Medicines Australia

Better health through research & innovation

Annual Report

2023–2024

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.

Contents

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 as a result 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 Roadmap 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 agreed 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.

Chair's report

On behalf of the Medicines Australia Board, I am pleased to present the Annual Report for the 2023–24 financial year.

This report reflects a year of progress, unwavering unity of purpose and our collective commitment to advancing healthcare and access to world-class medicines, biotherapeutics and vaccines for all Australians.

As I write, industry, patients and clinicians are awaiting the release of the Health Technology Assessment (HTA) Review. This will mark a significant milestone for industry and delivers on one of the key achievements of Medicines Australia's 2022–27 Strategic Agreement with the Commonwealth Government.

Throughout 2023–24, the HTA Review has been a priority for industry due to the long-term and transformational benefits for Australians that can be realised through bold reform and timely access to the latest and best treatments.

It has been essential for industry to have a seat at the table, which we achieved through the appointment of Medicines Australia CEO Liz de Somer to the HTA Review Reference Committee. Liz has done a remarkable job representing industry, under the guidance and leadership of the Medicines Australia Board, in a challenging forum, and I thank her for taking on this significant task.

There is now real momentum for modernising Australia's HTA system and the impetus for change has never been stronger. We know there is strong support from Government, the Opposition and Independents for real reform.

As we move from review into implementation, we stand ready to face the new and inevitable challenges. This year has shown that with good evidence, policy rigour, and a united industry that stays the course, we can get results for Australians.

As Chair I am impressed of the dedication shown by Directors. Despite heavy workloads they have taken on the tasks of ongoing governance improvements, strategic positioning and faced many difficult issues that confront any organisation seeking complex system reform. The effort takes people with courage as well as a sense of what is best for the whole industry and the country, particularly the patients we serve. The members can feel reassured that directors have taken positions that optimise our ability to negotiate and achieve change.

> **There is now real momentum for modernising Australia's HTA system and the impetus for change has never been stronger.**

I thank all past and current members of the Medicines Australia Board for your invaluable contribution over the last 12 months, the leadership and team at Medicines Australia, industry members who have contributed invaluable knowhow to working groups and issue specific committees and all members for your ongoing support.

Dr Anna Lavelle AM
Chair

CEO's report

To our Members and our stakeholders, it is with pleasure that I present the Medicines Australia Annual Report for the year 2023–2024.

This year has been one of significant progress for Australia's innovative pharmaceutical industry. Our vision to make a tangible difference to the health of Australians, by ensuring their access to innovative and world class medicines has remained at the heart of everything we achieved.

The Health Technology Assessment (HTA) Review has been the industry's priority and therefore Medicines Australia's priority for the year. Thank you to all members for their contribution to the consultations and submissions, extensive advice and support to Medicines Australia, and to Medicines Australia's Directors who provided strategic advice and counsel at each stage of the Review's work.

This Review is timely in putting a spotlight on the many areas of the HTA system that are inefficient, unnecessarily duplicative or complex, not recognising the true value of innovation and not inclusive of the patient voice. The current system delays patient access to new medicines and it must be reformed.

Our policy, stakeholder engagement and communications activities were geared to progressing the Review. I want to thank all stakeholders that engaged with the Review and particularly patient organisations that spent time writing valuable and insightful submissions and advocating for reform. Enhanced consumer engagement is critical to health outcomes.

The #StrongerPBS campaign, the first time industry has sought to have a long-term conversation with Australians about the importance of the Pharmaceutical Benefits Scheme (PBS), was another year's highlight. Powerful patient and clinician stories about the importance of the PBS and the impact of delayed access to new medicines have seen us reach nearly 4 million Australians over the year and supported our HTA Review efforts.

As we await the Review outcomes and move into reform implementation, Medicines Australia will continue to consult broadly and engage with Members and other stakeholders to maintain momentum.

In working to ensure our HTA system is fit for purpose to handle new and transformative therapies coming through global pipelines, we held our second Horizon Scanning Forum demonstrating we are now in a turbo-charged era of innovation. Effective horizon scanning is critical and we expect the Review will enable ongoing horizon scanning.

While industry was primarily focussed on HTA reform, other issues continued to progress, with significant achievements.

The May announcement by the Government of $80.8 million in funding for clinical trials, a centralised approach including $18.8 million for the One Stop Shop and the appointment of Prof Ian Chubb AC to lead this work is the outcome of decades of commitment by industry to improve our innovation system and provide earlier patient access to cutting-edge treatments.

Medicines Australia worked closely with the Therapeutic Goods Administration and the Department of Health on issues such as supply chain, stockholding requirements and compounding. We contributed to policy discussions and outcomes in the areas of Foreign Affairs and Trade; Industry, Science and Resources; Climate Change; and Environment and Water on issues of importance to Members.

