MAP) – an exciting initiative to better link clinicians and their cancer patients to special oncology access treatment programs.

The MAP website – initially only available for cancer treatments – is a single, secure online portal for pharmaceutical companies to inform Australian medical practitioners of the existence of special access programs available to patients.

The MAP is a secure, single portal that will provide fast, equitable access to information for clinicians across the country.

The MAP went through extensive beta testing from our Members and clinicians and went live in April 2022.

MAP is a joint initiative between Medicines Australia and Rare Cancers Australia and has been developed in collaboration with the Medical Oncology Group of Australia (MOGA), the Haematology Society of Australia and New Zealand (HSANZ), the TGA, PBAC, industry representatives and clinicians.

Working together guide

The Working Together Guide (WTG) is a resource providing guidance and examples for building collaborative relationships and ways of working between individuals, health consumer organisations and research-based pharmaceutical companies. It also highlights how successful collaborations require significant effort, openness, trust and respect.

The WTG is co-designed with key stakeholders including representatives from Medicines Australia, Consumers Health Forum (CHF), industry and the patient community.

The current edition of the WTG was published in August 2015 (originally published in 2005 and then 2008). Since its creation, patient advocacy groups and member companies have used the framework as an effective tool to guide mutual understanding and effective engagements.

The health environment has significantly changed since the 2015 version was published. Modern advances in medicines and treatment, especially since the pandemic, has empowered consumers who are now more engaged than ever.

There has been a cultural shift towards increased consumer engagement in health technology assessment (HTA) and developments both globally and nationally relating to ethical practices in collaborations between the bio-pharmaceutical industry and patient organisations, notably the establishment of the Australian Ethical Healthcare Alliance (AEHA).

“Compassionate access or special access programs are often a last hope for cancer patients. Up until now, clinicians and patients have had to rely on general knowledge and word-of-mouth to find these programs which means the patient risks missing out. The MAP is a simple solution to connect clinicians to pharmaceutical companies who offer these types of special access programs,”

Rare Cancers Australia's CEO,
Richard Vines.

This year, Medicines Australia and CHF collaborated on a project to update the WTG and make it fit for purpose in the current health context. It is timely for the WTG to be updated to reflect the changing health environment and to provide contemporary case studies and learnings. The WTF refresh project is expected to be finalised by the start of 2023.

Patient briefings

Throughout the year, Medicines Australia has held several patient briefings to provide information about our key policy priorities and issues. These have been a successful initiative that provides a united industry voice on our objectives and continues to build a collaborative, working relationship with the Australian patient community.

Highlights include:

- In September 2021, Medicines Australia provided a briefing to the patient community about the newly announced Strategic Agreement. Over 80 patient groups joined the briefing with a significant focus on the independent HTA Reform and enhanced consumer engagement in PBAC.
- In September 2021, Medicines Australia engaged Parker & Partners to run an interactive briefing about the National Medicines Policy Review for patient advisory groups. The session discussed opportunities for patient groups and highlighted ways to effectively engage with the Review to drive genuine change.
- In June 2022, following the outcome of the Federal Election, Medicines Australia hosted a roundtable for patient groups on the new incoming Labor Government and provided an update on the Strategic Agreement. Government relations expert, Jody Fassina, from Insight Strategy, presented to patient groups about engaging with the new Government and spoke about the role of other parties such as the Greens and the rise of the independent Teal MPs.

Feedback for patient briefings such as these has been overwhelmingly positive from participants. Medicines Australia is dedicated to empowering and supporting patient communities where relevant and will continue to do so in the future.

Women in Life Sciences

The Australian Biotechnology Sector Snapshot 2022 by AusBiotech shows that although the sector has grown by 43% since 2019, women in the biotechnology industry are still underrepresented (35%). Overall, women represent 53% of the life sciences workforce.

Medicines Australia and industry are united in celebrating the great work of women in the life sciences sector and ultimately driving new benchmarks to support greater diversity and inclusion.

As part of this work, Medicines Australia co-hosted the NSW Women in Life Sciences Luncheon with AusBiotech, held in Sydney in March 2022. This year's theme was amplify her voice with a keynote from Nirelle Tolstoshev, Managing Director, Organon ANZ - the largest biopharmaceutical company dedicated to women's health globally, and a panel of exceptional leaders as they share their unique experiences and insights into amplifying voices.

The annual event brings stakeholders together to further galvanise the diversity that is required to build a successful sector.



Image: Panel members at the NSW Women in Life Sciences Luncheon. Panel members included Medicines Australia's Deputy Chair, Chris Stemple (second from left) and Medicines Australia's Board Member, Anne Harris (fourth from the left).

#DontWaitMate

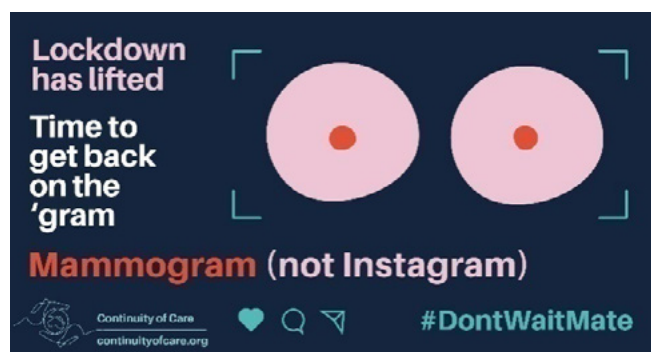
Medicines Australia is a founding member of the [CCC \(Continuity of Care Collaboration\)](#) – a collaboration of over 40 organisations of Peak Bodies, Industry and Healthcare Organisations coming together to stress the importance for people to continue with monitoring their health.

The #DontWaitMate campaign was started by the CCC in the height of COVID-19 encouraging people to continue with their health management during the COVID-19 pandemic and preparing for the future. The aim is to communicate the importance of ongoing health care and maintenance, and to not allow the ongoing pandemic to prevent this crucial healthcare activity.

Since its formation in March 2020, the CCC has conducted high impact public health messaging via earned media and social media, with the primary goal of encouraging Australians to return to healthcare.

As we move forward into the era of an endemic, the CCC continues to advocate for consumers, patients, and carers to 'get back on track' with their regular GP visits, vaccinations, preventative screening and pathology tests to prevent a furthering crisis of healthcare.

Medicines Australia continues to support the #DontWaitMate message including on social media and involvement in earned media stories.



Budget

Post-Budget Analysis – March 2022 (Coalition)

The post-budget breakfast briefing for Members in March 2022 included 90 Members and featured the expert insights from influential stakeholders: Glenys Beauchamp PSM, Nick Campbell, Jody Fassina, Richard Vines, and Medicines Australia Chair, Dr Anna Lavelle.

The briefing included analysis of the Budget announcements relating to health and innovation, including the NMFG, funding for onshore mRNA vaccine manufacturing capability in Australia, additional funding for the COVID-19 response, and the patent box proposal.

Following the Member briefing, Medicines Australia hosted our first Patient Group Budget Briefing which saw 26 patient groups attend in-person and many watched online. Conversations focused on budget implications for patient advocacy groups and how industry and the patient community can collaborate for better health outcomes.

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-face events in this brief window of the pandemic.

Medicines Australia also continued our partnership with AIPS to host 2 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 to discuss the Federal Health Budget.

138 attendees came to the Health Budget in Canberra with the then-Minister for Health, the Hon. Greg Hunt MP and 140 attended to Health Budget response in Sydney, with the then-Shadow Minister for Health, the Hon. Mark Butler MP.



Image: Just before he was due to retire from politics, CEO of Medicines Australia, Elizabeth de Somer, gave a vote of thanks to the Hon Greg Hunt MP for his service to Australia. L-R: Sue Martin, the Hon. Greg Hunt MP, Elizabeth de Somer and Biljana Naumovic.



Image: More than 140 attendees heard from the then-Opposition Minister for Health, the Hon. Mark Butler MP for a post-budget address.

L-R: Sue Martin, Biljana Naumovic, Professor Maria Kavallaris, the Hon. Mark Butler MP and Elizabeth de Somer.

Government engagement

Federal Election

Participating in public discussions around health

The Federal Election was announced on 10 April 2022 and held on 21 May 2022.

During the Election period, Medicines Australia proactively leveraged the momentum around the health narrative and drove key messages that aligned with Strategic Blueprint and Strategic Agreement work.

For the first time, Medicines Australia set up an Election Campaign Brains Trust², who met regularly during the Election period to monitor relevant issues, media and campaign promises.

A weekly report kept Members up to date on any new developments and the latest announcements. The Brains Trust also worked with Medicines Australia to decide where industry needed to respond publicly on issues.

In another first, Medicines Australia proactively engaged in public health debate and ran a six-week social media and media campaign, that coincided with the six-week Election period. The strategic communications campaign consisted of a series of videos from the CEO, pitches to the media and complementary digital assets used on social media.

