



Medicines
Australia

Better health
through research
and innovation

Annual Report 2022-23



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 leads the research-based pharmaceutical industry of Australia. Our members discover, develop and manufacture the medicines that are the foundation of a healthy and prosperous society, including prescription pharmaceutical products, biotherapeutic products and vaccines. Our members invest in Australian medical research and take local discoveries and developments to the world. We are trusted partners in the medicines ecosystem, ensuring that our conduct is of the highest ethical standard, and that the environment in which we provide access to our medicines is sustainable and fair.

Our vision

To achieve the world's best health for all Australians by ensuring they have immediate access to the best available medicines.

Our mission

To champion what is possible because of the latest advancements in medicine, and advocate for patients to have fast, universal access to new treatments. We communicate and partner with community, governments and health sector organisations to put the enabling policies and mechanisms in place.

Our Strategic Plan 2023-2028

Medicines Australia's workplan is driven by a 5-year Strategic Roadmap, which groups our priorities around three key pillars. The Roadmap was recently updated for 2023-2028 following a series of workshops with the Board, the Advisory Council and Managing Directors.

Patients at the Centre

We advocate for Australians to have reimbursed **access to world-class medicines** as soon as they are registered* in Australia.

We work to ensure patients are **active participants in decision-making** about current and future medicines.

* 'registered' means medicines that have been evaluated for quality, safety and efficacy by the Therapeutic Goods Administration

Value of Industry Innovation

We strive for a globally competitive ecosystem in Australia which attracts investment in **R&D, clinical trials and manufacturing**, contributing to economic prosperity.

We call for increased public investment in a **modern PBS**, because it results in better health outcomes and efficiencies for government, which in turn drives innovation in medicines.

A Thriving Society

We measure and communicate how Medicines help Australians **contribute to their full potential**, benefiting society and the economy.

We support nation-wide, integrated, patient-level **health data sets**, to provide real world evidence of better health outcomes and productivity.

We are trusted partners in the medicines ecosystem, ensuring that **our conduct is of the highest ethical standard**, and that the environment in which we provide access to our medicines is sustainable and fair.

2022-23 Snapshot

Key highlights for Medicines Australia include:



A new 5-year Strategic Roadmap (2023-2028) to better reflect how our medicines and our member companies make a difference to patients, science and society.



Appointment of CEO Liz de Somer to the HTA Review Reference Committee as the medicines industry's representative by the Minister for Health and Aged Care in March 2023.



In December 2022, Medicines Australia hosted

the first *Horizon Scanning Forum: Medicines of Tomorrow.*

The landmark event brought together stakeholders from across the Commonwealth Government, State and Territory Governments, the medicines industry, life sciences companies, researchers, clinicians, and patient organisations.



As per the Strategic Agreement, Medicines Australia made a submission to the PBAC's July 2023 meeting proposing to

lower the discount rate from 5% to 1.5% to better align with international best practice.

The PBAC acknowledged that the discount rate could be lowered, but should be considered in the context of the HTA Review.





The new National Medicines Policy includes modernised language that emphasises the need for good public medicines policy to ensure that the patients and the people it serves are central to the ambition.

It sets the aspiration for the outcomes of the HTA Review with

a bold new vision: to achieve the world's best health, social and economic outcomes for all Australians.



One year since its launch, there are now

over 600 clinicians and pharmacists registered and using the Medicines Access portal.

Developed by Rare Cancers Australia and Medicines Australia, this portal allows clinicians to view the latest medicines available to Australian cancer patients through Compassionate and Special Access Programs.



Medicines Australia was a platinum sponsor for this year's international

Health Technology Assessment International (HTAi) conference, held in Adelaide.

This annual event is an important forum that brings policy makers, industry and consumers together from many countries. The sponsorship allowed MA to host a booth throughout the conference and share our positions on the need for HTA reform with a wide range of stakeholders.



The Chair's Report

On behalf of the Medicines Australia Board, I am pleased to present to you the Annual Report for the 2022-23 financial year.

This report encapsulates a year of resolute progress, innovative thinking, and collective efforts that have positioned our organisation for continued success. Our commitment to advancing healthcare and access to world-class biotherapeutics and vaccines for all Australians has been unwavering, and this report reflects the tangible impact of our endeavours.

This year's Annual Report underscores the significant strides we have taken as an organisation in pursuit of our vision.

First and foremost, we have set the stage for a successful Health Technology Assessment Reform, for what could be a cornerstone achievement closely linked to the commitments outlined in our strategic agreement. The importance of this reform cannot be overstated. It represents not just a reimbursement evolution, but a fundamental shift in the way we approach biotherapeutics and vaccine innovation and access.

One of the defining features of our organisation's strength lies in the level of engagement demonstrated by our members. The myriad challenges and opportunities facing our industry necessitate a united front, and I am proud to acknowledge the extensive efforts put forth by our members. The numerous working groups, each addressing a unique facet of our industry, exemplify the commitment and collaborative spirit that underscore our collective journey.

A standout achievement this year has been the development of position papers that succinctly articulate our industry's stance on critical matters. These papers have not only showcased the depth of our knowledge and expertise but have also been instrumental in rallying industry alignment

around key issues. They serve as foundational documents that guide our advocacy efforts and help to influence policies that shape the future landscape of healthcare in Australia.

I extend my gratitude to my fellow directors on the Board (past and present). Together, we have steered our organisation through dynamic challenges and strategic opportunities, and our successes this year reflect the effectiveness of our collaborative leadership.

I also want to express my sincere appreciation to our members. Your support, active engagement, and willingness to contribute have been integral to our achievements. Your commitment to our shared vision continues to drive us forward and inspire positive change.

A special congratulations is due to our CEO, Liz de Somer, and her team. Their tireless efforts behind the scenes ensure that our strategic objectives are met with operational excellence.

As we reflect on the past year's accomplishments, we stand poised to embrace the challenges and opportunities of the future with renewed vigour, a shared commitment, and an unshakable belief in the positive impact we can make in the lives of all Australians.

Sincerely,



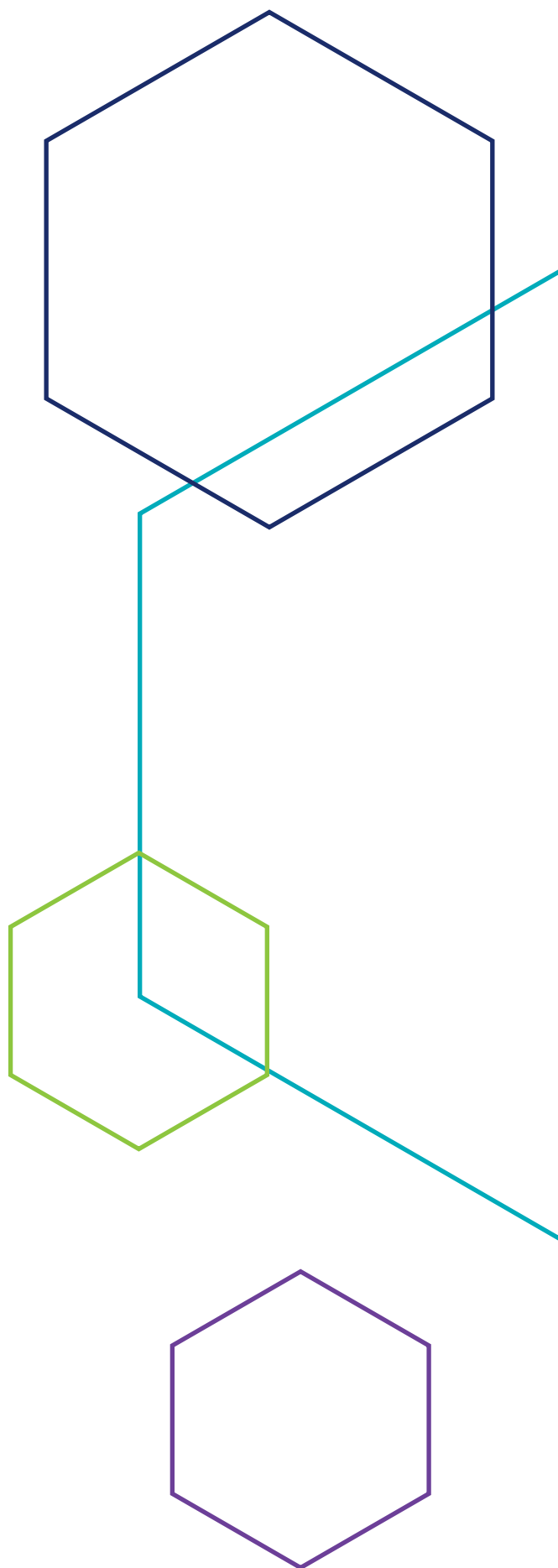
Dr Anna Lavelle AM
GAICD, FTSE

Medicines Australia
Board Chair

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As we reflect on the past year's accomplishments, we stand poised to embrace the challenges and opportunities of the future with renewed vigour, a shared commitment, and an unshakable belief in the positive impact we can make in the lives of all Australians.

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CEO's report

To our Stakeholders, it is with great pleasure that I present to you the Medicines Australia Annual Report for the year 2022-2023.

This year has been one of dynamic transformation, reinvigorated commitment, and unwavering dedication to our core mission. Our vision to make a tangible difference to the health of Australians by ensuring their access to world-class medicines remains at the heart of everything we do.

Over the past year, we have reoriented our organisation to prioritise Health Technology Assessment Reform. Recognising the critical role that health technology assessment plays in shaping healthcare decisions, we remain steadfast in our engagement with policymakers, consumers, and experts to ensure the HTA reforms will foster innovation while ensuring equitable and faster access to biotherapeutics and vaccines for all Australians.