The periodic review of the Medicines Australia Code of Conduct Edition 19 commenced in March 2023 and encompassed significant and systematic consultation with members and other stakeholders. Thank you to everyone that contributed to this important work on our Code that underpins the ethical conduct and strong reputation of our industry.

Again, I thank Members for your ongoing support, invaluable contribution and dedication to our industry and to Australia's healthcare system.

Elizabeth de Somer
Chief Executive Officer

Board of Directors

Thank you to the 2023–24 Board of Directors for your dedication and exemplary efforts. The Board that served between 1 July 2023 – 30 June 2024 includes:

Dr Anna Lavelle AM

Chair

Independent Director

Anne Harris

Managing Director

Pfizer Australia and New Zealand;

Cluster Lead

Pfizer Developed Asia

Adam Roach

Vice President, Head of Asia Pacific

BeiGene Australia Pty Ltd

Dirk Otto

General Manager

ANZ Boehringer Ingelheim Pty Ltd

Gabi Mittas

General Manager ANZ

Amgen Australia Pty Ltd

Professor John Skerritt AM

Independent Selected Director

Josie Downey

Managing Director

Merck Healthcare Pty Ltd

Lizzie Marett

Managing Director

Astellas Pharma Australia Pty Ltd

Nathalie McNeil

VP and Managing Director ANZ

Abbvie Pty Ltd

Patrick Desbiens

Senior Vice President & General Manager ANZ

GSK Australia Pty Ltd

Prashant Nikam

VP and Managing Director ANZ

Merck Sharp & Dohme (Australia) Pty Ltd

Urs Voegeli

Managing Director

Janssen ANZ

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.

Stuart Knight

Managing Director

Roche Products Limited;

Resigned 27 September 2023

Ashraf Al-Ouf

Managing Director

Bayer Australia Limited;

Resigned 19 October 2023

Working to accelerate access to new medicines for Australian patients

HTA Policy and Methods Review

The HTA Review is a key element of Medicines Australia's five-year Strategic Agreement (2022–2027) with the Federal Government, with the shared aims of reducing time to access of medicines for Australian patients, increasing the attractiveness of Australia as a first-launch country for new health technologies, and ensuring Australia's processes keep pace with rapid advances in science and health technology. The Review commenced in early 2023 and has been a key focus for the Board and the Executive. Medicines Australia CEO Elizabeth de Somer was a member of the Reference Committee, which ran two consultations throughout the Review, commissioned a number of expert academic papers and Departmental analyses, and conducted numerous 'deep dive' consultations with different stakeholder groups before preparing a final report with recommendations. This report was handed to the Minister for Health and Aged Care in May 2024.

Medicines Australia participated in many of the 'deep dive' consultations, supported by expert groups drawn from the membership, and also made a further submission to the second public consultation on the Reference Committee's Options Paper in February 2024. Medicines Australia considered that the Options Paper captured many of the recommendations that had been put forward by stakeholders throughout the review process, including options that offered an opportunity for transformative reform of our HTA system. However, some options were considered not to be appropriate for the final report.

Strategically, government relations activity was focussed on supporting the HTA Review via engagement with the Review decision makers (including the Department of Health and those with an interest in health policy), and keeping the Minister for Health & Aged Care, MPs, Senators and the Opposition briefed about progress. This allowed for early conversations and a wider recognition of the need for reform and new investment in the PBS. For example, ALP backbenchers asked about HTA Review progress in meetings, the Opposition asked questions in Senate Estimates about delays to the Review, and Dr Monique Ryan MP, Member for Kooyong, asked a question in question time:

> *The member for Kooyong has the call.*
>
> *Thank you. Speaker, I have a question for the Minister for Health. Minister, the approval and funding of new drugs and novel medical technologies in this country is too slow. Australians deserve best practise health care. But every week I hear from constituents in my electorate of Kooyong who are struggling to access emerging therapies for serious conditions. Today, on Rare Cancers Awareness Day, what assurance can we offer our constituents that the government is going to improve these processes?*

This then translated to social media posts amplifying concerns about time to access of new medicines.

Member companies were provided with talking points to assist in conversations with parliamentarians and HTA decision makers about the HTA Review. Messages about the Review – including the call for a Stronger PBS – were prominent at this year's PharmAus and Horizon Scanning events. HTA Reform was also central to Medicines Australia's budget asks. This year's launch of the Stronger PBS campaign also provided an opportunity to brief parliamentarians on HTA related issues while keeping them across the purpose and content of the campaign.

Further Stakeholder Engagement Briefings

Throughout the year, Medicines Australia held several briefings with key external stakeholders on policy priorities and issues, including the HTA review. These briefings provided a united industry voice and helped promote a collaborative, working relationship with the Australian health community. Medicines Australia remains actively engaged with stakeholders across the health ecosystem, including peak health bodies, clinicians, academics, and the patient community.