The campaign resulted in over 190 pieces of earned media coverage, an estimated 786,000 online views and more than 8,000 engagements on social media. A highlight included the CEO featuring on a Federal Election health debate, hosted by News Corp.



Top Tweet earned 264 impressions

A health technology assessment (HTA) is conducted on a lot of medicines, vaccines and medical devices before they become available to Australians.

A review of our HTA system will streamline the process, meaning patients don't have to wait as long. [#MedicinesMatter #auspol](https://twitter.com/FfiWhzOwv3) pic.twitter.com/FfiWhzOwv3



² The Brains Trust was made up of Fiona Tigar (Biogen), Sarah Aldridge (Abbvie), Maxwell Zhao (MSD) and Jamie Snashall (Head of Government Relations) and Chrysianna Moran (Media and Communications) from Medicines Australia.

Election asks

As the Election drew nearer, Medicines Australia sought commitment from both the Labor and Liberal Parties for four policy priorities, should either side form government. Both major parties committed to these election asks.

The election asks included:

1. Deliver on the commitments made in the Strategic Agreement
2. Accept the recommendations from the House of Representatives Inquiry
3. Finalise the NMP Review and commit to its vision and purpose
4. Establish a high-level, Government-Industry, life sciences roundtable forum

To read Medicines Australia's election asks, and the responses from the Labor and Liberal parties, visit www.medicinesaustralia.com.au/media-events/toolkits/election-campaign-2022/.

In May 2022, Labor leader Anthony Albanese became the 31st Prime Minister of Australia and the 47th Parliament opened in Canberra on 26 July 2022. Since then, Medicines Australia has been actively engaged with Ministers and their staff, hosting briefings to discuss key issues and priorities for the medicines industry.



Image: CEO, Elizabeth de Somer and the Minister for Health and Aged Care, the Hon. Mark Butler MP.

ACCC Authorisation for potential supply chain shortages

In December 2021, the ACCC [confirmed](#) an extension of the authorisation to continue to manage and minimise risks that could disrupt medicine supply to hospitals and patients. The authorisation allows Medicines Australia and

the GBMA to continue to work with the TGA to identify potential supply issues related to COVID-19, that may require coordination with relevant sponsors.

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.

The ACCC authorisation for Medicines Australia and GBMA is due to expire on 30 September 2022 and both organisations are considering the need for the authorisation to continue.

“This ACCC authorisation allows us to continue to manage and minimise risks that could disrupt medicine supply to hospitals and patients,”

Elizabeth de Somer,
CEO of Medicines Australia.

Deepening partnership with broader Federal Government departments

This year, Medicines Australia has worked to deepen our engagement across government departments such as the Department of Foreign Affairs and Trade, Industry, Treasury, Finance, Prime Minister & Cabinet and Home Affairs on issues including domestic manufacturing, supply chains, trade agreements, intellectual property and workforce.

Medicines Australia has also developed a proposal, supported by the MTAA and AusBiotech, for a new high-level government-industry Life Sciences Forum. The forum was a key election ask and aims to improve coordination, consistency and collaboration between States, agencies, and industry. Importantly, the forum would also send a positive message to global companies that the Australian Government is committed to improving social, health and economic outcomes through a vibrant life sciences sector.

Industry – government forum for supply chain issues

Supply chain delays continued throughout 2021 and into 2022, exacerbated by COVID-19 lockdowns, lack availability of rapid antigen tests and the war in Ukraine.

Medicines Australia has continued to represent the pharmaceutical industry in a regular 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.

Medicines Australia has periodically surveyed members to establish potential supply chain concerns to raise at the roundtable. 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.

Repurposing medicines

Repurposing medicines is the process of identifying potential new therapeutic uses (or 'indications') for older medicines through new research and evidence. Recently, repurposing older medicines has been a prominent area of research for potential COVID-19 treatments.

The Department of Health ran a public consultation to better understand potential obstacles and/or incentives to repurposing of medicines that may influence a sponsor's decision to extend an indication for an existing medicine and to identify regulatory and reimbursement policy options.

Medicines Australia's Regulatory Affairs Working Group (RAWG) led the organisation's response and our submission led to an in-person workshop with Adjunct Professor John Skerritt and other key TGA staff, where industry representatives provided feedback on the TGA's proposed repurposing model.

The Department is now using this and other feedback to shape regulatory reforms and policy. Consultation with internal and external stakeholders continues and recommendations are expected to be presented to Government.

In addition, RAWG has worked collaboratively with the TGA throughout the year on a range of other issues such as inconsistencies in the prescription medicine registration process and the wider policy environment such as the National Medicines Policy (NMP) and the independent HTA Reform.



Clinical trials in Australia

Clinical trials are an essential step in the global efforts to discover and develop the new breakthrough medicines, vaccines and biotherapeutics. Despite having significant benefits for Australia, clinical trials are difficult to set up in Australia due to long start-up times, high costs, and fragmented systems between States and Territories.

Clinical trials drive better healthcare outcomes for Australian patients, makes a significant contribution to the Australian economy and has benefits the broader healthcare system and medical research industry. The Federal and State Governments are currently working to improve Australia's clinical trials environment by creating a nationally harmonised system known as the National One Stop Shop and National Clinical Trials Front Door.

This year, a major focus of the Research & Development Taskforce (RDTF) has been

improving governance and regulation frameworks for clinical trials in Australia. The RDTF is co-sponsored by Medicines Australia, AusBiotech and the Medical Technology Association of Australia (MTAA).

The RDTF is working closely with the Department of Health and the Australian Commission on Safety and Quality in Health Care (ACSQHC) to inform development of the One Stop Shop and Front Door. Elizabeth de Somer, CEO of Medicines Australia, sits on the Medical Research Advisory Group which oversees the initiatives.

The Commission has completed two phases of consultations to collect feedback from relevant stakeholders on the user requirements for the One Stop Shop and Front Door. The results from these consultations will present an opportunity to achieve a national, interconnected, rapid and streamlined pathway for attracting clinical trials to Australia.



Days of significance

Medicines Australia continued to support patient causes...

Kosi Challenge 2022

Since its launch in 2013, the Kosi Challenge event – run by Rare Cancers Australia – has raised much-needed awareness about the challenges rare cancer patients face.

Those participating in the Kosi Challenge, climb to the summit of Mount Kosciuszko, which is 2,228 metres above sea level.

Medicines Australia was proud to be part of the 2022 Kosi Challenge on its 10-year anniversary, where 100% of the funds raised go towards RCA's work of improving the lives and outcomes of Australians living with a rare or less common cancer.

The Medicines Australia Kosi team included Elizabeth de Somer, Greg de Somer, Anne-Maree Englund, Jan Frieding, Brent Weston, Chrystianna Moran, Emily Skillin, Michael Coffey and Deborah Monk. Together, our team raised \$4,940 for Rare Cancers Australia.



Image: Some of the Medicines Australia team at the Kosi Challenge.

L-R: Emily Skillin and Michael Coffey. Anne-Maree Englund and Jan Frieding.



Image: Some of the Medicines Australia team at the top of Mount Kosciuszko.

L-R: Jan Frieding, Anne-Maree Englund, Chrystianna Moran, Brent Weston and Elizabeth de Somer.

Stride for Stroke 2021

The Medicines Australia Stride4Stroke team included Jamie Snashall, Brent Weston, Chrystianna Moran, Sophie Hibburd, Kaity Harris, Andrew Donaldson, Elizabeth de Somer, Tony Marks, Eric Johnsson and David Newman. As a collective, we clocked up 11,645 moving minutes during October and raised \$2,311 for the Stroke Foundation Australia.



Image (L-R): Medicines Australia staff members Kaity Harris, Anne-Maree Englund, Tony Marks, Emily Skillen and Brent Weston contribute to Stride4Stroke and take a walk around Lake Burley Griffin in Canberra.



Image: Medicines Australia staff participated in International Women's Day. In 2022 the theme was 'Break the Bias' which focused on imagining a gender equal world without bias, stereotypes, and discrimination.

COVID-19

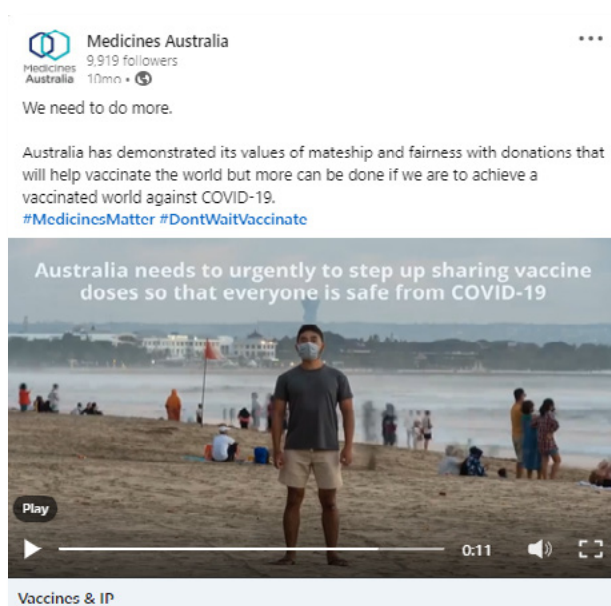
End COVID for all

At the start of 2022, with the emergence of the Omicron variant, it was clear that if the COVID-19 virus remained unchecked, more cases and more mutations would continue to occur. By February 2022, despite there being sufficient COVID-19 vaccines for every adult in every continent already produced, less than 6% of people in low-income countries were fully vaccinated.