While advancing our strategic agreement implementation, we have maintained our vigilance to adapt to emerging priorities within the external landscape. We have been attuned to the dynamic shifts in clinical trials (continuing to push for finalisation of the Front Door and One Stop Shop initiatives), the evolving pharmacy environment (60 day dispensing), the national reconstruction fund, and the pressing issue of climate change. Our ability to remain responsive to these changing dynamics underscores our commitment to agile leadership and effective stewardship of our industry's future.

The creation of our new 5-year roadmap was both a necessity and an aspiration. In an era of rapid advances and transformative shifts, we recognised the need to chart a course that aligns with the evolving needs of our industry and society. This roadmap not only guides our strategies but also underscores our commitment

to proactive leadership and innovation in the ever-evolving landscape of healthcare.

I must acknowledge the invaluable contributions of our members. Their active engagement across all working groups has fuelled our collective progress. The synergy of ideas, expertise, collaboration and unity within our diverse membership has been the driving force behind our achievements.

I extend my sincere gratitude to the Board and Chair for their guidance and leadership. Their strategic vision has provided the compass that guides our actions, ensuring that we remain true to our purpose and committed to our objectives. Their support has been instrumental in our accomplishments this year.

I also want to express my deepest appreciation to our dedicated staff. In the face of evolving demands and dynamic challenges, our team has exemplified resilience, adaptability, and a passion for improving the health and well-being of all Australians.

In addition, it is important to recognise the value of our collaborative efforts with the Health Minister, the Hon. Mark Butler and his staff. Through open dialogue and constructive exchanges, we have worked to ensure that our industry's perspectives and expertise are considered within the framework of the strategic agreement that stands to benefit all Australians.

Finally, I would like to address the Catch-up price cuts in April 2023. I acknowledge the resilience and adaptability of our member companies in the face of these changes. The industry's ability to navigate these challenges is a testament to

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This year has been one of dynamic transformation, reinvigorated commitment, and unwavering dedication to our core mission. Our vision to make a tangible difference to the health of Australians by ensuring their access to world-class medicines remains at the heart of everything we do.

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its capacity for innovation, perseverance, and its dedication to serving the needs of Australians.

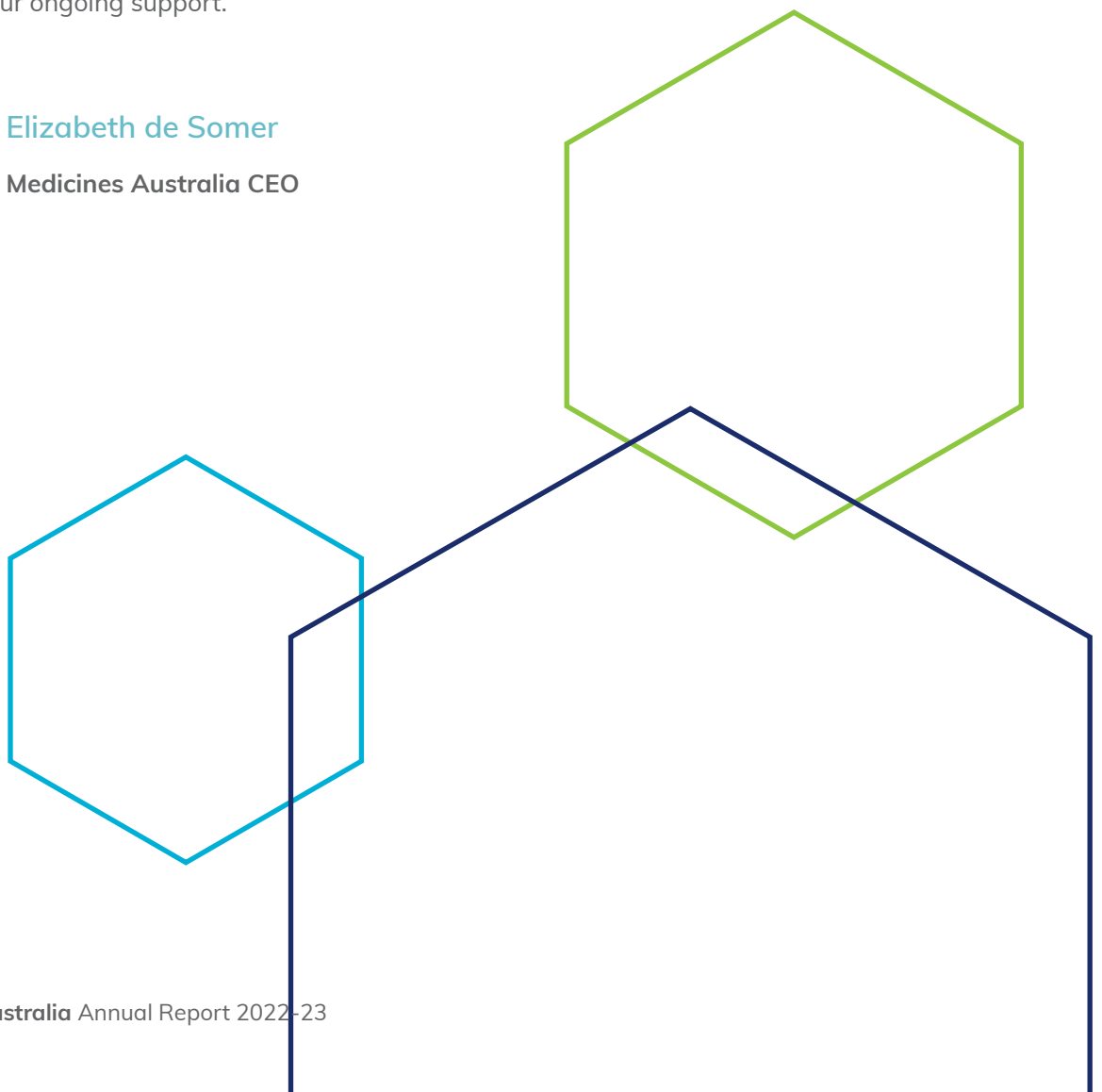
This year has been a testament to the power of collaboration, adaptability, and a shared commitment to improving healthcare outcomes for all Australians. We remain committed to our vision and purpose, confident that our efforts today will continue to make a lasting impact on the health and well-being of Australians and the economy.

Thank you for your ongoing support.



Elizabeth de Somer

Medicines Australia CEO



2022-23 Board of Directors

Thank you to the 2022-23 Board of Directors for your dedication and exemplary efforts. The Board who served between 1 July 2022 - 30 June 2023 includes:



Dr Anna Lavelle AM
Chair
Medicines Australia
Independent Director



Anne Harris
Deputy Chair
Managing Director, Pfizer
Australia and New Zealand
Cluster Lead, Pfizer Developed Asia



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



Nathalie McNeil
VP and Managing Director ANZ,
Abbvie Pty Ltd



Ashraf Al-Ouf
General Manager,
Bayer Australia Limited



Prashant Nikam
VP and Managing Director,
ANZ, Merck Sharpe & Dohme
(Australia) Pty Ltd



James McDonnell
VP and General Manager,
Vifor Pharma Australia



Liz'e Marett
Managing Director,
Astellas Pharma Australia Pty
Ltd



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



Stuart Knight
Managing Director,
Roche Products Limited



Josie Downey
Managing Director,
Merck Healthcare Pty Ltd

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.



Bruce Goodwin
Selected Director
Resigned effective
3 November 2022.



Chris Stemple
Vice President and General
Manager Australia and New
Zealand,
Abbvie Pty Ltd
Resigned effective 30
September 2022.



Neil MacGregor
Managing Director,
Bristol-Myers Squibb Australia
Resigned effective
26 September 2022.



Shannon Sullivan
Vice President & Managing
Director Australia and New
Zealand
Amgen Australia Pty Ltd
Resigned effective
6 August 2022.

United efforts to champion faster access to innovative medicines

Commencement of the HTA Review

As part of Medicines Australia's 2021 five-year Strategic Agreement with the Federal Government, an independent review of Australia's HTA system is currently underway – a once-in-a-generation opportunity for bold reform. The goals of the review are to reduce time to access of medicines for Australian patients, increase the attractiveness of Australia as a first-launch country for new health technologies, and ensure Australia's processes keep pace with rapid advances in science and health technology.

CEO Liz de Somer appointed to the Reference Committee

CEO Liz de Somer was appointed to the HTA Review Reference Committee as the medicines industry's representative by the Minister for Health and Aged Care in March 2023. Liz brings a strong voice for reform with a collaborative approach. This position was previously held by John Young, who was appointed to the Novartis board and advised he was unable to continue to serve the Committee in a voluntary capacity. Mr Young made a strong contribution to the Committee on behalf of industry, particularly through the process of setting the Terms of Reference and ensuring they were sufficiently broad.

Strategic Focus for the Board and the Executive

Though the HTA Review officially started in January 2023, a comprehensive program to prepare for the Review has been underway since early 2022, overseen by a dedicated Board subcommittee. Members have been actively engaged via agile 'action groups' to develop and align on policy positions, culminating in a

comprehensive submission to Consultation 1 of the Review. In addition there has been a strong program of stakeholder engagement, to help raise awareness about the Review and align on the need for bold reform to reduce the access gap.

Medicines Australia's overarching recommendations

Medicines Australia made a number of recommendations about policy and methods in the submission to Consultation 1 of the Review. Our overarching recommendations were:

1. The HTA Review should ensure that we meet the vision of the recently updated National Medicines Policy (NMP), as informed by the 2021 House of Representative's Standing Committee on Health, Aged Care and Sport's, "The New Frontier Report". This will require a commitment to the principle that investing in medicines secures valuable health, social and economic benefits for all Australians, and that this should be reflected in HTA policy and methods.
2. Bold and pragmatic reform should be undertaken to remove the patient access gap so that patients can access medicines as soon as possible after TGA registration. This can be achieved by embracing the concepts outlined in the HTA Review terms of reference – faster, more equitable access, patient-centricity and alignment with international best practice.

HTA reform timeline

The HTA Review commenced in January 2023 with the release of the draft terms of reference, and is due to conclude in December 2023 with the release of the Reference Committee's recommendations.