Highlights include:

- In February 2024, Medicines Australia hosted a webinar titled "Unpacking the Proposed Options for HTA Reform." The expert panel included Deidre Mackechnie from the Australian Patient Advocacy Alliance (APAA), Sharon Winton from Lymphoma Australia, and Petrina Keogh and Anne Maree Englund from Medicines Australia, and each shared their perspectives on the HTA options paper. The event was well attended by representatives from over 80 patient groups.
- In May 2024, Medicines Australia organised a post-Budget briefing followed by a networking event at the National Press Club, attended by over 50 patient groups. The event provided detailed insights into key health measures and financial announcements, highlighting potential challenges and opportunities for the patient community. The evening concluded with valuable connections and discussions among attendees.
- Medicines Australia has actively engaged with Chambers and Embassies on HTA reform, seeking their support and collaboration. These discussions have highlighted opportunities for bold reform through the HTA Review, emphasising the significant contributions of European companies to the Australian health ecosystem. By exploring areas for improvement, Medicines Australia will continue holding discussions with the Chambers and Embassies to ensure Australia remains an attractive destination for foreign investment and a priority market for stakeholders in the health industry

Clinical Trials

Clinical trials play an important role in Australia's healthcare system by providing patients with access to the latest medical technologies. They also contribute to the economy by creating jobs and reducing healthcare costs for individuals and the Government. Furthermore, clinical trials bring investment into Australia's research and health sectors and offer world-class experience to Australian clinicians.

Our global reputation for research excellence has made Australia a preferred destination for companies wanting to conduct clinical trials. However, our federated clinical trials environment is fragmented and complex, and often acts as a barrier to investment and patient access to cutting-edge medical treatments.

Furthermore, clinical trials bring investment into Australia's research and health sectors and offer world-class experience to Australian clinicians.

The National One Stop Shop

Following decades of advocacy, including conversations over the past year with relevant Ministers, Medicines Australia welcomed the announcement by the Albanese Government of $80.8 million in funding for clinical trials. This includes $18.8 million for a centralised approach (the "One Stop Shop"). This is a significant step towards improving access to medicines for all Australians.

Members of the Research & Development Taskforce (RDTF) – a multi-sector collaboration between Medicines Australia, AusBiotech and the Medical Technology Association of Australia (MTAA) – have tirelessly advocated for the One Stop Shop initiative. The RDTF will continue to work closely with the Government to ensure the implementation of the National One Stop Shop remains fit for purpose now and into the future, with the Inter-Governmental Policy Reform Group (IGPRG) overseeing the next steps.

Horizon Scanning

Under our Strategic Agreement with the Commonwealth, Medicines Australia convenes an annual Horizon Scanning Forum to identify major therapeutic advances that may represent a significant disruption to the treatment paradigm and potential implications for the Commonwealth of the introduction of these advances, in terms of resources, systems and processes.

The second Horizon Scanning Forum, held on 22nd March 2024 in Canberra in the midst of HTA Review public consultations, highlighted the urgent need for reform to accommodate new therapies that are not years away, but are entering the market now.

Continuing with the theme of the first Horizon Scanning Forum held in 2022, the Horizon Scanning Action Group identified four therapeutic areas in which innovative new classes of treatments stand to disrupt treatment paradigms in Australia and require innovation in system planning: cell and gene therapies, vaccine technology for infectious diseases, novel antimicrobials, and digital technologies.

The Forum featured presentations and panel discussions which included perspectives from innovative pharmaceutical companies, researchers, patients and patient advisory groups across these four therapeutic areas. Consistent themes emerged from each session that highlighted the need for innovation in regulation, reimbursement, and delivery of medicines, vaccines and biopharmaceuticals.

The Forum attracted more than 230 delegates (in person and online), a significant increase in attendee numbers compared with 2022. Senior Executive representation included the Australian Government Chief Medical Officer, the Chair of PBAC, the Deputy Secretary of the Therapeutic Goods Administration (TGA), the Chief Scientist of Australia and the Chief Scientist of Western Australia (WA). Other delegates included CEOs and representatives from 15 patient groups: Senior representatives from State/Territory Health and Industry departments in NSW, QLD, VIC, ACT and WA including the Acting Chief Medical Officer and Acting Chief Pharmacist of the ACT. Representatives from leading hospitals and cancer centres also attended, including from the Royal Adelaide Hospital, Royal Perth Hospital, Mater Services Brisbane, Westmead Hospital, Peter MacCallum Cancer Centre, and Epworth Healthcare. Senior industry executives were well represented. The strong attendance provides further evidence of the demand for a nationally coordinated Horizon Scanning system in all areas of the healthcare industry.

Medicines Australia thanks our members for generously contributing their time and expertise through the Advisory Committee and insightful presentations at the Forum. We look forward to continuing to work with the Department of Health and Aged Care and Commonwealth Government to progress and entrench horizon scanning in this remarkable new era of medical research and therapy development.