Medicines Australia [joined forces](#) with over 70 of Australia's leading epidemiologists, GPs, global health, business, development and aid organisations to sign [an open letter](#) calling on the Prime Minister to make a Budget commitment to accelerate the global vaccination effort and prevent the emergence of another COVID variant of concern.

Following public advocacy (led by Micah Australia) the Australian Government [pledged](#) an additional \$85 million and at least 10 million COVID vaccine doses to the COVAX Advanced Market Commitment (AMC). During the March Federal Budget, an increase in aid to address global vaccine inequity [was announced](#) as well as the extension of key pandemic support packages for the Indo-Pacific.

This work complemented a successful social media campaign Medicines Australia ran over November and December 2021 that advocated for renewed efforts to improve the COVID-19 vaccination rates in low-income countries.



Promoting vaccines, science and industry efforts

Medicines Australia united with IFPMA in its global social media campaign, #TeamVaccines which aimed to build confidence in COVID-19 vaccines and positive perceptions of the medicines industry's efforts to develop and deliver these vaccines.

In 2022, this social campaign broadened its focus and built on positive momentum to create two separate campaigns; #AlwaysInnovating and #VaccinesForLife.

Medicines Australia supported #AlwaysInnovating campaign which showcased the full scope of the medicine industry's continued response to the COVID-19 pandemic, including treatments such as anti-virals.

The 2022 #VaccinesForLife campaign leveraged the positive perceptions and global uptake of the COVID-19 vaccine to build confidence in all vaccines.

All of these social media campaigns included a mix of films, case studies and personal stories from different experts across the international biopharmaceutical network.



International work

BIO International Convention

Medicines Australia CEO, Elizabeth de Somer, attended the world's leading biotech convention, BIO International Convention 2022 in San Diego in June 2022. Over 10,000+ international and domestic companies attended BIO 2022 from across the biotech industry.

Medicines Australia hosted a stand on the Australia Pavilion which was visited by stakeholders such as Australia's Ambassador to the USA, the Hon. Arthur Sinodinos AO.

Highlights included a roundtable discussion with the Ambassador to discuss Australian and USA collaborations in areas such as the post-pandemic response, clinical trials, manufacturing and digital health.

BIO ran over four days and was a welcome opportunity to network and connect with international and domestic government officials, health experts and leaders in biotech and medicine.



Image: CEO, Elizabeth de Somer and Australia's Ambassador to the USA, the Hon. Arthur Sinodinos AO, at BIO International Convention in San Diego.



Image: Some of the Australian delegation at the BIO International Convention in San Diego, June 2022.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

Medicines Australia is a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). IFPMA and its members promote sustainable solutions that encourage innovation and improve patients' health around the world.

Intellectual Property (IP) and innovation

Throughout the year, Medicines Australia supported several important initiatives from the IFPMA, including the global statement [opposing the TRIPS waiver](#) on intellectual property (IP) rights for COVID-19 vaccines and pointed to the negative impacts the waiver would have on innovation.

In June, the WTO Ministerial Conference in Geneva, adopted an IP waiver – known as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver – for COVID-19 vaccines.

It is now evident that IP is not a barrier to vaccine access. If anything, noise around a waiver is a distraction from the key issues. We must reduce the toll of the pandemic on lives and livelihoods, which will require global equitable access to vaccines and country readiness for vaccination.

Waiving IP does not deliver the sufficient know-how, ingredients, workforce, and infrastructure to manufacture COVID-19 vaccines, nor will it address the trade restrictions, regulatory inadequacies, or healthcare system deficiencies that are currently posing real barriers to vaccine equity.

Since the start of the pandemic, strong IP frameworks have supported pharmaceutical companies, scientists, researchers and manufacturers to create safe and effective COVID-19 vaccines in record time. The TRIPS waiver pulls apart the very system that supported the fastest development of vaccines and enabled unprecedented collaboration and partnerships.



Submissions

Medicines Australia has continued to work with member companies, patient organisations, the Australian Government and other sector stakeholders to improve healthcare benefits for Australians through timely access to medicines and strengthen the Australian economy. Over the course of the past year, Medicines Australia has made 19 submissions, many of which relate to the access of medicines, supply chain resilience, clinical trials, and regulatory affairs. An overview of the key submissions is provided below.

Key submissions made in 2021-22

[R&D Taskforce position paper: One Stop Shop and Clinical Trials Front Door](#)

December 2021

The R&D Taskforce (RDTF), under the auspice of Medicines Australia, AusBiotech, and the Medical Technology Association of Australia (MTAA), published a position paper that strongly supports the focus and investment in the One Stop Shop and National Clinical Trials Front Door. If implemented effectively, the initiatives would be a significant step forward in increasing Australia's global competitiveness in clinical trials.

[Medicines Australia's Submission to the Review of the National Medicines Policy \(NMP\)](#)

October 2021

The National Medicines Policy (NMP) aimed to provide Australians with equal and affordable access to medicines. Since it was first published over 20 years ago, patient and public expectations of our health system have risen, and there have been rapid developments in medicines and medical technologies. The Strategic Agreement between Medicines Australia and the Commonwealth offers important direction to review the current NMP and reflect on what has worked and what could be done better. Medicines Australia submitted a response to the review which started in 2021 which was subsequently postponed until after the Federal Election in May 2022.

[Medicines Australia submission to the Senate Standing Committee on Economics inquiry on the Australian manufacturing industry](#)

September 2021

Medicines Australia highlighted how Australian biopharmaceutical manufacturing is inextricably linked to and reliant on the wider R&D ecosystem, including R&D incentives, reimbursement processes, the regulatory landscape, a skilled workforce and a strong Intellectual Property (IP) regime.

[Medicines Australia response to the Treasury's consultation on the Patent Box policy design](#)

September 2021

Medicines Australia outlined how while we support the establishment of a patent box in Australia, the design proposed in the Treasury consultation paper is unlikely to be sufficient incentive for multinational pharmaceutical companies to redirect R&D activity and other IP commercialisation activities to Australia.

[Submission to PBAC Discount Rate Submission](#)

February 2022

The Discount Rate Review was one of the first aspects of the Strategic Agreement to be implemented. Medicines Australia's submission argued that the discount rate should be decreased from 5% to 1.5%, in line with international best practice.

[Medicines Australia Pre-Budget Submission 2022-2023](#)

January 2022

The Medicines Australia 2022-2023 Pre-Budget submission focused on need to commit to the previous year's budget commitments. These

include improving access to newly developed medicines through new medicines funding guarantee, the harmonisation of clinical trials across the federation, and to finalise the Strategic Agreement between Medicines Australia and the Commonwealth. We also highlighted how Government and industry need to work together to understand the implication of International Reference Pricing on patients in Australia and globally.

Submission on the National Medicines Traceability Framework

February 2022

Medicines Australia highlighted concerns about the National Medicines Traceability Framework (NMTF) to the Department of Health. While the aim of the NMFT is to improve patient safety by tracking medicines at various stages of the supply chain, Medicines Australia raised concerns regarding the implementation and funding of the proposed NMFT. Medicines Australia will continue to remain engaged with our Members and the Department as the NMTF progresses.

Submission on the Priority Review pathway for biologicals

March 2022

Medicines Australia's Regulatory Affairs Working Group (RAWG) submitted a response to the TGA proposal to implement a priority review option for products meeting the criteria for biologicals. The response emphasised that the innovative industry sector is highly supportive of a priority review option but highlighted several critical reforms needed to enable the framework for advanced therapies in Australia to be fit for purpose and internationally aligned.

Submission on the repurposing of medicines

March 2022

Medicines Australia responded to the TGA's consultation on the repurposing of medicines, which was a continuation of the consultations held by the TGA in 2021. In our submission, we re-emphasised our commitment to engage in good faith to consider potential policy options as part of the Strategic Agreement and outlined key commercial and IP concerns.

Submission on the Australian Cancer Plan 2023-2033

March 2022

Medicines Australia's Oncology Industry Taskforce (OIT) submitted a response to the consultation led by the Department of Health for the development of the new Australian Cancer Plan. The response focussed on the long-term universal goal, which is to reduce the incidence, morbidity and mortality of cancer. We emphasised the importance of timely access to cancer medicines, preventative strategies, patient-centred care, investment in clinical trials and optimisation of data collection and management.