First Year of the new Strategic Agreement

In addition to the HTA Review, the 2021 Strategic Agreement contains a raft of policy measures that are in the process of being implemented according to the timelines set in the Agreement. The main items of note from the first year of the Agreement are shown below.

Medicines of Tomorrow: The first Horizon Scanning Forum

In December 2022, Medicines Australia hosted the first *Horizon Scanning Forum: Medicines of Tomorrow* in Canberra and online. The landmark event brought together stakeholders from across the Commonwealth Government, State and Territory Governments, the medicines industry, life sciences companies, researchers, clinicians, and patient organisations.

The Forum explored how horizon scanning could enable the sector to forecast Australia's future health needs better and facilitate faster access to new and emerging medicines for Australian patients. Two recommendations emerged from the Forum:

1. Define the purpose and aims of horizon scanning by conducting a roundtable discussion with key stakeholders to agree on the purpose, aims and framework for Australian horizon scanning.
2. Develop a Horizon Scanning Roadmap, detailing the steps all stakeholders must take to implement nationally coordinated horizon scanning.

Moving forward, Medicines Australia will work with the Department of Health and Aged Care and other key stakeholders to ensure the momentum and enthusiasm for Australian horizon scanning is realised.

Enhanced Consumer Engagement

A new Enhanced Consumer Engagement process is being 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). Medicines Australia is part of the consumer-led co-design process, which will deliver a report in December 2023. The 'Conversations for Change' survey conducted by the Department of Health and Aged Care's Consumer Evidence and Engagement Unit during 2022 will be a key input to the process.

Discount Rate

As per the Strategic Agreement, Medicines Australia made a submission to the PBAC's July 2023 meeting, proposing to lower the discount rate from 5% to 1.5% to better align with international best practice. A high discount rate has contributed to delays in accessing vital therapies including vaccines for human papillomavirus (HPV) in adolescents, meningococcal disease in children and adolescents as well as medicines to treat hepatitis C, and treatments for spinal muscular atrophy in children. The PBAC acknowledged that the discount rate could be lowered, but should be considered in the context of the HTA Review. Medicines Australia has continued to urge the Government to apply a reduced discount rate as soon as possible.

Exchange and Sharing of Information

Medicines Australia has been working with the Department of Health and Aged Care to co-design a trial to facilitate the exchange of information between sponsors and the evaluators early in the PBAC process in order to increase efficiencies. This design work is progressing well and a pilot will commence in due course.

National Medicines Policy

The updated National Medicines Policy (NMP) was published in December 2022 after a comprehensive review process – the first time it has been updated in over 20 years. An earlier draft had met with criticism from stakeholders, however calls from Medicines Australia, patient bodies and industry to extend the time for the review to allow further and more detailed consultation were heeded by the Government.

The new NMP includes modernised language that emphasises the need for good public medicines policy to ensure that the patients and the people it serves are central to the ambition. It sets the aspiration for the outcomes of the HTA Review with a bold new vision: *to achieve the world's best health, social and economic outcomes for all Australians.*

Patients

Medicines Access Portal (MAP)

A new online pathway for accessing cancer treatments



Medicines^{AP}

In an Australian-first, clinicians can now view the latest medicines available for Australian cancer patients through Compassionate and Special Access Programs using the Medicines Access Portal (MAP), developed by Rare Cancers Australia (RCA) and Medicines Australia (MA).

Compassionate and Special Access Programs allow clinicians to access medicines and medical devices that are not publicly available or funded, while they are going through regulatory approval.

Compassionate access or special access programs are often the last avenue for cancer patients. Clinicians and patients have traditionally relied on general knowledge and word of mouth to find these programs.

The MAP seamlessly connects clinicians to pharmaceutical companies and offers easy access to information about medicines and treatment options for their patients.

One year since its launch, there are now over 600 clinicians and pharmacists registered and using the Medicines Access portal.



View the Medicines Access Portal at <https://medicinesap.com>

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 and continues to build a collaborative, working relationship with the Australian patient community.

Highlights include:

- In August 2022, Medicines Australia and the Australian Pharmaceutical Professionals Association hosted a webinar with an expert panel of healthcare professionals, patients and industry representatives to share views on the health technology assessment reform with special guest speakers including Professor John Zalcberg OAM, Head of the Cancer Research Program at Monash University and Mr Richard Vines, CEO of Rare Cancers Australia
- In April 2023, Medicines Australia provided briefings to the patient community about the Health Technology Review (HTA) including a webinar on *Driving Genuine Change for HTA Reform*. Over 60 patient groups joined the briefing with 70% stating they would provide a submission to the HTA review.
- In May 2023, Medicines Australia hosted a networking event for patient groups and industry members for an evening of valuable connections and discussions at the National Press Club with almost 70 guests attending.
- For Labor's first full Federal Budget in May, Medicines Australia hosted a post-budget briefing for the patient community to provide a high-level analysis of the Federal Budget with relevance to the health sector and what it means for the patient community in terms of potential challenges and opportunities. The event was well attended with over 40 patient groups in-person and 30 virtually.

- In June 2023, Medicines Australia collaborated with Rare Cancers Australia and Medical Affairs Professional Association (MAPA) and hosted a webinar with over 230 attendees on 'Putting the access into Access Programs' discussing the issue and importance of equitable access for patients to innovative therapies in Australia.

The feedback received for patient briefings has been exceptionally positive, reflecting the valuable contribution of these initiatives to patient communities. Medicines Australia remains steadfast in its dedication to the empowerment and support of these communities whenever applicable.

Events

Medicines Australia CEO, Liz de Somer, was invited as a guest speaker at *Humanise Health A Moment in Time*, an event held on 15 May 2023 that brought together leading voices from across the health landscape to spark change-driven conversations and action. Spinal Muscular Atrophy Australia's former CEO, Julie Cini, won the inaugural Our Moment in Time Advocacy Award. The Award was presented by Senator Anne Ruston and Sally Obermeder, CEO and co-founder of SWIISH, in front of more than 125 people from across the health sector.

Medicines Australia CEO, Liz de Somer, was invited as a panellist to speak at the National Patient Organisation Network (NPN) conference *Breaking the Cycle* on 15-16 May 2023.



Images: Humanise Health A Moment in Time event

Women in Life Sciences

The Australian Biotechnology Sector Snapshot 2022 by AusBiotech shows that the sector has grown by 43% since 2019. However, women in the biotechnology industry are still underrepresented (35%), especially when compared to the fact that, 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 on 10 March 2023. This year's theme was gender equality with a keynote from Dr Kathryn Evans, Managing Director, BioMarin Pharmaceutical Australia & New Zealand and author of *Advance Australia Fairly: How a Plan for Gender Equality can Drive Australia's Economic Success*, and a panel of exceptional leaders who shared 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: NSW Women in Life Sciences Luncheon

Budget

Post-Budget Analysis –

The 2023-2024 Federal Budget was the Labor Government's first real full Federal Budget in 10 years, and despite several years of a challenging economic climate, it forecast a surplus of \$4.2 billion.

The post-budget breakfast briefings in May 2023 for Medicines Australia Members, and Patient and Consumer Groups, featured the expert insights from Jody Fassina, CEO of Insight Strategy; Peta Lange, Head of Public Affairs at Parker & Partner; and Pradeep Philip, Partner at Deloitte Access Economics.

This budget had a focus on relieving the cost-of-living pressures brought on and exacerbated by the pandemic. The pandemic has shown us that the health of Australians and the health of the economy are intertwined. There was an unmistakable focus on acknowledging the social determinants of health in this budget, with funding directed to social services and housing. There were also changes to dispensing at pharmacies which would lead to more affordable and accessible medicines.

Although there was an uptick in PBS spending during the pandemic, there was a lack of growth in PBS spending in this year's Federal Budget forecasts compared to other Health Programs. This Government has realised the importance of a healthy population as a key factor in Australia's economic growth. Medicines Australia will continue to remind the Government of the important role innovative medicines play in supporting the health of Australians, and the economy through pandemics and beyond.

With the HTA Review wrapping up at the end of 2023, Medicines Australia will be seeking Government commitments to bold HTA reform in the lead up to the next Federal Budget.

Government engagement

Government support for HTA review

Australia's HTA system has not been comprehensively reviewed or reformed in 30 years and in many aspects is no longer fit for purpose. Ensuring consumers and our industry are heard with respect to what aspects of HTA need changing is a key focus. For the HTA review, Medicines Australia has been working with all our stakeholders and we are pleased there is strong alignment on the need for reform. This alignment is evident across all political parties.

"I think it is clear ... that the system is a little clunky in terms of dealing with just the speed of technology that's coming through Australia and the rest of the world. [This review] will keep HTA in Australia at the forefront of public health and ensure Australians continue to enjoy the best possible access to health technologies, at a cost the public can afford".

- Minister for Health and Aged Care, the Hon. Mark Butler MP, affirmed what many others have been saying in a radio interview in late May 2023.

"I'm pleased to see that the government is getting on with the HTA review...because if there was one consistent message that I've heard from many of you that I've spoken to in this room in the last five months is that our system is too slow, it's too cumbersome, it's extremely expensive, it's too bureaucratic and it often lacks transparency."

- Shadow Minister for Health and Aged Care, Senator Anne Ruston, Biopharma Dispatch Post Budget Summit - November 2022.

Clinical Trials One Stop Shop

The National One Stop Shop will provide a harmonised approach to clinical trial start up that will allow sponsors and investigators to more efficiently initiate trials and start enrolling patients and give greater visibility to patients of the clinical trials occurring for their illnesses. All the states and territories are currently supportive of this model and have signed an interjurisdictional agreement. Over many years, Minister for Health and Aged Care, the Hon. Mark Butler MP, has been a strong advocate for clinical trial harmonisation. Medicines Australia continues to work with stakeholders to secure urgent Commonwealth funding to enable essential infrastructure to be implemented.