Other elements of the Strategic Agreement

The Enhanced Consumer Engagement Process (ECEP)

The ECEP aims to integrate 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). This will assist the PBAC and other independent HTA advisory bodies to understand consumer-related implications of new technologies and innovations at an earlier stage.

This project was guided by a Co-design Working Group (CWG) consisting of consumer, industry (including Medicines Australia), and Department of Health and Aged Care representatives. Established in November 2023, the CWG conducted an open consultation on its proposed recommendations in March 2024. Feedback from this consultation has shaped the final recommendations, and the report has been provided to the Minister for Health & Aged Care for consideration.

Exchange and Sharing of Information with HTA Evaluators

Medicines Australia and the Department of Health and Aged Care have co-designed a process to facilitate the exchange and sharing of information between sponsors and evaluators early in the PBAC process to increase efficiencies. Until now, such information exchange has not been allowed. The process has now been agreed and a pilot is scheduled for the evaluation period in the lead up to the November 2024 PBAC meeting.

Rapid Post-Market Reviews

Medicines Australia and the Department of Health and Aged Care worked together on a revised Post-Market Review (PMR) Framework during the year, with the goal of improving the process and reducing the time taken for PMRs to 12 months or less. Following public consultation, the revised framework was implemented on 31 January 2024.

Strengthening the life sciences ecosystem and the value of innovation

Stronger PBS campaign

The Stronger PBS campaign was launched in September 2023 as a long-term consumer-facing education and awareness campaign about the Pharmaceutical Benefits Scheme and delays in access. The campaign provides a public-facing platform to drive our HTA reform priorities and provides the industry with a foundation to launch future campaigns on any issue that relates to access to medicines or the PBS.

The campaign is led by industry with support from patient advocacy groups and clinicians and tells the real-life stories of Australian patients who are waiting for funded access to life-changing medicines that are already available overseas. It also shares the stories of patients whose lives have drastically improved after being able to access the medicine they need, offering a deeper understanding of the broader benefits that medicines bring to society. Clinicians have also contributed to the campaign, sharing their concern of knowing new medicines exist that may be well-suited to a patient, but being unable to prescribe them if they are not yet on the PBS.

In addition to the social media activity across Facebook, Instagram, LinkedIn and Twitter/X, the campaign is being amplified with additional funding raised by a Special Interest Group (SIG) comprising 11 members of Medicines Australia. The SIG elected Ogilvy from a competitive tender process to develop an amplification strategy, including paid advertising on radio stations across Australia and in News Limited publications, and additional waves of activity that provide a focal point for content creation, media opportunities and awareness-raising.

Medicines Australia has played a key role in working collaboratively with other peak bodies to enhance health outcomes for all Australians. Including but not limited to Pathology Technology Australia (PTA), Australian Patient Advocacy Alliance (APAA), Royal Australian College of General Practitioners (RACGP), The Society of Hospital Pharmacists of Australia (SHPA) – now Advanced Pharmacy Australia, Pharmaceutical Society of Australia (PSA), Medical Technology Association of Australia (MTAA), Rural Doctors Association of Australia (RDAA) and Royal College of Pathologists Australasia (RCPA), The Pharmacy Guild of Australia, National Aboriginal Community Controlled Health Organisation (NACCHO), and The Australian Medical Association (AMA).

PharmAus

PharmAus 2023: Partnering for Future Health built on the significant health reform agenda of the current Government and set the scene for a soft launch of our Stronger PBS campaign.

The full-day event, held on 9 September 2023 in the Great Hall of Parliament House, Canberra, brought together more than 240 delegates for an afternoon of panel discussions and presentations followed by an industry showcase.

Led by experienced facilitator, former ABC journalist Virginia Haussegger, presenters including industry leaders, patients and patient representatives, and Department of Health and Aged Care representatives, discussed the bold reforms required to strengthen our PBS for Australian patients and explored opportunities for equitable partnerships.

The afternoon culminated in a lively panel debate between Parliamentarians: Jerome Laxale MP, Member for Bennelong; Hon Dr David Gillespie MP, Member for Lyne; Dr Mike Freelander MP, Member for Macarthur; Dr Gordon Reid, Member for Robertson; and Dr Anne Webster MP, Member for Mallee.

> **“The integration of patient stories into each session and throughout the breaks reminded delegates of the very real impacts that Australians experience every day while waiting to access the medicines they need.”**

The central themes throughout the day were the need for the Government, Health Department officials, patient advocacy groups, private sector and industry to partner more effectively to help Australians gain faster access to new medicines, and the significant opportunity for stakeholders to shape policy reform by participating in the HTA review.

The integration of patient stories into each session and throughout the breaks reminded delegates of the very real impacts that Australians experience every day while waiting to access the medicines they need.

A showcase by our innovative pharmaceutical company members was held in the evening, with health checks, entertainment, research and innovation on display for delegates seeking to learn more about the industry.