Submission on Supporting economic resistance through regulatory responsiveness

June 2022

Medicines Australia's Regulatory Affairs Working Group (RAWG) submitted a response to a consultation led by the Department of the Prime Minister and Cabinet on using the lessons learnt from COVID-19 to design more responsive regulatory systems to lift regulator performance, capability, and culture. The response highlighted the importance of a deep understanding of industry operating models and global supply chains, putting patients first by investing in and boosting access to innovation, a connected digital health ecosystem, and a cultural change to drive collaboration.

Submission to NSW Health System Capabilities Consultation

August 2022

Medicines Australia highlighted how NSW is well-equipped to conduct clinical trials. However, the lack of harmonisation in the sector nationwide is a barrier for multinational sponsors to fully embrace Australia's potential as an innovation destination. We recommended that NSW strongly supports the implementation of the National One Stop Shop and Clinical Front Door.



Ethics and Compliance

Ethical exchange of vital information has a positive impact on Australian patients. Medicines Australia Members remain aligned with global standards of ethical conduct by demonstrating high levels of compliance with the [Medicines Australia's Code of Conduct](#). The industry continues to embrace the principles-based Code Edition 19, which provides a strong ethical decision-making framework and supports innovation in our industry, whilst balancing risk.

Ethics and Compliance activities in 2021-2022 focused on 'bedding down' the ongoing implementation of Edition 19 of the Code and supporting Members and the wider industry in interpreting and applying the Code to their work.

Throughout the year, multiple touchpoints were created to support Members in the application of the new principles-based Code. These included newly developed [Code resources](#) and Code engagement opportunities, alongside the [Continuing Education Program \(CEP\) Bridging Course](#).

This past year continued to work through the unpredictability of COVID-19, and more recently a tentative sense of certainty as our Members start to re-engage with face-to-face opportunities and events. With this optimistic trend, Medicines Australia resumed our monitoring activities of selected promotional material to support Member compliance with the Code.

The Code of Conduct Committee, the Appeals Committee and the Monitoring Committee have all been revitalised with new members, as have the Code pages of our website – all designed to ensuring industry's conduct is of the highest ethical standard, and that the environment we provide access to our innovative medicines is sustainable and fair.

“We take our compliance obligations extremely seriously and thank the Committee for its feedback and suggestions. These will be shared, reviewed and discussed within the business as part of our organisation's strive towards continuous improvement”

Comment from a Member in response to feedback received by the Monitoring Committee

Complaints, Appeals and Monitoring

Complaints Handling

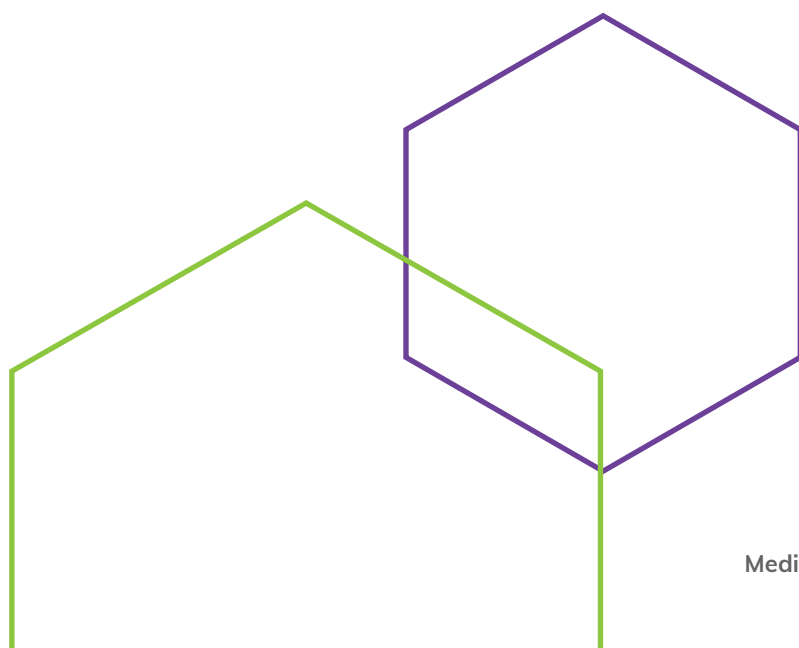
Medicines Australia received four complaints in 2021-2022. As shown in the table below, two of these complaints were received against a non-member company. In accordance with Section 16.3 of the Code, Medicines Australia invited the non-member to have the complaint adjudicated by the Code of Conduct Committee. In each instance, the non-member company declined that invitation. Medicines Australia has the right to refer the complaints to the Therapeutic Goods Administration (TGA) for its adjudication, however in each case, an alternative course was mediated.

Medicines Australia reports full details of any complaint that has been adjudicated by the Code Committee, including the rationale for decision, which is available on [our website](#) within 30 days of finalisation of the complaint. Our website provides complaint details dating from 2018, in the spirit of industry-wide learning and improvement.

Whilst the number of complaints from year-to-year has remained consistent, this year the Code Committee only heard one of the four complaints – a significant reduction from previous years. The reasons for this could be a conflation of factors; maturity of our industry, a high-performing and compliant membership base, or possibly a careful and conservative approach to activities where Members impose an even stricter standard on themselves that the Code requires. What we know is that multiple complaints are being debated across our membership through intensive inter-company dialogue – a pre-requisite for complaints being accelerated to the Code Committee.

Intercompany dialogue is a vital component of the complaint process, with meaningful dialogue and a willingness from both companies to consider each other's concerns and with the intention of resolution, as articulated in a revised [Guidelines for Industry-generated Complaints](#).

Complaint	Subject Company	Complainant	Outcome
1163	Member Company	Member Company	No breach
1164	Non-member Company	Member Company	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Returned to Inter-Company Dialogue.
1165	Member Company	Non-member Company	Complaint did not proceed due to lack of evidence of involvement by member company.
1166	Non-member Company	Member Company	Non-Member declined to have the complaint adjudicated by the Code of Conduct Committee. Subject material withdrawn from use.



Monitoring Compliance

The [Monitoring Committee](#) is a Member-benefit that proactively monitors the conduct and compliance of our Members, providing an opportunity for reflection, new perspectives and improvements.

After having paused its monitoring in recent years due to the disruptions of COVID-19, the Monitoring Committee was reconvened with new independent members contracted for a 3-year term and a meeting schedule. Kicking off its annual monitoring activities in March 2022, a selected cohort of Members provided policies, procedures and promotional material depending on the activity and in accordance with the Code at Section 16.7.

Under Code Edition 19, companies may be asked to participate in monitoring requests on no more than three occasions within a calendar year, representing a streamlined improvement from previous years and striking a favourable balance between resourcing pressures whilst maintaining integrity and accountability.

At the end of every calendar year, Medicines Australia reports on the outcomes of reviews conducted by the Monitoring Committee [on our website](#), including previous years. An interim snapshot of activities in 2022 is below:

Activity	Date	Members submitting material	Outcomes	Resource generated from the activity
Review of policies/procedures relating to medical representative training (CEP)	March 2022	10	70% satisfactory, 30% were initially required to provide further clarification/information. On subsequent review, all were then satisfactory. Constructive feedback provided to most.	Good Practice Guide: Quality Inclusions for Staff Education Policies
Review of policies/procedures relating to hospitality spend at educational events	May 2022	9	100% satisfactory. No further action required from any members. Constructive feedback provided to most.	Good Practice Guide: Quality Inclusions for Hospitality Policies



Transparency Reporting

Medicines Australia strongly advocates for transparency, recognising it as a cornerstone in fostering trust between patients, healthcare professionals, industry and Government. Through the Code, Members commit to transparency in their interactions with healthcare professionals and other stakeholders.

Transfers of Value to Healthcare Professionals

All Members report payments and transfers of value made to healthcare professionals, which are hosted in a searchable database on www.disclosureaustralia.com.au.

During this year we published in August 2021 and February 2022, representing our 11th and 12th reporting rounds since we started with transparency measures in 2015. The public remain interested in this data, with 50,645 searches undertaken since the launch of the searchable database in 2019, and 17,740 of those being during this financial year.

Third Party Meeting Sponsorship Reports

Biopharmaceutical companies support enhancing medical knowledge and the quality use of medicines by sponsoring independently organised educational activities, primarily offered by colleges, universities and other recognised healthcare professional organisations. Sponsorship is provided by companies to support running the event, under the requirements of the Code. Medicines Australia continues to publish sponsorships by our Members, which are available on [our website](#).