Reducing the Discount Rate used in HTA assessment

Discount rates reflect how society values future outcomes compared to present outcomes. Many medicines, vaccines and treatments provide long-term health benefits and discount rates reflect how society values future outcomes compared to present outcomes. The rate was set at 5% in 1990. Since that time, this discount rate hasn't changed, despite other international countries (including Canada and England) recommending lower base discount rates to make way for more preventative and curable medicines, vaccines and treatments. In November, the PBAC considered the case put to the Committee from Medicines Australia and published advice recommending Australia's discount rate could be lowered between 3.5% – 4% to bring the country closer to other recommended international standards. Medicines Australia continues to urge the Government to apply a reduced discount rate as soon as possible.

Deputy Secretary of Health Products Regulation Group (TGA), Prof. Skerritt retires.

After 11 years leadership of the TGA, Prof John Skerritt retired in April. Professor Skerritt has been a cornerstone of our health system for many years. To highlight just a couple of examples, Medicines Australia and member companies worked closely with his Department during the Medicines and Medical Devices Review, and the rapid registration of COVID-19 vaccines and treatments. On behalf of our industry, members and Board, we thank him for his service and dedication to Australia.



Image: Professor John Skerritt

Clinical trials in Australia

Clinical trials are important to Australia's healthcare system. They provide patients access to cutting-edge medical technologies, and they benefit the economy through job creation and reduced healthcare costs. Additionally, clinical trials inject investment to Australia's research and health sector and provide world-class training to Australian staff.

Despite the benefits Australia could reap from conducting more clinical trials here, a fragmented system between States and Territories results in increased costs and start-up times. These barriers continue to make Australia a less desirable place to conduct clinical trials.

The harmonisation of clinical trials in Australia has been on the agenda of industry for decades. The Research & Development Taskforce (RDTF) – a multi-sector collaboration between Medicines Australia, AusBiotech and the Medical Technology Association of Australia (MTAA) – has been working with various stakeholders advocating to the Federal Government to establish a clinical trials National One Stop Shop and Front Door (NOSS). This initiative would create a streamlined national platform for clinical trial processes for sponsors and patients.

Following its release in January 2023, the NOSS Consultation Report had strong support from industry, academia, and the state jurisdictions. The report outlined the need and urgency for ensuring guaranteed resourcing and governance structures to implement for the establishment of the NOSS. However, the NOSS did not receive any funding commitments in the 2023-2024 Federal Budget. This is concerning.

The RDTF, and industry broadly, will continue advocating for the establishment of the NOSS, as well as supporting initiatives that help to improve the clinical trials landscape in Australia. These initiatives include programs that aim to expand patient access to clinical trials for people living in regional areas and for people of culturally diverse backgrounds. Programs building a stronger research workforce and streamlining processes for both sponsors and patients will also be supported.

“The remarkably deep and wide-ranging consultation leads me to see the clear need for a ‘One Stop Shop’ as a nation-wide resource with sustainable funding”.

- Chair of the Health and Medical Advisory Group, Prof. Ian Chubb, reflected in the NOSS report.

Dr Lavelle AM

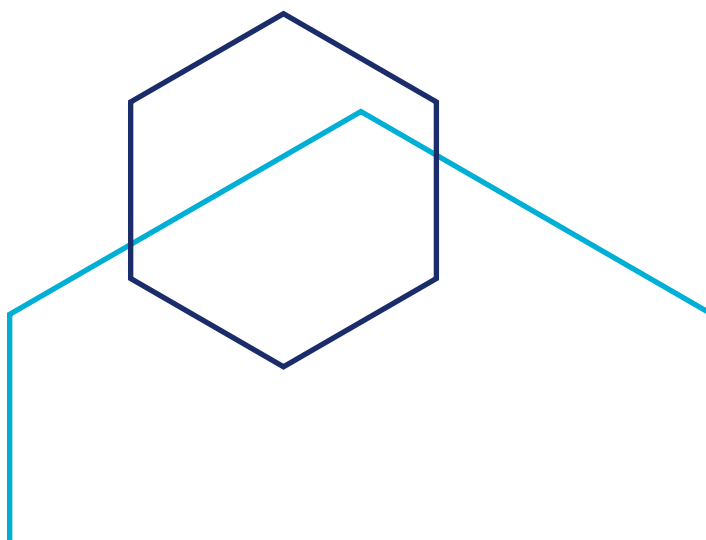
Medicines Australia Chair, Dr Anna Lavelle, has been appointed a Member of the Order of Australia (AM) for her significant service to science and innovation.

Dr Lavelle was named in the King's Birthday Honours Roll in June 2023.

Over the course of her career, Dr Lavelle has contributed significantly to Australia's medicines, research and biotechnology industries. She has been a pioneer for women in these industries, holding executive and board positions and driving innovation for the benefit of society for more than 25 years.

“Dr Lavelle has been fearless leader throughout her career, combining her extensive understanding of Australia's medicines and biotechnology policies with deep experience in medical research. Her unwavering commitment to improving patient outcomes and quality of life is resolute,” Medicines Australia CEO Liz de Somer said.

“Medicines Australia is extremely fortunate to have Dr Lavelle as our Chair and on behalf of the pharmaceutical industry, we congratulate Dr Lavelle on this prestigious and most deserved achievement.”



Days of Community Participation

Medicines Australia provided continued support to the below causes.

Kosi Challenge 2023

Since its launch in 2013, the Kosi Challenge event – held 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.



Image: Con Tablan, Josh Vines, Emily Skillin, Brent Weston



Image: Last few steps to the top of Mt Kosi



Image: Michael Coffey, Con Tablan, Emily Skillin, Sophie Seck, Tony Marks, Petrina Keogh, and Steve Warwick on the descent after walking to the summit.

Medicines Australia was proud to be part of the 2023 Kosi Challenge, and together we raised \$8,250, which is the highest amount we've ever raised.

The Medicines Australia Kosi team, the MA Mountain G.O.A.T.S was well represented this year by Liz and Greg de Somer, Anne-Maree England and Jan Frieding, Tony Marks, Petrina Keogh, Sophie Seck, Emily Skillin and Michael Coffey, Con Tablan and Steve Warwick, Josh Vines and Amelie.

CCReW Conference Support Scholarships

Medicines Australia contributed \$5,000 as one of the inaugural sponsors for the 2022-2023 Community & Consumer Research Workforce (CCReW) Conference Support Scholarships Program. With the combined funding of all the sponsors (\$12,000), 14 consumers from diverse backgrounds who otherwise could not have afforded to do so were able to travel and attend scientific conferences. These learning and networking opportunities are critical for expanding the capacity of consumers to contribute early and effectively in research and development.



Learn more about the scholarship program at <https://ccrew.accesscr.com.au/ccrew-support/ccrew-scholarships>

Women in Life Sciences – Big Sister Programme

Medicines Australia sponsored two students in the later part of a life sciences degree to attend the Women in Life Sciences Lunch and be paired with an industry mentor as a part of the AusBiotech Big Sister Programme. The Big Sisters programme invites leaders in the sector to connect with those aspiring to a career or career progression in the life sciences. It provides a practical and tangible way to support and encourage women in the late stages of their studies to enter a career in life sciences.

International work

Collaborating on HTA

Medicines Australia has been meeting regularly with our UK, Canadian and New Zealand counterparts (the Association of the British Pharmaceutical Industry, Innovative Medicines Canada, and Medicines New Zealand, respectively) to discuss a range of issues, including HTA. In particular, the group is mirroring the Collaboration Arrangement between the governments of Australia, the UK, Canada and New Zealand, in which the partners have agreed to work together on shared priorities such as COVID-19, HTA Systems, work-sharing and artificial intelligence.

Medicines Australia also meets regularly with the Pharmaceutical Research and Manufacturers of America on topics of mutual interest. PhRMA made a submission to Consultation 1 of the HTA Review.

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.



International Conferences: HTAi and Bellberry

The HTAi (Health Technology Assessment international) 2023 Annual Meeting was held in Adelaide, Australia, June 24-28. Over 700 delegates from 42 countries attended the five-day event, which included two days of pre-conference workshops and three days of conference presentations. The conference reinforced that Australia is not alone in seeking to improve access to new medicines while navigating budget pressures, with many countries expressing similar views.

Medicines Australia was a platinum sponsor of the meeting and hosted a booth throughout the conference, which provided the avenue to share our positions on the need to HTA reform with a wide range of stakeholders.

Prior to the conference, Bellberry hosted an international, invitation-only workshop on early access to new and emerging technologies, which was attended by CEO Liz de Somer.

Prof. Frank Lichtenberg also attended HTAi to present his new report, sponsored by a consortium of Medicines Australia Members, about The Effect of New PBS Medicines on Mortality and Hospitalisation in Australia.



Image: Prof. Frank Lichtenberg presenting his new report on the Effect of New Medicines Provided by the PBS on Mortality and Hospital in Australia, at an HTAi breakfast event.

The findings of this report highlight the reductions in mortality and hospital expenditure due to the addition of innovative medicines on the PBS. The findings reaffirm the need for bold reform through the HTA Review to maximise these benefits.

Prof. Frank Lichtenberg met with stakeholders during his trip to Australia, including the Department of Finance, the Office of the Minister of Health, the ANU College of Business & Economics, and the BioMelbourne Network.



View Prof. Lichtenberg's report 'From Hospital Beds to Healthy Lives: The Impact of Innovative Medicines' at <https://medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/06/From-Hospital-Beds-to-Healthy-Lives-The-Impact-of-Innovative-Medicines.pdf>



Image: The Medicines Australia team at the HTAi 2023 Annual Meeting in Adelaide.

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 to strengthen the Australian economy. Over the course of the past year, Medicines Australia has made 22 submissions, many of which relate to the access of medicines, government processes, clinical trials, regulatory affairs, and emerging technologies that may affect our industry. An overview of the key submissions is provided below.