#StrongerPBS
Medicines Australia
PharmAus
#StrongerPBS


#StrongerPBS


Medicines Australia

Partnering with Government

Medicines Australia must ensure the long-term sustainability of our industry for the benefit of the Australian taxpayers. To that end, the pharmaceutical industry is an essential partner to Government across wide-ranging areas of policy where medicines, innovation, manufacturing, supply chain, climate, trade and international relations intersect.

Throughout this financial year, Medicines Australia has actively strengthened relationships across all areas of Government and worked proactively to ensure the early engagement of the pharmaceutical industry in relevant matters. Whilst the HTA Review was the focus of government relations for the year, advocacy on other issues continued. These included the implementation of the Strategic Agreement, stockholding arrangements, and issues related to 60-day dispensing and the potential flow-on impacts from the new Pharmacy Guild Agreement. It also included advocacy around packaging regulation, a proposed Life Sciences Council and the potential for a further reduction in the PBS co-pay.

Medicines Australia CEO Liz de Somer has made valuable contributions to significant working groups, committees and inquiries including: the Chief Medical Officers Advisory Group to Health and Climate Strategy, The Finance and Industry Ministers' Roundtable on Procurement, The National Reconstruction Fund's Industry Working Group on enabling capabilities, The Health Sector Critical Infrastructure Group to Home Affairs, the Strategic Industry Taskforce for the Manufacturing Industry Jobs and Skills Alliance, and Trade and Defence Trade Controls. This work positions Medicines Australia and the pharmaceutical industry in the centre of Government policy priorities.

Medicines Australia has also played a key role in establishing dedicated meeting days between the industry and the office of the Minister for Health and Aged Care to assist with coordination and discussions regarding our industry issues with the office. This has been well received by all stakeholders including members.

Medicines Australia is continuing to build upon our interactions with government including discussions with the Ministries of Foreign Affairs and Trade, Home Affairs, Climate, Defence and Industry and have commenced discussions with the Space Industry Association of Australia to insert the role of the pharmaceutical industry into the space industry – a government priority.

Policy Submissions

This financial year, Medicines Australia responded to multiple Government consultations, Parliamentary Inquiries and Hearings, and various key stakeholder consultations, showcasing our dedication to advancing the innovative pharmaceutical industry. Through these submissions and engagements, Medicines Australia strives to shape policies that foster industry growth, improve patient access to innovative medicines, and contribute to better health outcomes and economic prosperity in Australia.

Key submissions

The following are key submissions made by Medicines Australia and our members in 2023-24. These and additional submissions can be accessed on our website.

1. Improving Alignment between MRFF and MREA
2. National Health and Climate Strategy
3. Supporting Responsible AI
4. Equitable access to diagnosis and treatment for individuals with rare and less common cancers
5. Priorities for future improvements to Australian medicine labelling rules
6. Further details of proposed reforms to the regulation of vapes in Australia
7. The Australian Government's approach to negotiating trade and investment agreements
8. National Science and Research Priorities
9. Review of the National Freight and Supply Chain Strategy
10. Vaccines Indemnity Bill
11. Understanding our RNA potential: discussion paper
12. Unleashing the potential of our health workforce – Scope of practice Review
13. Active Ingredient Prescribing
14. Updated draft of the Companion Diagnostics (CDx) Guidance document
15. Exposure Draft Medicines, Poisons and Therapeutic Goods Regulation
16. COVID-19 Response Inquiry
17. Development of a joint National Health and Medical Research Council/Medical Research Future Fund Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research
18. Australian National Audit Office: Administration of the Pharmaceutical Benefits Scheme
19. HTA Review Consultation 2
20. Pre-Budget Submission 2023–24
21. The RDTF's Pre-Budget Submission Advocating for the National One Stop Shop
22. Repurposing of medicines TGA targeted consultation
23. TGA *Section 61* Consultation
24. Use of genetic testing results in life insurance underwriting
25. Proposed TGA fees and charges 2024–25
26. Medicine shortages in Australia – Challenges and opportunities
27. NSW Innovation Blueprint
28. Enhanced Consumer Engagement Process
29. The Draft Cost Recovery Implementation Statement (CRIS)
30. TGA updated draft companion diagnostics guidance document – public consultation
31. TGA Instructions for Use for Medical Devices
32. 12-Month Review of the Minimum Stockholding Requirements
33. Exposure Draft of the Defence Trade Legislation Amendment Regulations
34. Public Consultation of the Discussion Paper Towards the National Immunisation Strategy 2025–30

Of the 34 publicly available submissions, 14 particularly substantive submissions are described below:

The Australian Government's approach to negotiating trade and investment agreements

In the Joint Standing Committee on Trade and Investment Growth's Parliamentary Inquiry, Medicines Australia supported trade and investment principles aligned with international counterparts like ABPI (The Association of the British Pharmaceutical Industry) and EFPIA (The European Federation of Pharmaceutical Industries and Associations). To ensure transparency and accountability trade policies, Medicines Australia proposed that the Australian Government develop a legislative framework to establish a trade advisory committee and cleared advisor system, informed by the United States model. This was included as the first recommendation in the interim report.