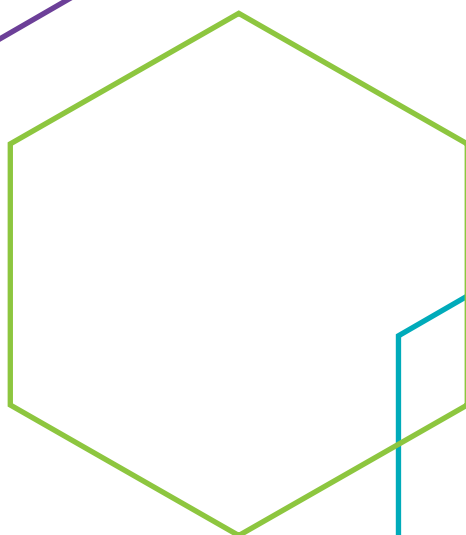
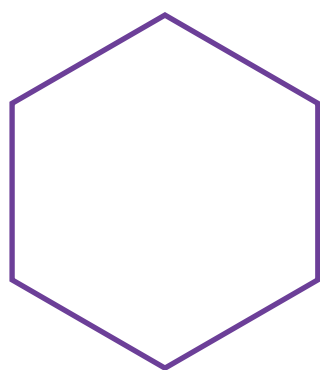
On 31 October 2021, 26 member companies published reports for the period November 2020 – April 2021, which reported on 721 events delivering 4,934 hours of education to 148,810 healthcare professionals in that six-month period.

On 30 April 2022, 27 member companies published reports for the period May 2021 – October 2021, which reported on 1,127 events delivering 8,707 hours of education to 285,135 healthcare professionals in that six-month period.

The impact of COVID-19 remains evident in the reduced number of events sponsored in the financial year as many events were cancelled or transitioned to virtual platforms. This is also reflected in reduced payments being made to healthcare professionals for similar reasons.

Health Consumer Organisation Support Reports

In June 2022, Medicines Australia published the ninth annual reports of Members' financial support for Health Consumer Organisations (HCO). Members' supported 116 different HCOs across Australia in calendar year 2021, ranging from national consumer organisations to small local groups, relating to 289 different projects or events to the total value of \$7,323,601 of support.



Ethical Engagement and Education Activities

The success of our industry's self-regulation relies on a high level of awareness of the Code, and our Members having the confidence to understand and apply the Code in practice. Medicines Australia regularly engages in a wide variety of activities to promote understanding of the Code and to encourage compliance, some of which are available exclusively to Members.

Over this financial year, these include:



Our stakeholders include biopharmaceutical companies (members and non-members), 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.

Continuing Education Program

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

In 2021-2022, 1,520 individual students enrolled in one or more Programs offered under the CEP which demonstrates the real value of the CEP to our Members and others.

Of this total, nearly 700 enrolled in Program 1: Code of Conduct, which remains consistently our highest performing program, and 249 company personnel undertook the updated Bridging Course which helped transition knowledge from Code Edition 18 through to Edition 19. These figures show the high level of interest across industry in ensuring that their personnel and the external agencies they engage are well informed about the new Code requirements. Aside from enrolment statistics, the positive feedback received from students remains outstanding.

Whilst not part of the CEP, UTAS launched a new "Foundations of Vaccine Immunology" course in January, providing an opportunity to gain a comprehensive understanding of vaccines at a time when this subject is a critical focus for the pharmaceutical industry and community health.

"The Medicines Australia Continuing Education Program has provided me with a solid foundation in the pharmaceutical industry, underpinning my interactions with healthcare professionals to further support the quality use of medicines which benefits Australian patients."

Louise Welsh,
GSK Australia, CEP Achievement Award 2020.



CEP Awards

Every year we 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, with detailed information [on our website](#). Of these, there are 10 CEP Achievement Awards, the Code of Conduct Award awarded to the highest achiever in Program 1, and additionally, the University of Tasmania Prize for Excellence per Semester.

During this year we hosted two celebrations;

- The CEP Awards for 2020 (initially delayed due to COVID-19 challenges) were [announced](#) in December 2021.



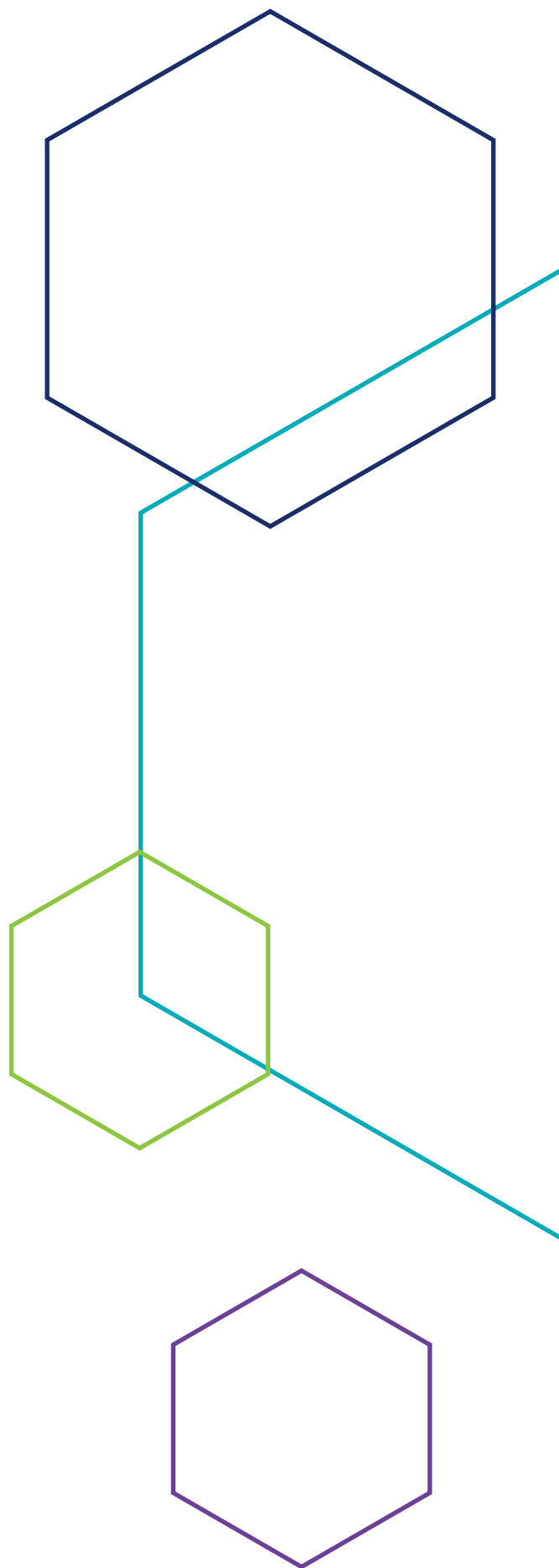
The CEP Awards for 2021 were announced in May 2022 – watch a 2-minute video highlighting their personal reflections and achievements.

Governance

The Code is owned by Members, for Members, and Medicines Australia administers the Code on behalf of our Members. The effective and equitable administration of the Code of Conduct relies on the commitment, skill and professionalism of the Medicines Australia staff and Members of the Code, Appeals and Monitoring Committees, including valuable contributions of our Members. We are very grateful for their continued commitment to assisting Medicines Australia to ensure that industry self-regulation through a world class industry Code of Conduct remains strong and effective. Short biographies of all permanent members of the [Code and Appeals Committee](#) and the [Monitoring Committee](#), as well as a [schedule of meeting dates](#), is available on the Medicines Australia website.

Medicines Australia does not work in isolation. Medicines Australia recognises its place as a global leader in ethical behaviour in the innovative medicines industry and are proud signatories to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice and ensure its principles are reflected within our Code.

Our Code is internationally recognised for its effectiveness and success in self-regulation. The Code supports regulatory framework and is consistent with the Therapeutic Goods Act. Being a Medicines Australia member signals a company's commitment to behaving ethically and working transparently; walking the talk and being part of a community committed to the highest of ethical standards.





Medicines Australia in the community

Corporate Social Responsibility Initiatives

As part of Medicines Australia's Corporate Social Responsibility commitment, Medicines Australia continues to support the Shalom Gamarada Indigenous Residential Scholarship Program. The Program 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 \$521,600 in funding for Shalom Gamarada.

The two students we sponsor are Jorge Hormovas (pictured left), a fifth-year medical student, due to graduate at the end of 2023, and Anne Dillon (pictured right) who is a second-year medical student. Their student profiles can be found on our [website](#).

Patient Voice Initiative

Medicines Australia continues to partner with Patient Voice Initiative (PVI).

The Patient Voice Initiative is a Patient-Chair led multi-stakeholder initiative which works to promote and support valuing the patient voice in health policy, especially health technology assessment (HTA).

PVI have improved the patient voice in HTA in Australia through Training and Guidance, Communication and Evidence Generation.



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

Establishment of a People & Culture committee

Staff members representing a cross section of the organisation were nominated by their peers to form the People and Culture committee, sponsored by the Head of Operations.