For a full list of publicly available policy submissions visit <https://medicinesaustralia.com.au/policy/submissions/>

Key submissions made in 2022-23

[RDTF response to the TGA's proposed regulatory changes for clinical trials of medical devices](#)

October 2022

The TGA proposed changes to increase its oversight in high-risk medical device clinical trials. This had the potential to negatively impact the clinical trials sector and make Australia less attractive to conduct all types of clinical trials. The R&D Taskforce, a collaboration between Medicines Australia, AusBiotech, and the Medical Technology Association of Australia, confirmed that current evidence demonstrates the current processes are safe and efficient for participants.

[Medicines Australia submission to Centre for Disease Control Consultation](#)

December 2022

Medicines Australia supported the establishment of an Australian Centre for Disease Control (CDC). To ensure success, Medicines Australia recommended the CDC be independent with a clear remit, and that the implementation was phased to prevent overstressing resources. Medicines Australia also noted it was also important that the CDC had a secure nationalised

data infrastructure, maintained stakeholder engagement, and had national oversight of the supply of medicines.

[Medicines Australia response to Draft Australian Cancer Plan](#)

December 2022

Medicines Australia strongly supported the aim and vision outlined within the draft Australian Cancer Plan (ACP). Medicines Australia also highlighted that although the ACP focuses on the need to improve early diagnosis and screening, it fails to consider the need for timely access to treatments following diagnosis. Additionally, although the inclusion of equitable access to clinical trials were welcomed, the ACP should include more comprehensive actions to support attracting clinical trials to Australia.

[Medicines Australia response to draft Post Market Review Framework](#)

December 2022

Medicines Australia identified that key changes in the Post Market Review (PMR) should not result in alterations to the PMR process beyond the scope of the Strategic Agreement. Medicines Australia recommended that a more rapid PMR process should have patients' best interests at its core and retain due diligence, consultation and transparency. These proposed changes require further discussion and clarification to ensure that they do not result in negative consequences for patients and other stakeholders.

[Joint letter from the life sciences industry regarding TGA funding](#)

January 2023

Together with other life sciences peak bodies, Medicines Australia wrote to key ministers ahead of the Federal Budget to request that the government should fund TGA's work on public health in the short term and review its funding model in the medium term. The TGA's public health work is currently funded through industry fees and charges, which is unique compared to other world-leading regulatory agencies such as the FDA, MHRA and EMA.

[Medicines Australia Pre-Budget Submission](#)

January 2023

In Medicines Australia's Pre-Budget Submission for 2023–2024, the key recommendation was to urge the Government to lower the discount rate to 1.5% for vaccines and 3% for other medicines. The submission highlights how Australia has systematically undervalued vaccines and other treatments with long-term benefits.

[Medicines Australia response to TGA fees and charges 2023–24](#)

March 2023

In response to the TGA's proposal to increase fees and charges, Medicines Australia argued while it do not oppose increases in fees and charges in line with inflation, it opposed the proposed the extent of the increases, which were well beyond inflation. Medicines Australia also highlighted that the TGA's funding model was unviable, and that the government needs to fund the agency's public health work and review its funding model.

[Medicines Australia submission on advanced manufacturing](#)

March 2023

In response to the House of Representatives Standing Committee on Industry, Science and Resources inquiry into advanced manufacturing in Australia, Medicines Australia highlighted the need for a holistic view of healthcare innovation to attract and build advanced manufacturing. Medicines Australia argued that global investment in Australian advanced manufacturing requires a stable policy environment and a clear market access pathway, and that establishing a government-industry Life Sciences Council would collaboratively drive health innovation.

[Medicines Australia's submission to Privacy Act Review Submission](#)

April 2023

Medicines Australia supported broadening the scope of research permitted without consent, broadening the research exemption. Strict

safeguards already exist to protect the personal information of research participants should these changes be implemented. The changes will help facilitate new research, attracting more global companies to invest in Australia. In addition, Medicines Australia highlighted that amendments to meet General Data Protection Regulations should align with global regulations, and that amendments to definitions should aim to avoid uncertainty or make consent processes more complicated.

[Medicines Australia response to CRIS 2023–24](#)

June 2023

In its response to the 2023–2024 Cost Recovery Impact Statement (CRIS), Medicines Australia expressed concerns about and called for greater transparency on the derivation of certain cost recovery fee increases in the order of 14–20%. Medicines Australia also requested commencement dates for significantly increased cost recovery fees to allow for business planning; early consultation with the industry and other stakeholders on the design of cost recovery fees; a commitment to early and ongoing consultation on PBS process improvements; and continued measurement of PBS improvements to reduce time to PBS listing.

[Medicines Australia submission to the HTA Review Consultation](#)

As part of the strategic agreement, the HTA review is of critical importance to our industry. Medicines Australia submitted its recommendations which have been published on our website.

June 2023

Medicines Australia responded to Consultation 1 of the HTA Review with a comprehensive set of recommendations for reform – the result of many months' work with the membership. Medicines Australia emphasised the principle that investing in medicines secures valuable health, social and economic benefits for all Australians, and that there is a need for reform to remove the patient access gap.

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 2022-2023 continued to focus on 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.

There is an evolving and expanding number of educational opportunities across industry on the Code and how to apply ethical decision-making to different subject areas as well as multiple other opportunities for members to improve and upskill. Through this focus, Medicines Australia seeks to instil confidence and certainty in the way the Code is applied and to avoid ambiguity.



View Medicines Australia's Code of Conduct at <https://www.medicinesaustralia.com.au/code/about-the-code/code-of-conduct-current-edition/>

Complaints, Appeals and Monitoring

Complaints Handling – an effective reactive compliance mechanism

Medicines Australia received four complaints in 2022-23, as detailed in the table below.

Three of the complaints were adjudicated by the independent Code Committee, with the full details of those complaints available on the Medicines Australia website. The website provides Committee decisions from the past three years, providing industry with opportunities for learning.

| Complaint | Subject Company | Complainant | Outcome |
|----------------------|-----------------|-------------------------------|---|
| 1167 | Member Company | Non-member Company | Withdrawn before proceeding |
| 1168 | Member Company | Non-member Company | Four aspects to the complaint <ul style="list-style-type: none">• Breach on one aspect• No breach on the other three aspects |
| 1169 | Member Company | Member Company | Four aspects to the complaint <ul style="list-style-type: none">• Breach on two aspects• No breach on one aspect• No separate breach on the other pect |
| 1170 | Member Company | Provider of pharmacy services | No breach |

*"We hold ourselves to **higher standards** than other industries. We owe it to the patients who rely on our medicines"*

*"**Patient trust** is the lifeblood of our industry: we must take every opportunity to earn, sustain and grow that trust."*

- The Medicines Australia's Code of Conduct observes the same principles as the global [IFPMA Code of Practice](#), which centres its ethos on Trust.

Monitoring Compliance – an effective proactive compliance mechanism

Medicine Australia proactively monitors the conduct and compliance of members and provides tailored feedback to help improve compliance of promotional material and improvement of internal policies and procedures.

The independent Monitoring Committee proactively reviews a small selection of

promotional materials, policies and procedures of members in accordance with the spirit of the Code. These reviews provide the opportunity for the independent [Monitoring Committee](#) to distil good-practice benchmarks and provide examples in guidance documents in the [Code Resource Toolkit](#). The outcomes of reviews conducted by the Monitoring Committee in 2022-23 are as follows:

| Review Activity | Subject area | Date | Number of members participating in the review | Outcomes |
|--|--|----------------|---|---|
| Promotional materials | Cardiology | July 2022 | 12 | <ul style="list-style-type: none">• 5 satisfactory• 7 were initially required to provide further clarification/information. On subsequent review, all were then satisfactory. |
| Promotional materials & HCP-only websites | Endocrinology | September 2022 | 14 | <ul style="list-style-type: none">• 10 satisfactory• 4 were initially required to provide further clarification/information. On subsequent review, all were then satisfactory. |
| Policies and procedures | Interactions with non-HCP stakeholders | November 2022 | 11 | <ul style="list-style-type: none">• 7 satisfactory• 4 were initially required to provide further clarification/information. On subsequent review, all were then satisfactory. |
| Promotional material | Alimentary | March 2023 | 2 | <ul style="list-style-type: none">• All satisfactory. |
| Policies and procedures | Medical representative training (CEP) | May 2023 | 12 | <ul style="list-style-type: none">• 10 satisfactory• 2 were initially required to provide further clarification/information. On subsequent review, all were then satisfactory. |
| There were no Code of Conduct complaints generated as a result of the above monitoring activities. | | | | |

Spotlight on review of policies/procedures relating to medical representative training (CEP)

Monitoring compliance from year to year in the same subject areas enables us to track compliance trends within the membership. With regards to medical representative training, in 21/22 the Committee reviewed policies and procedures of one third of our membership, and in 22/23, another third of our membership. The comparison of the two indicated an overall improvement in the way members approach medical training requirements in their policies and procedures. A significant factor in enabling this improvement is the way the Committee shares their reflections with membership and distils this into Good Practice Guidance accessible across industry.

Transparency Reporting – a public benefit

Disclosing payments and significant support to stakeholders demonstrates Medicine's Australia's ongoing commitment to transparency, which is critical in building public trust in the industry. It allows stakeholders to better understand the nature and extent of the programs supported, in the interest of increasing quality use of medicines, educating clinicians on medicines, and ultimately advancing patient care. This remains one of the key features that sets Medicines Australia members apart from non-members, demonstrating their commitment to good practice and ethical interactions.

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. Medicines Australia published these reports in August 2022 and February 2023, representing the 13th and 14th reporting rounds since transparency measures commenced in 2015. The public remains interested in this data, with 71,636 searches undertaken since the launch of the searchable database in 2019, 26,010 of which were during this financial year – an increase of 46% since the previous year. Medicines Australia published 9,720 transfers of value during this financial year.