Understanding our RNA potential: Department of Industry, Science and Resource – discussion paper

Our submission reiterated the importance of ensuring the entire innovative medicines ecosystem (e.g. research and development, supportive intellectual property system, national coordination, effective and efficient regulatory and reimbursement policies and processes, etc.) is structured to support and drive the medicines, biopharmaceutical and vaccines industry in Australia.

Australian National Audit Office: Administration of the Pharmaceutical Benefits Scheme

During late 2023 and early 2024, the Australian National Audit Office (ANAO) undertook an audit of PBS administration. In its response to the audit, Medicines Australia highlighted the need shift focus from cost containment to investment, to improve access to new treatments for Australian patients. The Department of Health and Aged Care (DoHAC) has managed PBS costs through price reductions for older medicines, reinvesting savings into new ones. While this has kept PBS spending stable, it has also led to low medicine prices, which has affected the time from registration to PBS listing for these medicines.

HTA Review Consultation 2

Medicines Australia submitted its response to Consultation 2 of the HTA Review in February 2024. The consultation focused on an Options Paper prepared by the HTA Review Reference Committee. Medicines Australia noted that the paper captured the issues and included many recommendations that had been put forward by stakeholders, including those in Medicines Australia's HTA Roadmap of Reforms. Medicines Australia noted, however, that there were five options that would be detrimental to patient access or would fail to recognise value and choice, and that these should not appear in the Reference Committees final report.

Medicines Australia's Pre-Budget Submission 2024–25

In Medicines Australia's Pre-Budget Submission 2024–25, the key recommendations included implementing a comprehensive suite of policy reforms to Australia's HTA system to ensure Australians have equitable and timely access to new medicines. Medicines Australia also recommended that PBS spending data in the budget papers are disaggregated so that investment in innovative medicines can be more easily tracked, and the impact of HTA reform can be measured.

The RDTF's Pre-Budget Submission Advocating for the National One Stop Shop

The RDTF urged the Government to provide appropriate and sustainable funding to the National One Stop Shop for clinical trials in the 2024–25 Federal Budget, so that Australian patients obtain access to the latest medical therapies and for the country to remain a globally competitive R&D destination, benefiting both Australian patients and the economy. The Albanese Government announced $18.8 million in the Federal Budget 2024–25 to fund the development of the National One Stop Shop.

Repurposing of medicines TGA targeted consultation

Medicines Australia supports the repurposing of medicines where appropriate and recognises the benefits to patients of broadening access for indications where limited options exist.

The proposed framework lacked detail, making it difficult to understand how the program will be implemented in practice. Notwithstanding this, Medicines Australia highlighted that the Therapeutic Goods Administration (TGA) should work with the Office of Health Technology Assessment (OHTA) to undertake an early review of the opportunities and barriers for reimbursement for the repurposed medicine. Any process for repurposing of medicines should also ensure that unintended consequences are avoided, such as impeding the commercial viability of bringing a medicine to market outside of the MRP.

Use of genetic testing results in life insurance underwriting

Medicines Australia supported legislating a ban, without limits, caps or exceptions for the use of genetic testing results in life insurance underwriting, a regulatory intervention similarly in place in Canada. Anything less will create uncertainty for consumers and prevent patients from accessing critical healthcare and participating in life-changing research.

Proposed TGA fees and charges 2024–25

Medicines Australia did not oppose the inflation-based increase of 4.7% to the TGA's fees and charges for the 2024–25 financial year. However, there was opposition to the increase to annual charges beyond the inflation increase of 4.7% to fund the TGA's digital transformation and enhancement of the Unique Device Identification (UDI) system. Further clarification was sought on the new fees to request variations to conditions of listing and registration of medicines. This prompted the TGA to delay this fee to 1 January 2025, so it could better prepare its guidance for industry and processes in preparation for its introduction.

Medicine shortages in Australia – Challenges and opportunities

Medicines Australia provided an overview of industry's approach to managing shortages and discontinuations, including challenges and opportunities. This submission also stressed the importance of communication between government departments for effective management of medicines shortages. This approach fosters cooperation, enhances our medicine supply chain resilience, and ensures timely access for all Australians.

NSW Innovation Blueprint

The value of pharmaceutical manufactures exports in 2019–20 was ranked second, only to aluminium, with an export value of $3.6 billion – a 22% increase on the preceding financial year. The innovative pharmaceutical industry therefore presents a significant opportunity for the NSW Government. However, reforms to address the existing structural barriers to innovation are needed. Barriers in need of reform include intellectual property rights, a national one stop shop for clinical trials and health technology assessment policies and processes reform.