The committee members are encouraged to discuss the workplace and workplace matters with staff and vice versa. The committee prepared a People Plan following the 2021 staff survey, to respond to areas identified for improvement.

The People Plan lays out a roadmap of actions to ensure Medicines Australia provides an outstanding work experience for its staff and to attract, retain, develop and value staff, within any reasonable constraints. Medicines Australia is committed to supporting staff development and career growth; building on the capability, leadership, skills and motivation of our staff in order for them to deliver on the strategic objectives of the organisation while creating a rewarding and engaging place to work.

The success of Medicines Australia relies on our staff including a combination of the efforts, talent, commitment, and teamwork. Our employees are our most valuable resource, and we genuinely encourage the innovative and distinctive ideas that come with staff contribution. We encourage staff to share their ideas, thoughts and wisdom.

The deliverables in the first year, including a contemporary flexible working policy, transparent position classifications and work level standards, enhanced annual planning and development agreements and performance reviews, staff coaching, a 360-degree feedback instrument and a range of other initiatives were highly successful, as demonstrated by the significant improvement in the 2022 staff survey leading to two workplace culture awards (see below).

Streamlining processes and reviewing systems

A new cloud-based Financial Management Information System was introduced on 1 July 2021 and has provided efficiencies in processing times and superior budgeting and reporting capabilities providing greater clarity to managers.

The Board approved more granular delegations to empower staff to control and manage budgets under their control and renewed processes were introduced for staff for travel and office purchases, relieving staff of administrative tasks and allowing them to focus more on key deliverables.

The Members Portal continued to be refined providing quick and directed communications with Members.

The longstanding working group structure and composition was reviewed which saw the cessation of some groups and the standing up of action-oriented, specific-issue driven 'action groups', to drive strategic agreement implementation.

As a knowledge organisation, secure, efficient and effective access to information is critical and to this end the development of a more concise information architecture and move to SharePoint in the cloud commenced and will be completed during 2022/23.

A review of the industry landscape was commenced and the Board, with selected Members, considered the positioning of Medicines Australia within that landscape and whether the Constitution allows for effective coverage of the industry now and in the future.

The Member classification and constitutional review continues into 2022/23 and will also consider representational issues such as Board director diversity, and 'reserved' seats on the Board – such as for small/medium members as well as the member fee structure. The membership

will be consulted widely should it be considered any changes are necessary to the Constitution or current practices.

Workplace culture awards

Medicines Australia was awarded Best Workplace and Change Champions for 2022 by Voice Project for the small-medium category.

Voice Project is engaged by Medicines Australia to measure staff culture and performance each year.

The survey was completed by 100% of staff. The survey results showed high levels of staff engagement and confidence in the organisation and a sustainable level of wellbeing. Average staff satisfaction across the survey questions was exceptional at 80.5%, leading to the two awards.

Perception survey

During the year, Medicines Australia engaged an independent assessor, NEXUS APAC Group, conducted a perception survey of our stakeholders to establish the current state of perceptions, performance and engagement efficacy.

The results will guide Medicines Australia's policy, communications and engagement strategies and establish additional benchmarks for monitoring over time.

Respondents identified several things that Medicines Australia does well, such as represent its Members' interests, government engagement and leadership. Of what could be improved, respondents identified social policy, economic benefit and stakeholder collaboration.



Image: Some of Medicines Australia staff celebrate the Best Workplace and Change Champions for 2022 Awards.

Back row (L-R): Kaity Harris, Emily Skillin, Liz de Somer and Eric Johnsson

Front row (L-R): Hoor Ahktar, Tony Marks, Anne-Maree Englund, Brent Weston, Sophie Seck and Josh Vines

Corporate Governance

Advisory Council

The Advisory Council supports the Medicine Australia Board's role in shaping strategy and providing advice on trends and issues likely to impact industry in the medium to long term.

Members of the Advisory Council participating during the year were:

Anna Lavelle (Chair)	Chair of the Board, Medicines Australia
Belinda Wood	Senior Director Government Affairs ANZ, Gilead Sciences
David Norton	Formerly Chair, Global Pharmaceuticals, Johnson & Johnson
Glenys Beauchamp	Formerly Secretary, Departments of Health and Industry
Greg Allen	Finance Manager, Epworth Freemasons Hospital
Jane Hill	CEO, Ovarian Cancer Australia
Kelly Constable	CEO, AULUS Partners
Leigh Farrell	Executive Advisor, Certara C-Suite
Richard Vines	Chairman, Rare Cancers Australia

Appointment of directors to the Board

Medicines Australia's constitution prescribes the composition of the Board. The number of directors must be between five and 13. Between two and 10 directors (from classes 1,2 or 3 and including at least two from small to medium sized entities) are elected by Members and between one and three directors may be appointed by the Board (including at least one independent director). 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, Nominations and Remuneration 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 two Directors. The committees meet four times 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 the annual budget on the advice of the Finance, Risk and Audit Committee, which monitors financial performance at each meeting and presents the operating position to the Board. The management of the investment portfolio is governed within a specific investment policy by an external specialist provider.

Risk management

A focus on 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, action and working groups, the Members Portal, CEO briefings and MD strategic workshops. The Board encourages full participation of Members at the AGM.

Values

Medicines Australia's values are excellence, integrity, passion and collaboration. Leaders are required to model these values and staff to demonstrate them in the performance of their duties and interactions with each other, Members, patient groups and stakeholders.

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 cascades down to annual scorecards which set out KPIs against which the Board assesses the Executive and its performance, in conjunction with member feedback and independently run Board performance. The performance of the CEO is evaluated annually by the Board Chair and the Chair of the Performance, Nomination and Remuneration Committee, with recommendations made to the Board.

Staff performance evaluation

Each year all staff prepare a planning and development agreement with their manager setting out individual priorities and goals aligned to the corporate plan and strategic blueprint. 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.

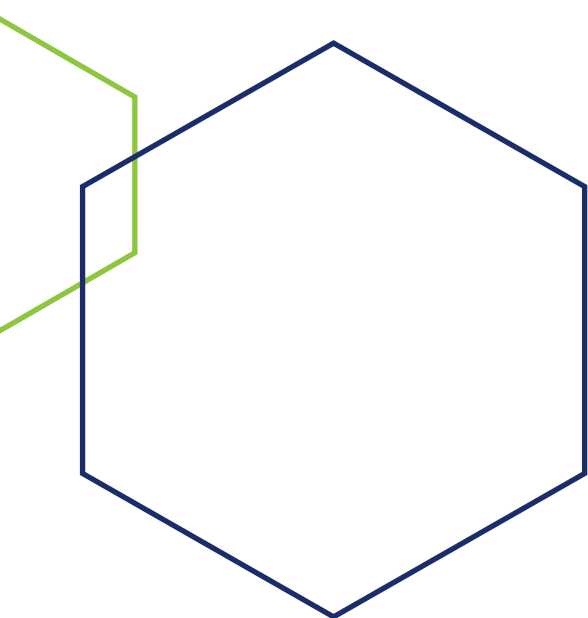
Fair and responsible remuneration

Directors

Member directors are not remunerated. The remuneration paid to Board appointed independent directors (including the Chair) is assessed against market indicators by the Performance, Nominations and Remuneration committee and approved by the Board.

Executive and staff

The remuneration and performance bonuses of all Executives is reviewed annually by the CEO in the context of performance outcomes with recommendations to the Performance, Nominations and Remuneration committee. Executives make recommendations regarding staff remuneration within classification bands and moderate all staff assessed performance with recommendations to the CEO.



Working with our Members

Medicines Australia acknowledges the incredible contribution our Members make to furthering the collective position of the Australian medicines industry on important national and international issues. The achievements in this Annual report could not have been made without your commitment and contributions. Your support is remarkable.

Action groups

The Strategic Agreement sets the scene for bold reform and new initiatives that will help support faster access to the latest, innovative medicines, vaccines and therapies.

To support the implementation of the Strategic Agreement, eight agile, action groups were set up to map out areas that needed immediate focus, such as the HTA Review and the Horizon Scanning Forum.

The eight Action Groups were deliberately set up to be flexible in design and assigned work packages that could be completed during short, 5-week sprints.

Medicines Australia was overwhelmed with interest and enthusiasm from the membership and are grateful for the significant amount of work which was completed in a short amount of time.

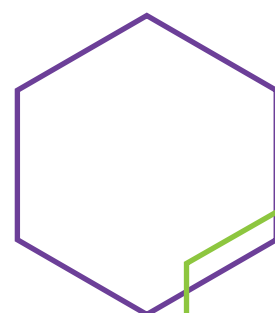
The eight Action Groups are outlined below:

Horizon Scanning Forum

Working on the Horizon Scanning Forum event, which is a deliverable in the new Strategic Agreement.