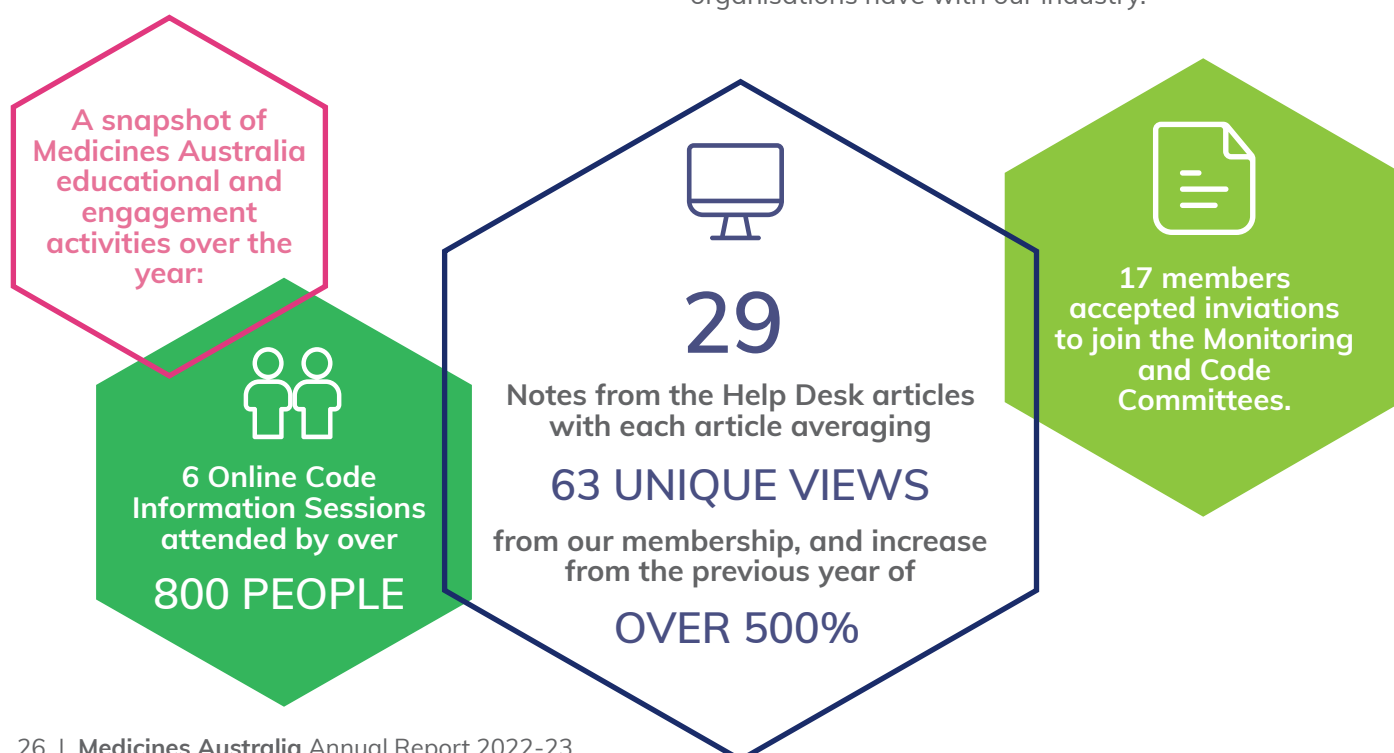
Third Party Meeting Sponsorship Reports

Biopharmaceutical companies are invested in the education of healthcare professionals through sponsorship of meetings and symposia organised by third parties. These independently organised educational activities are primarily offered by colleges, universities and other recognised healthcare professional organisations. Member companies make sponsorship decisions in line with their ethical responsibilities articulated through the Code. Medicines Australia continues to publish sponsorships by members, which are available on [our website](#).

Published reports in October 2022 and April 2023, detailed a total of 2,461 sponsored independent events delivering 20,845 hours of education to 546,577 healthcare professionals in a twelve-month period.

Health Consumer Organisation Support Reports

In June 2023, Medicines Australia published the tenth annual report of Members' financial support for Health Consumer Organisations (HCO). Members supported 146 different HCOs across Australia in the calendar year 2022, ranging from national consumer organisations to small local groups, relating to 382 different projects or events to the total value of \$8,207,031. This level of support represents the highest since 2018 and demonstrates the breadth of positive and beneficial relationships health consumer organisations have with our industry.



Ethical Engagement and Education Activities

Code Edition 19 continues to give industry the confidence to innovate and make meaningful connections with the best interests of patient communities at heart. Given the significant shift to the current principles-based Code, Medicines Australia supports the industry through educational activities so that members can understand and apply the Code in practice. These educational activities have been well attended, demonstrating healthy engagement with the Code and underpinning its success in self-regulation.

Most notably are the ever-increasing numbers of people attending the free online bi-monthly **Code Info Sessions**. These sessions are recorded and available online, and form an ongoing perpetual resource for our growing Code Resource Toolkit. 95% of attendees surveyed indicated they were more confident in understanding how to interpret and apply the Code to the subject area covered in the session.

"I get so much value from these training sessions. So good. THANK YOU!"

- Code Info participant

"Very good session. Love the "ethical crunch time" questions as analyzing the question and possible answer/s really unpack and provide guidance how to approach some situations".

- Code Info participant

Also attracting a health following is the fortnightly **Notes from The Help Desk** (NFTHD)– taking a deeper dive into some ethical dilemmas and mapping them against the Code principles. Medicines Australia is proud to have published 29 articles over the past year and these are available exclusively for our members.

"Receiving guidance from the CodeHelpDesk was great! It is incredibly useful and provides strength to our arguments to share internally, as well as understanding and mitigating any risks."

- Code Help Desk function feedback

"Thank you for an engaging session today. I really love the idea of the ethical crunch and having robust discussions amongst us for these types of challenging cases."

- Code Compliance Network feedback



350

pieces of considered advice given (in response to bespoke situations) via a responsive Code Help Desk and

70% OF QUERIES

were answered within 24 hours.



5 Code Compliance Network meetings with an average of

50 MEMBERS

attending each session, 2 guest speakers and an opportunity to connect our members and knowledge share within membership.



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 (UTAS) Unit for Medication Outcomes, Research and Education (UMORE); information on these courses is available on the [Medicines Australia website](#).

In 2022–2023, 998 individual students enrolled in one or more programs offered under the CEP. Of this total, nearly 650 enrolled in PConduct, consistently the highest performing program. 143 member company personnel attended the updated Bridging Course, an expected reduction from previous years due to the majority of people having already familiarised themselves with the transition knowledge from previous Code editions through to the current Edition 19.

Surveys indicate that overall program satisfaction was exceptionally high across both semesters for all six core programs (range 87-95%). The use of multimedia content remains highly regarded and the programs are regularly refreshed to present interactive learning opportunities. Students strongly felt that assessments supported their ability to apply knowledge to real situations (agreement rate 80-95%).

"The Medicines Australia Continuing Education Program is a fantastic way to understand the Code of Conduct and to guide and enhance our conversations with HCPs to support evidence based decision making and the quality use of medicines for their patients"

– 2022 CEP Award Winner Simon Kiker (AbbVie)

Whilst not part of the CEP, UTAS has responded to feedback from our members and in January launched a number of new "Just In Time training" modules which are 3-5 hours in duration, covering key concepts on vaccines as well as one fit for new sales representatives.

CEP Awards

Every year Medicines Australia celebrates 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](#). Each semester offers 10 CEP Achievement Awards, the Code of Conduct Award (awarded to the highest achiever in Program 1), and the University of Tasmania Prize for Excellence.

In April 2023 we announced the 2022 Award winners, which was well-reported in trade media and remains one of our most widely shared social media posts.

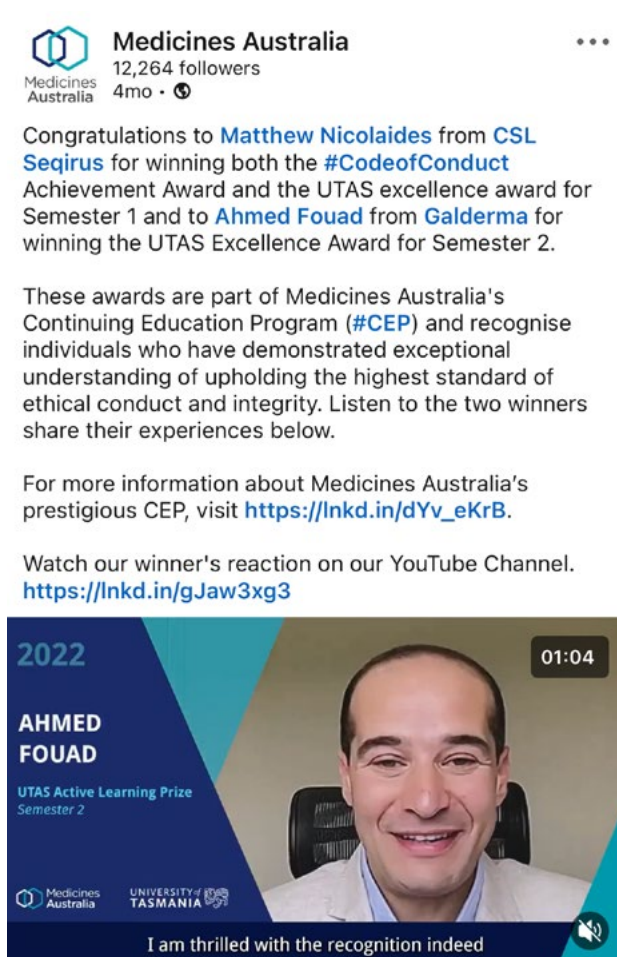


The CEP Awards for 2022 were announced in April 2023 – watch a 2-minute video highlighting their personal reflections and achievements.



“Medicine Australia’s CEP has helped me evolve from being just a target-oriented medical sales representative, to becoming a more conscientious, ethical and patient-oriented part of the bigger Australian health system. I am grateful not only for the recognition but more importantly for the valuable learning.”