Enhanced Consumer Engagement Process

In the consultation for the Co-design of an Enhanced Consumer Engagement Process for health technology assessment, Medicines Australia advocated to enhance consumer engagement throughout the lifecycle of medicine and ensure greater transparency in the utilisation of consumer evidence by HTA agencies, it is imperative to establish a robust and formal consumer engagement framework. The current PBAC process lacks mechanisms for providing direct feedback on the outcomes and the value of consumer evidence in the overall decision-making process.

The Draft Cost Recovery Implementation Statement (CRIS)

Medicines Australia provided feedback to the Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP 1 July 2024 – 30 June 2025. It was noted that a number of fee increases proposed were significantly higher than the CPI increase of 3.5%, which was driven primarily by capital costs (depreciation in IT). Medicines Australia also called for fee waivers for orphan products for all submissions, not just the first one; and more time for the implementation of fee increases to allow for better business planning.

Exposure Draft of the Defence Trade Legislation Amendment Regulations

In this joint submission with MTAA, the lack of industry consultation during the drafting of the amendments to the Defence Trade Controls Act 2012 was highlighted. Changes in this Act add complexity and uncertainty with severe consequences for non-compliance for sponsors conducting trials that may fall under the Defence and Strategic Goods List. This could negatively impact clinical trials and life science research commercialisation in Australia. Medicines Australia and MTAA proposed clear exemptions for clinical trials in the regulations to provide multinational sponsors the assurance needed to conduct trials in Australia without facing unintended penalties.

Stakeholder Engagement

ARCS 2024 conference

Medicines Australia CEO Liz de Somer, Head of Strategic Policy Implementation Anne-Maree Englund, and Senior Manager Ethics and Compliance Sophie Seck delivered presentations at the ARCS 2024 conference on HTA reform, the Code of Conduct review, policy implications for the convergence of technologies, and cell and gene therapies.

Women in Life Science

The NSW Women in Life Sciences Luncheon, co-hosted by AusBiotech and Medicines Australia, was held on International Women's Day, 8 March, to celebrate women's achievements, support efforts to remove barriers, and build a better future for all. Medicines Australia also sponsored the Big Sisters program, which invites leaders in the sector to connect with individuals aspiring to advance their careers in life sciences. This program offers practical and tangible support to encourage women in the late stages of their studies to pursue careers in the life sciences.

Cell & Gene catalyst

Medicines Australia and AusBiotech have partnered to establish Australia's Cell and Gene Catalyst, a joint venture aiming to accelerate the development, manufacture and commercialisation of cell and gene therapies, including RNA, to ensure everyone in Australia has access to advanced therapeutics.

In September 2023, Dr Margeurite Evans-Galea AM was appointed inaugural Director of the Catalyst. With the support of an Expert Steering Group comprising influential industry leaders in cell and gene therapies, business development and policy, five strategic objectives have been set:

1. Attract, build, and retain world-class talent.
2. Collaborate across the value chain.
3. Secure long-term investment in the sector.
4. Create a clear market access pathway aligned to leading global markets.
5. Build Australian capability and capacity across the cell and gene value chain.

Following the Steering Group's establishment and the appointment of a dedicated Director, the Catalyst's workplan priorities for the next 24 months were determined and three expert working groups formed. These three Expert Working Groups collaborate with the Catalyst team and the Steering Group to support the Catalyst's strategy implementation in three priority areas:

- Policy and advocacy
- Collaboration and knowledge-sharing
- Workforce development

Throughout 2023-24, work continued to raise the profile of the Cell and Gene Catalyst in state, national and international forums and position as a potential strategic partner to bring the ecosystem together and capitalise on the significant opportunities present.

The Catalyst also made submission to key policy consultations including the HTA Review.

Vaccine Value Chain conference

Medicines Australia was a proud contributor sponsor of Biointelect's inaugural Vaccine Value Chain conference held in May 2024. Leaders along the vaccines value chain, from government, industry, academia, NGOs, and representatives from the immunisation community, participated in the important conference. The event examined the need for greater collaboration between all stakeholders in vaccine development to address public health needs and overcome barriers, accelerate access to technologies, and enhance public-private partnerships.

Omico Board representation

Omico is a national, independent, not-for-profit organisation, uniting Australia's world-class cancer institutes, researchers, clinicians, industry partners and government like never before. By leveraging a nationwide network of expertise and resources, Omico aims to improve outcomes for all Australian cancer patients. With fast-tracked molecular and genomic screening, biomarker-led trial set up and patient enrolment from the entire nation, they're accelerating access to next generation treatments and preventive strategies.

Following the departure of Mr Bruce Goodwin as a member of the MA Board, Omico offered the opportunity to nominate a replacement Board member as the MA Nominated Director. Dr Anna Lavelle AM was nominated by Medicines Australia in November 2023 and has served as a Director on the Omico Board since that time.