Members of the Horizon Scanning Action Group as at 30 June 2022:

Lee Davelaar (co-chair)	Pfizer
Christine Pollicino (co-chair)	Roche
Eric Johnsson (co-chair)	Medicines Australia
Greg Cook (SASC sponsor)	Bristol Myers Squibb
Ayaat Mahmoud (Biointelect project manager)	Biointelect
Dani Miroso	Takeda
David Thomson	Amgen
Jason Mak	HTAnalysts
Jo Atkins	Commercial Eyes
Kerrie McDonald	AstraZeneca
Linda Ponkshe	Janssen
Louise Larkin	Lilly
Pallavi Ghosh	Novartis



Consumer Engagement

Working on the Enhanced Consumer Engagement Process, which is a deliverable in the new Strategic Agreement.

Members of the Consumer Engagement Action Group as at 30 June 2022:

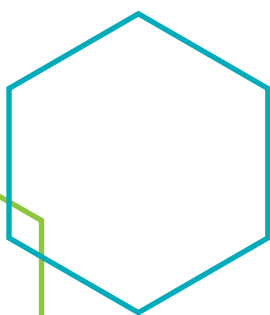
Todd Stephenson (co-chair)	Janssen
Petrina Keogh (co-chair)	Medicines Australia
Julie Ellis (SASC sponsor)	Menarini
Ayaat Mahmoud (Biointelect project manager)	Biointelect
Cathy Sertori	AstraZeneca
Eduardo Pimenta	Bayer
Fiona Tigar	Biogen
Hayley Anderson	Bristol Myers Squibb
Kate Applegarth	MSD
Kate Richards	AbbVie
Libby Noble	Alexion
Peta James	GlaxoSmithKline
Peter Murphy	Novartis

Advocacy

Supporting the stakeholder engagement process for the HTA Review with mapping, messaging and feedback.

Members of the Advocacy Action Group as at 30 June 2022:

Andrew Thirlwell (co-chair)	Pfizer
Jamie Snashall (co-chair)	Medicines Australia
Nicola Richards (SASC sponsor)	MSD
Camille Shanahan (Biointelect project manager)	Biointelect
Ben Gommers	MSD
Byron Muntz	Novartis
Emma St-Clair Pearce	Biogen
Irene Deltetto	HTAnalysts
Karyn McIntosh	Sanofi
Lisa Julian	Lilly
Luke Fitzgerald	GlaxoSmithKline
Meriana Baxter	Amgen



Process Improvement

Developing the process improvements from the current and new Strategic Agreements and measuring success.

Members of the Process Improvement Action Group as at 30 June 2022:

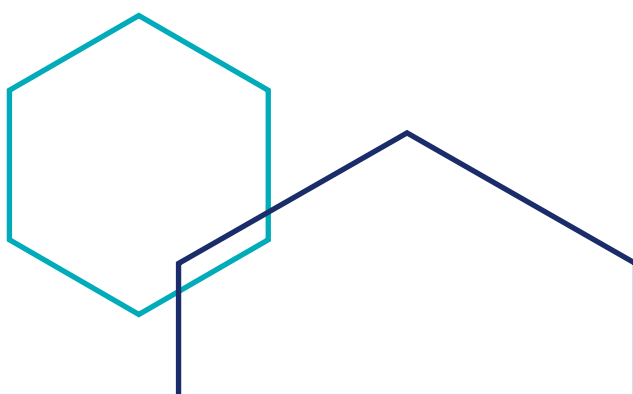
Julie Lewis (co-chair)	AbbVie
Emily Skillen (co-chair)	Medicines Australia
Vanessa Stevens (SASC sponsor)	Vifor Pharma
Ayaat Mahmoud (Biointelect project manager)	Biointelect
Angela Maclean	Amgen
Daniel Thut	Bayer
Dylan Jones	MSD
Kieran Schneeman	AstraZeneca
Margaret Jorgensen	HTAnalysts
Sara Trafford-Jones	Alexion
Shabnam Valiya	Novartis
Simon Barnfather	GlaxoSmithKline
Vanessa Xavier	Sanofi

HTA Technical

Developing positions on the full range of HTA technical matters.

Members of HTA Technical Action Group as at 30 June 2022:

Rachael Anderson (co-chair)	AstraZeneca
Sara Pantzer (co-chair)	Medicines Australia
Colmon Taylor (SASC sponsor)	HTAnalysts
Camille Shanahan (Biointelect project manager)	Biointelect
Brandon Jones	Janssen
Bronwyn Fitzgerald	Alexion
Douglas Miller	Commercial Eyes
Jing Bo Li	MSD
Lucas Tocchini	Biogen
Natalie Betts	Roche
Peter Germanos	Boehringer Ingelheim
Peter Moore	Ipsen
Scott Brydon	Vifor Pharma



System Reform

Mapping the ideal reimbursement process

Members of HTA Technical Action Group as at 30 June 2022:

Gabby Mears (co-chair)	AbbVie
Sara Pantzer (co-chair)	Medicines Australia
Alex Best (SASC sponsor)	Janssen
Camille Shanahan (Biointelect project manager)	Biointelect
Ailsa Surman	Amgen
Claire Parken	Roche
David Hacking	Bayer
James McAdam	Bristol Myers Squibb
Kate Scott-Murphy	Novartis
Katja Berg	AstraZeneca
Penny Lovell	Alexion
Sophie Schulz	Takeda
Valda Struwig	Pfizer

Decision-Making Remit

Getting clarity on the decision-making remit of the PBAC

Members of Decision-Making Remit Action Group as at 30 June 2022:

Jackson Busse (co-chair)	MSD
Sophie Hibburd (co-chair)	Medicines Australia
Ian Black (SASC sponsor)	Roche
Ayaat Mahmoud (Biointelect project manager)	Biointelect
Alasdair Godfrey	HTAnalysts
Alice Morgan	AstraZeneca
Darin Kottege	Janssen
Josh Bowen	Roche
Kathy Cargill	AbbVie
Melinda Flowers	Amgen
Vincent Tran	Novartis



Evidence-Based Narrative

Developing Industry's value story and the case for change, with supporting proof points.

Members of Evidence-Based Narrative Action Group as at 30 June 2022:

Stuart Englund (co-chair)	Janssen
Chrystianna Moran (co-chair)	Medicines Australia
David Pullar (SASC sponsor)	GlaxoSmithKline
Camille Shanahan (Biointelect project manager)	Biointelect
Alison Miles	HTAnalysts
Camilla Chan	Biogen
Duncan Purvis	Organon
Gary Maclachlan	Takeda
Mark Stewart	Roche
Monica Saba	Bayer
Rebecca Stratford	AstraZeneca
Sara Aldridge	AbbVie
Stephen Richardson	Sanofi

Strategic Agreement Steering Committee (SASC)

Strategic Agreement Steering Committee (SASC) was formed in 2021 to assist Medicines Australia to deliver the Strategic Agreement in accordance with the Board strategic priorities, in particular through advising and monitoring the work plans of the Action Groups.

Anne-Maree Englund (Co-Chair)	Medicines Australia
Ian Noble (Co-Chair)	Amgen
Alex Best	Janssen
Alice Morgan	AstraZeneca
Colman Taylor	HTAnalysts
David Pullar	GlaxoSmithKline
Gabbie Reppen	Lilly
Greg Cook	Bristol Myers Squibb
Ian Black	Roche
Jodie Thomas	Novo Nordisk
Julie Ellis	Menarini
Louise Graham	Pfizer
Megan Bohensky	BeiGene
Nicola Richards	MSD
Penny George	Sanofi
Sarah Bridge	Bayer
Vanessa Stevens	Vifor Pharma
Wade McMonagle	AbbVie

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 any 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:

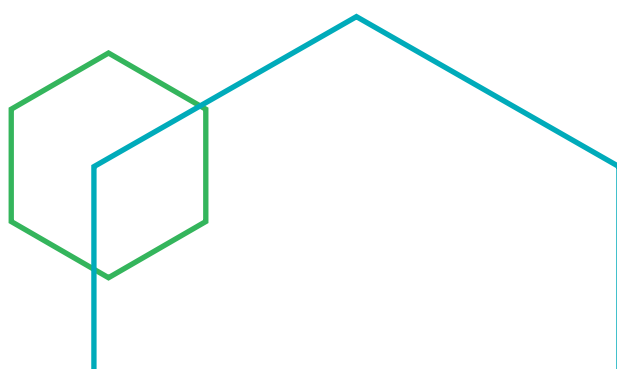
Jodie Wilson (Co-Chair)	AbbVie
Vincent Tran (Co-Chair)	Medicines Australia
Yelitte Ho (Co-Chair)	Medicines Australia
Greg Cook	Bristol Myers Squibb
Louise Graham	Pfizer
Lucas Tocchini	Novartis
Megan Bohensky	MSD
Michael Haberl	GlaxoSmithKline
Paul Alexander	Roche
Peter Germanos	Boehringer Ingelheim
Sarah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

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
Andrew Thirlwell	Pfizer
Darin Kottege	MSD
David Thomson	Amgen
Gillian Sharratt	AbbVie
Guillaume Herry	Biointelect
Martin Snoke	Roche
Sophie Schultz	Takeda
Stacey Bolto	Novartis



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 HCAP to support the HCOs and the patients they serve.