– Joanne Catubay, CEP Achievement Award winner from DKSH



Governance

Effective implementation and administration of the Code of Conduct relies on the commitment, skill and professionalism of Medicines Australia staff and the Code, Appeals and Monitoring Committees, including valuable contributions of our members. Through the committees, lawyers, healthcare professionals and patient representatives contribute diverse perspectives to the work of our members, enabling our members to do better, to stay true to our values, and deliver ethical decisions in line with our Code. 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 recognises its place as a global leader in ethical behaviour in the innovative medicines industry. We remain a signatory to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code

of Practice and ensure its principles are reflected within our Code. Through our involvement with eBIC – the Ethics and Business Integrity Committee of the IFPMA, we contribute feedback to emerging advice; such as the [2023 update of the IFPMA Note for Guidance on sponsorship of events and meetings](#). Just as our Code Committee incorporates member representatives to adjudicate complaint, Medicines Australia's Ethics & Compliance team performs a member role in the adjudication of global complaints.

The Code supports our regulatory framework and is consistent with the Therapeutic Goods Act. The past year has seen a multitude of activities, and opportunities which have enhanced compliance across the industry. The Therapeutic Goods Administration is a key stakeholder and attends adjudication processes as observers.

By behaving ethically and working transparently, through the effective governance and administration of our Code, our members strive to provide access to our medicines in an environment which is sustainable and fair.

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 proudly sponsored seven medical students who have since graduated. We sponsored two students studying medicine at UNSW this financial year which brings the total to \$280,259 in funding for Shalom Gamarada since 2015.

The two students we currently sponsor are Anne Dillon and Jorge Hormovas. Their student profiles can be found on the [website](#).



Images: Anne Dillon (left), Jorge Hormovas (right).

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:

| | |
|--------------------------|---|
| Patrick Desbiens (Chair) | Director, Medicines Australia |
| Tamara Dawson | Founder, Director Melanoma & Skin Cancer Advocacy Network |
| Glenys Beauchamp | Formerly Secretary, Departments of Health and Industry |
| Greg Allen | Finance Manager, Epworth Freemasons Hospital |
| Renae Beardmore | CEO, EvoHealth |
| Richard Tew | Pharma Country Head and Country President Australia and New Zealand |
| Leigh Farrell | Executive Advisor, Certara C-Suite |
| Richard Vines | Chairman, Rare Cancers Australia |

Former members serving from 1 July 2022 – December 2022:

| | |
|----------------------------|---|
| Jane Hill | CEO, Ovarian Cancer Australia |
| Kelly Constable | CEO, AULUS Partners |
| Belinda Wood | Senior Director Government Affairs ANZ, Gilead Sciences |
| David Norton | Formerly Chair, Global Pharmaceuticals, Johnson & Johnson |
| Dr Anna Lavelle AM (Chair) | Chair of the Board, Medicines 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

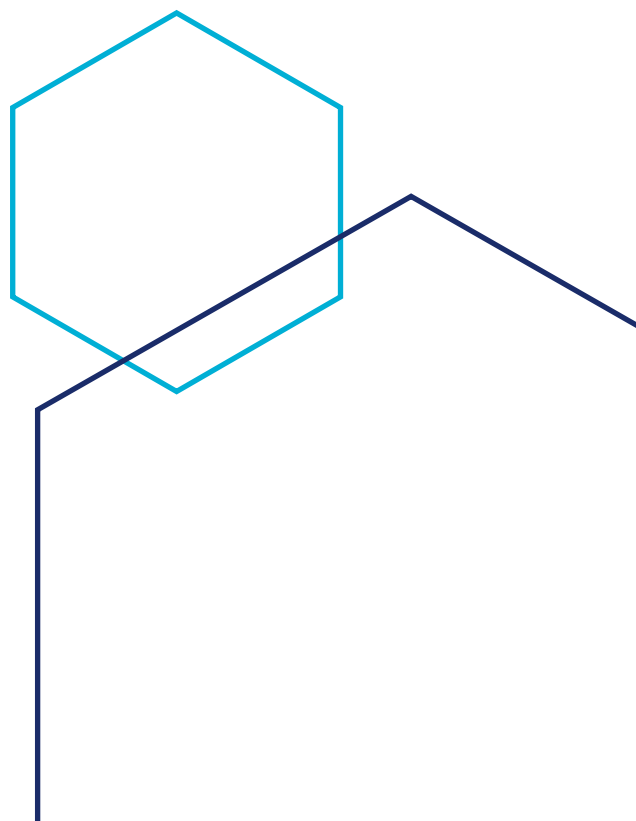
A focus on company risks is a specific responsibility of the Finance, Risk and Audit Committee. The Executive and staff review and assess risk frequently in terms of business environment, work health and safety, financial sustainability, internal control, program delivery and reputation. Internal audit 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 Managing Director 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 Roadmap guides the Board's priorities which are cascaded down to annual scorecards setting out KPIs against which the Board assesses the Executive and its performance in conjunction with member feedback. The KPIs also measure, independently, the performance of the Board. The performance of the CEO is evaluated annually by the Board Chair and the Chair of the Performance, Nomination and Remuneration Committee, with recommendations then made to the Board.

Staff performance evaluation

Each year, all staff commit to a planning and development agreement with their manager which sets out individual priorities and goals aligned to the corporate plan and strategic roadmap. 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.

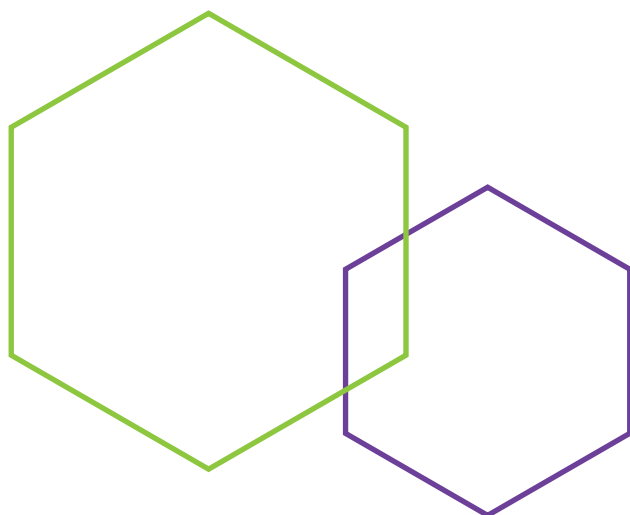
Fair and responsible remuneration

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 are reviewed annually by the CEO in the context of performance outcomes with recommendations made 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.

Standing Working Groups

SASC

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

Members of SASC as at 30 June 2023:

| | |
|-------------------------------|----------------------|
| Anne-Maree Englund (Co-Chair) | Medicines Australia |
| Ian Noble (Co-Chair) | Amgen |
| Alex Best | Janssen |
| Colman Taylor | HTAnalysts |
| Gabbie Reppen | Lilly |
| Greg Cook | Bristol Myers Squibb |
| Julie Ellis | Menarini |

| | |
|-----------------|--------------|
| Louise Graham | Pfizer |
| Megan Bohensky | BeiGene |
| Nicola Richards | MSD |
| Sarah Bridge | Bayer |
| Vanessa Stevens | Vifor Pharma |
| Wade McMonagle | AbbVie |

Health Economics Working Group (HEWG)

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

Members of HEWG as at 30 June 2023:

| | |
|------------------------------|----------------------|
| Julia Lewis (Co-Chair) | AbbVie |
| Heather Wrightman (Co-Chair) | Medicines Australia |
| Louise Graham | Pfizer |
| Lucas Tocchini | Biogen |
| Megan Bohensky | Beigene |
| Peter Germanos | Boehringer Ingelheim |

| | |
|---------------|-----------|
| Sarah Bridge | Bayer |
| Allan Wu | Merck |
| Brandon Jones | Janssen |
| Louise Larkin | Eli Lilly |
| Byron Muntz | Novartis |

Immediate past members:

| | |
|---|-----------|
| Vanessa Stevens (Co-Chair, to 30 June 2023) | CSL Vifor |
| Paul Alexander | Roche |

| | |
|----------------|----------------------|
| Michael Haberl | GlaxoSmithKline |
| Greg Cook | Bristol Myers Squibb |

Consumer Advocacy Working Group (CAWG)

The CAWG's focus is to ensure patient voices are involved, valued, and embedded in healthcare decision-making. The CAWG aims for the patient community and the pharmaceutical industry to have a respectful working relationship.

Members of CAWG as at 30 June 2023:

| | |
|--------------------------|----------------------|
| Petrina Keogh (Co-Chair) | Medicines Australia |
| Cathy Sertori | AstraZeneca |
| Hayley Andersen | Bristol Myers Squibb |
| Jamie Nicholson | Roche |
| Katherine Tocchini | Novo Nordisk |

| | |
|-------------------|---------|
| Todd Stephenson | Janssen |
| Fiona Savio | Amgen |
| Gabrielle Bietola | Sanofi |
| Paula Dry | Takeda |
| Vanessa Stevens | Vifor |

Government Working Group (GWG)

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

Members of GWG as at 30 June 2023:

| | |
|-------------------|--------------------------------|
| Gail Morgan | Medicines Australia (Co-Chair) |
| Alison Crosweller | Janssen |
| David Thomson | Amgen |
| Fiona Tigar | Biogen |
| James McAdam | Bristol Myers Squibb |

| | |
|--------------|---------------------|
| Josh Bihary | Pfizer |
| Martin Snoke | Roche |
| Monica Saba | Bayer |
| Stacey Bolto | Novartis (Co-Chair) |
| Sam Howes | Organon |



Regulatory Affairs Working Group (RAWG)

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

Members of RAWG as at 30 June 2023:

| | |
|----------------------------|---------------------|
| Eric Johnsson (Co-Chair) | Medicines Australia |
| Helen Critchley (Co-Chair) | Sanofi |
| Michael Parker (Co-Chair) | AstraZeneca |
| Ailsa Surman | Amgen |
| Brian Hewitt | Pfizer |

| | |
|-----------------------|----------------------|
| Mary Flannery | Bayer |
| Marina Gebara-Coghlan | Boehringer Ingelheim |
| Kirpal Kaur | BMS |
| Sean Abel | Menarini |
| George Lillis | Novartis |

Medicines Australia Vaccination Industry Group (MAVIG)

The Medicines Australia Vaccination Industry Group (MAVIG) provides advice and support related to the registration and funding of vaccines and aims to enhance processes and policies supporting a strong evidence-based vaccines sector.

Members of MAVIG as at 30 June 2023:

| | |
|------------------------------|---------------------|
| David Pullar (Co-Chair) | GlaxoSmithKline |
| Heather Wrightman (Co-Chair) | Medicines Australia |
| Crissa Kyriazis | Biointelect |
| Dylan Jones | MSD |
| Sarah Lindeman | Sanofi |

| | |
|------------------|-----------------|
| Valda Struwig | Pfizer |
| Vanessa Xavier | Sanofi |
| Penelope Kaltzis | GlaxoSmithKline |
| Andrew Thirlwell | Pfizer |
| Candice Burch | AstraZeneca |

Rare Diseases Working Group (RDWG)

Medicines Australia has formed a new Rare Diseases Working Group (RDWG). The new group has replaced the Rare Disease Industry Working Group, which previously operated outside the Medicines Australia structure. The RDWG's vision is to create a sustainable, world-leading healthcare system that makes a meaningful difference to the lives of Australians living with a rare disease. This includes amplifying the importance of early screening and diagnosis; and fast, equitable access to innovative medicines.

Members of RDWG as at 30 June 2023:

| | |
|-------------------------------|---------------------|
| Kathryn Evans (Co-Chair) | BioMarin |
| Constantine Tablan (Co-Chair) | Medicines Australia |
| Nicole Gaupset | Alexion |
| Warren Brooks | Ipsen |
| Anne-Maree Englund | Medicines Australia |
| Eric Johnsson | Medicines Australia |
| Julie Ellis | Menarini |

| | |
|----------------|------------------|
| Valda Struwig | Pfizer |
| Nikhil Jayaram | PTC Therapeutics |
| Kylie Earle | Sanofi |
| Sophie Schultz | Takeda |
| Penny Lovell | UCB |
| Jo Atkins | Commercial Eyes |

Chief Financial Officer (CFO) Network

The Chief Financial Officer (CFO) Network is an open group for member company representatives. Three meetings were convened during the year to consider topical issues including, international tax updates, modern slavery legislation and reporting obligations, patent box, and critical infrastructure reporting. The network assisted with two submissions to Treasury regarding the Multinational tax transparency and Deductions for payments relating to intangible assets connected with low corporate tax jurisdictions exposure drafts.

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

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, agile Action Groups are convened as needed for areas requiring immediate focus. To date nine Action Groups have been convened: Horizon Scanning Forum, Consumer Engagement, Advocacy (Specialist Action Group), Process Improvement, HTA Technical, System Reform, Decision-Making Remit, Evidence Based Narrative, and Cell & Gene & Rare Disease.

Medicines Australia is grateful for the interest and enthusiasm that the members have shown for the Action Groups, and the significant amount of work which they complete in a short amount of time.

Four Action Groups were active as at 30 June 2023:

Horizon Scanning Forum

Following the first Horizon Scanning Forum held in December 2022, work is now progressing on the 2 recommendations that came out of the Forum, which is a deliverable in the new Strategic Agreement.

Members of the Horizon Scanning Action Group as at 30 June 2023:

| | | | |
|--------------------------|----------------------|---------------------|-------|
| Eric Johnsson (Chair) | Medicines Australia | Christine Pollicino | Roche |
| Greg Cook (SASC sponsor) | Bristol Myers Squibb | David Thomson | Amgen |

Advocacy Action Group

The advocacy action group supports the stakeholder engagement process for the HTA Review with mapping, messaging and feedback.

Members of the Advocacy Action Group as at 30 June 2023:

| | | | |
|-----------------------------|---------------------|-----------------|-----------------|
| Andrew Thirlwell (co-chair) | Pfizer | Irene Deltetto | HTAnalysts |
| Petrina Keogh | Medicines Australia | Karyn McIntosh | Sanofi |
| Ben Gommers | MSD | Lisa Julian | Lilly |
| Byron Muntz | Novartis | Luke Fitzgerald | GlaxoSmithKline |
| Emma St-Clair Pearce | Biogen | | |

Consumer Engagement

The Consumer Engagement Action Group works 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 2023:

| | |
|---|---------------------|
| 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 |

Cell & Gene and Rare Disease

The Cell & Gene and Rare Disease Action Group works to build Medicines Australia's position on cell and gene therapies as part of the HTA Review.

Members of the Cell & Gene and Rare Disease Action Group as at 30 June 2023:

| | |
|-----------------------|---------------------|
| Eric Johnsson (Chair) | Medicines Australia |
| Sara Pantzer | Consultant |
| Warwick Shaw | Janssen |
| Monique Jonson | Novartis |
| Kylie Earle | Sanofi |

| | |
|---------------------|-------------------------|
| Valda Struwig | Pfizer |
| Sophie Schultz | Takeda |
| Michelle Frost | Roche |
| George Papadopoulos | Lucid Health Consulting |

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 2023:

| | |
|--------------------|----------------------|
| Petrina Keogh | Medicines Australia |
| Andrea Kunca | Roche |
| Andrew Thirlwell | Pfizer |
| Angela Lai | Lilly |
| Anne-Maree Englund | Medicines Australia |
| Catherine Vaughan | Novartis |
| Dani Thut | Bayer |
| David Cain | Astellas |
| David Thomson | Amgen |
| Elise Kelly | Pfizer |
| James McAdam | Bristol Myers Squibb |
| Jan Lewis | AbbVie |
| Katrina Vanin | GlaxoSmithKline |
| Kylie Earle | Sanofi |
| Laura Issa | AbbVie |
| Liliana Chavez | Novartis |
| Matt Douglas | Bristol Myers Squibb |

| | |
|--------------------|-------------------|
| Matthias Brunner | Roche |
| Natalie Betts | Roche |
| Nicki Conway | Lilly |
| Pinky Dharmshaktu | Merck (Co-Chair) |
| Rebecca Stratford | AstraZeneca |
| Sally Ryan | Pfizer |
| Sophie Schultz | Takeda |
| Stephen Richardson | Sanofi (Co-Chair) |
| Annie Quan | Bayer |
| Elise Kelly | Pfizer |
| Kate Scott-Murphy | Novartis |
| Gregory Blanch | AbbVie |
| Nicola Richards | MSD |
| Jingobo Li | MSD |
| Belinda Wood | Gilead |
| Fiona Savio | Amgen |
| Ben Gommers | MSD |



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) | Johnson & Johnson |
| 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) | Johnson & Johnson |
| David Fitz-Gerald | GlaxoSmithKline |
| Eleanor Clifford | Novo Nordisk |
| Fabienne Connect | Biogen |
| Fiona Sheppard | Johnson & Johnson Family of Companies |
| Gabby Reppen | Lilly |
| Ilona Alsters | Boehringer Ingelheim |
| Jacinta McCarthy | Healthcare Logistics/EBOS |
| Jason Strachan | Boehringer Ingelheim |

| | |
|--------------------|-------------|
| Jenn Jones | Takeda |
| John Kim | Vifor |
| Lisa Johnston | 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 Team

Please note this is a list of staff as at 30 June 2023.



Elizabeth de Somer
Chief Executive Officer



Anne-Maree Englund
Head of Strategic Policy
Implementation



Gail Morgan
Head of Strategic
Engagement and
Communications



Alison Bleathman
Head of Operations



Brent Weston
Finance Officer



Constantine Tablan
Policy Analyst



David Newman
ICT Manager



Eric Johnsson
Senior Manager, Industry
and Regulatory Policy



Gerry Rossiter
Executive Officer to the
CEO and Chair



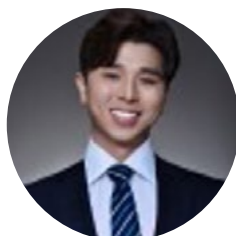
Heather Wrightman
Senior Manager Access
and Funding



Somi Jaafarino
Executive Assistant/
Office Manager



Claire Mazitelli
Ethics and Compliance
Officer



Theodore Seng
Communications and
Events Officer



Petrina Keogh
Senior Manager,
Stakeholder Relations



Sophie Seck
Manager, Ethics and
Compliance

Medicines Australia Membership as at 30 June 2023

Medicines Australia welcomes our new members who joined in 2022-2023:

Lucid Health Consulting – commenced March 2023

Daiichi Sankyo Australia Pty Ltd – commenced March 2023

PTC Therapeutics Australia Pty Ltd – commenced November 2022

Class 1

abbvie

AMGEN

astellas

AstraZeneca



BeiGene

Biogen

Boehringer
Ingelheim

Bristol Myers Squibb

Celgene

Eisai

GSK

IPSEN
Innovation for patient care

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Kyowa KIRIN

Lilly

MENARINI

MERCK

MSD

NOVARTIS

novo nordisk

ORGANON
Here for her health

Pfizer

Roche

sanofi

Takeda



Class 2



Class 3



Class 4



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 – Haematology Society of Australia & New Zealand

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

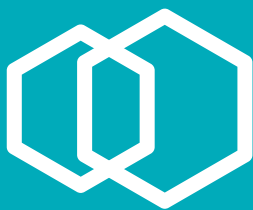
PSWG – Policy Scanning Working Group

PVI – Patient Voice Initiative

RAWG – Regulatory Affairs Working Group

SASC – Strategic Agreement Steering Committee

TGA – Therapeutic Goods Administration



Medicines
Australia

Better health
through research
and innovation

www.medicinesaustralia.com.au