Members of CAWG as at 30 June 2021:

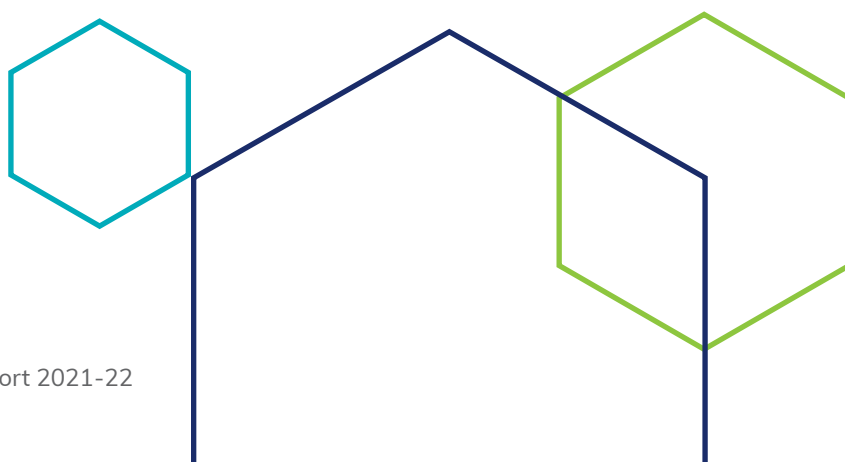
Petrina Keogh (Co-Chair)	Medicines Australia
Andi Bennett	Novartis
Cathy Sertori	AstraZeneca
Hayley Andersen	Bristol Myers Squibb
Jamie Nicholson	Roche
Katherine Tocchini	Novo Nordisk
Leigh Simmonds	Pfizer
Lisa Julian	Lilly
Zarli French	MSD

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 2022:

Meriana Baxter (Co-Chair)	Amgen
Jamie Snashall (Co-Chair)	Medicines Australia
Alison Crosweller	Janssen
Ben Gommers	MSD
Fiona Tigar	Biogen
James McAdam	Bristol Myers Squibb
Josh Bihary	Pfizer
Kieran Schneemann	AstraZeneca
Martin Snoke	Roche
Monica Saba	Bayer
Stacey Bolton	Novartis



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

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)	MSD
Birgit Beisner	GlaxoSmithKline
Crissa Kyriazis	Biointelect
Danica Prodanovic	Biointelect
David Pullar	GlaxoSmithKline
Dylan Jones	MSD
Louise Graham	Pfizer
Marcello Blanch	Janssen
Michael Parker	AstraZeneca
Pierre Niles	Pfizer
Sarah Lindeman	Sanofi
Valda Struwig	Pfizer
Vanessa Xavier	Sanofi

Chief Financial Officer (CFO) Network

During the year the Chief Financial Officer (CFO) Network was re-established with 29 member company representatives. Two meetings were convened to consider topical issues including ATO transfer pricing audit foci, international tax updates, modern slavery legislation and reporting obligations, patent box, and critical infrastructure reporting.

The CFO network is co-chaired by Members on a rotational basis with Medicines Australia's Head of Operations, Tony Marks.

Special interest groups

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)	MSD
Petrina Keogh (Co-Chair)	Medicines Australia
Amy Moore	AbbVie
Andrea Kunca	Roche
Andrew Thirlwell	Pfizer
Angela Lai	Lilly
Anne-Maree Englund	Medicines Australia
Catherine Vaughan	Novartis
Dani Thut	Bayer
Darin Kottege	MSD
David Cain	Astellas
David Thomson	Amgen
Elise Kelly	Pfizer
James McAdam	Bristol Myers Squibb
Jan Lewis	AbbVie
Katrina Vanin	GlaxoSmithKline
Kerrie McDonald	AstraZeneca

Kieran Schneeman	AstraZeneca
Kylie Earle	Sanofi
Laura Issa	AbbVie
Liliana Chavez	Novartis
Matt Douglas	Bristol Myers Squibb
Matthias Brunner	Roche
Meg Simmonds	AstraZeneca
Meriana Baxter	Amgen
Natalie Betts	Roche
Nicki Conway	Lilly
Paul Lindsay	Merck
Pinky Dharmshaktu	Merck
Rebecca Stratford	AstraZeneca
Sally Ryan	Pfizer
Sophie Schultz	Takeda
Stephen Richardson	Sanofi
Todd Stephenson	Janssen

Pharma Australia Inclusion Group (PAIG)

Pharma Australia Inclusion Group (PAIG) was established in 2017 to build a more inclusive industry where all people are equally valued, rewarded and thrive.

Inclusion is the foundation of equity and impacts all aspects of an organisation. 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 inclusion.

Fiona Sheppard (Co-Chair)	Janssen
Lee Davelaar (Co-Chair)	Pfizer
Dani Miroso (Treasurer)	Takeda
Lisa Kurian (Legal)	Amgen
Anne Harris (Steering Committee)	Pfizer
Chris Stemple (Steering Committee)	AbbVie
Elizabeth de Somer (Steering Committee)	Medicines Australia
Kathy Connell (Steering Committee)	Janssen
David Fitz-Gerald	GlaxoSmithKline
Eleanor Clifford	Novo Nordisk
Fabienne Connet	Biogen
Gabby Reppen	Lilly
Ilona Alsters	Boehringer Ingelheim
Jacinta McCarthy	Healthcare Logistics/EBOS
Jason Strachan	Boehringer Ingelheim
Jenn Jones	Takeda
John Kim	Vifor
Johnston, Lisa	BMS

Kristin Reading	Vifor
Kylie Brophy-Pryor	AstraZeneca
Lee Davelaar	Pfizer
Linda Matthews	Sanofi
Lisa Kurian	Amgen
Louise Bell	Gilead
Natasha Dithmer	UCB
Neil Perrett	Merck
Nicolas Goncalves	Abbvie
Pebble Johns	Roche
Peter Koetsier	Ipsen
Samar Girgis	MSD
Sarah Bridge	Bayer
Sasha McInnes	Bayer
Vanessa Craze	Pfizer
Victoria Hoad	Astellas



Medicines Australia Membership as at 30 June 2021

Class 1

abbvie

AMGEN

astellas

AstraZeneca



Biogen

Boehringer
Ingelheim

Bristol Myers Squibb



CSL Vifor



GILEAD

gsk
GlaxoSmithKline

IPSEN
Innovation for patient care

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Lilly

MENARINI

MERCK

MSD

NOVARTIS

novo nordisk

ORGANON
Here for her health

Pfizer

Roche

sanofi

Takeda



Class 2



NEW



Class 3



NEW



NEW



NEW



Class 4



Medicines Australia Team

Please note this is a list of staff who were employed during the FY21-22.



Elizabeth de Somer
Chief Executive Officer



Anne-Maree Englund
Head of Strategic Policy
Implementation



Jamie Snashall
Head of Government
Relations



John Flannery
Government Affairs
and Media



Margaret Cresswell
Head of Communications &
Stakeholder Engagement



Tony Marks
Head of Operations &
Company Secretary



Hoor Akhtar
Policy Analyst



Kaity Harris
Member Communications
and Events Coordinator



Sophie Hibburd
Director Ethics &
Compliance



Eric Johnsson
Senior Manager, Industry
and Regulatory Policy



Petrina Keogh
Senior Manager,
Stakeholder Relations



Chrystianna Moran
Manager, Media and
Communications



David Newman
ICT Manager



Gerry Rossiter
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Acronyms

ABPI – Association of the British Pharmaceutical Industry

CAWG – Consumer Advocacy Working Group

CCC – Continuity of Care Collaboration

CEP – Continuing Education Program

DoH – Department of Health

GWG – Government Working Group

HEWG – Health Economics Working Group

HCO – Health Consumer Organisation

HSANZ

HTA – Health Technology Assessment

IFPMA – International Federation of Pharmaceutical Manufacturers & Associations

MA – Medicines Australia

MAP – Medicines Access Portal

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

PBAC – Pharmaceutical Benefits Advisory Committee

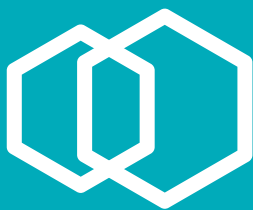
PBS – Pharmaceutical Benefits Scheme

PSWG – Policy Scanning Working Group

PVI – Patient Voice Initiative

RAWG – Regulatory Affairs Working Group

TGA – Therapeutic Goods Administration



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