Parliamentary events

This financial year has been marked by active parliamentary engagements and a variety of impactful events hosted by patient groups. Highlights included the launch of the Arthritis Australia report, the Melanoma Skin Cancer Network breakfast advocating for a national screening program, and the Facioscapulohumeral Muscular Dystrophy (FSHD) Global Research Foundation showcasing the critical support they provide to the Australian FSHD community, and a press event urging the government to prohibit life insurers from using genetic testing information. These gatherings provided valuable opportunities for Medicines Australia representatives to engage in meaningful discussions about Health Technology Assessment (HTA) Reform and the industry's path forward.

Medicines Australia CEO Liz de Somer spoke at the 2023 BMS Patient & Parliament Summit, themed "Medicines For All: Unlocking Universal Patient Access". The event gathered key health sector voices to discuss and promote reforms as part of the HTA Review. Patients and representatives emphasised the need for timely access to medicines and patient-centred decision-making.

Memberships

Medicines Australia is a member of the following:

Continuity of Care Collaboration (CCC): The CCC is a pioneering initiative uniting health peak bodies, industry, and healthcare organisations to emphasise the importance of ongoing health monitoring for achieving optimal long-term outcomes. By integrating patient and consumer groups, industry leaders, and various health organisations, the CCC serves as a think tank for health promotion, advocacy, and the advancement of Australia's healthcare system, all supported by authoritative data.

Blood Cancer Taskforce: The Blood Cancer Taskforce is a group of leading haematologists, researchers, patients and members of the blood cancer ecosystem. It was established by the Leukaemia Foundation with the support of the Federal Government in 2019 to develop Australia's first National Strategic Action Plan for Blood Cancer.

International Engagement

Medicines Australia's CEO Liz de Somer, attended BIO2024 to continue international stakeholder engagement with members' global counterparts, strengthen ties with international sister associations and promote the announcement of the National One Stop Shop. Medicines Australia supported AusBiotech and BIO to convene an industry roundtable with the Minister for Industry and Science, the Hon. Ed Husic MP and global senior leaders from our member MNCs. The CEO met with the ABPI in London on the way to BIO2024 to discuss the HTA Review reform agenda and met with organisers of the Patient Centred Value Based Health Care conference.

Medicines Australia Supporting the Community

Medicines Australia is committed to supporting Australian patients by participating in fundraising and volunteering events. In this financial year, our People and Culture Committee organised the following opportunities for staff to get behind important causes while building stronger relationships with colleagues. Kosi Challenge 2024

Since its launch in 2013, the Kosi Challenge event – run by Rare Cancers Australia – has raised much-needed awareness about the challenges faced by patients with rare or less common cancers.

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 2024 Kosi Challenge, where the funds raised go towards Rare Cancer Australia's work of improving the lives and outcomes of Australians living with a rare or less common cancer.

The Medicines Australia Kosi team included Liz de Somer, Greg de Somer, Anne-Maree Englund, Jan Frieding, Heather Wrightman, and Con Tablan, who together raised $4,376.18 for Rare Cancers Australia. Over the past 11 years, Medicines Australia has raised over $50,000 in addition to the sponsorship of the 'Pharma Cup', a much coveted trophy awarded to the pharmaceutical company team who raise the most funds.

Medicines Australia supporting Ronald McDonald House

Ronald McDonald House Charities provides a 'home away from home' for families with seriously ill children receiving treatment at nearby hospitals. Their programs offer comfort, support, and resources, ensuring families can stay together during challenging times.

With some former chefs in the mix, a dedicated team from Medicines Australia generously spent their evening supporting Ronald McDonald House Charities ACT & South East NSW by preparing a heartfelt dinner for families with children undergoing medical treatment away from home.

The Medicines Australia volunteers sitting with the man himself, Ronald McDonald – from left to right: Gerry Rossiter, Clare Mazitelli, Con Tablan, Somi Jaafarino, Brent Weston.

Jeans for Genes Day

Jeans for Genes Day is an annual fundraising event where people wear jeans to raise awareness and funds for genetic research. The campaign supports the Children's Medical Research Institute in finding cures for children's genetic diseases.

Medicines Australia held a 'Denim and DNA' Trivia (complete with a denim themes playlist) to raise funds for Jeans for Genes Day, with some interesting facts about jeans, genetics, and a reminder of why we raised funds for this cause – because almost no genetic diseases have a cure!

Corporate Social Responsibility Shalom Gamarada

As part of Medicines Australia's Corporate Social Responsibility commitment, Medicines Australia continues to support the Shalom Gamarada Indigenous Residential Scholarship Program.

Established in 2009, the program is helping to close the gap between Aboriginal and Torres Strait Islander people with other Australians through higher education and by increasing the number of Indigenous healthcare professionals.

To date, Medicines Australia has sponsored seven medical students who have since graduated. This year, we continued to sponsor Anne Dillon, who is studying medicine at UNSW.

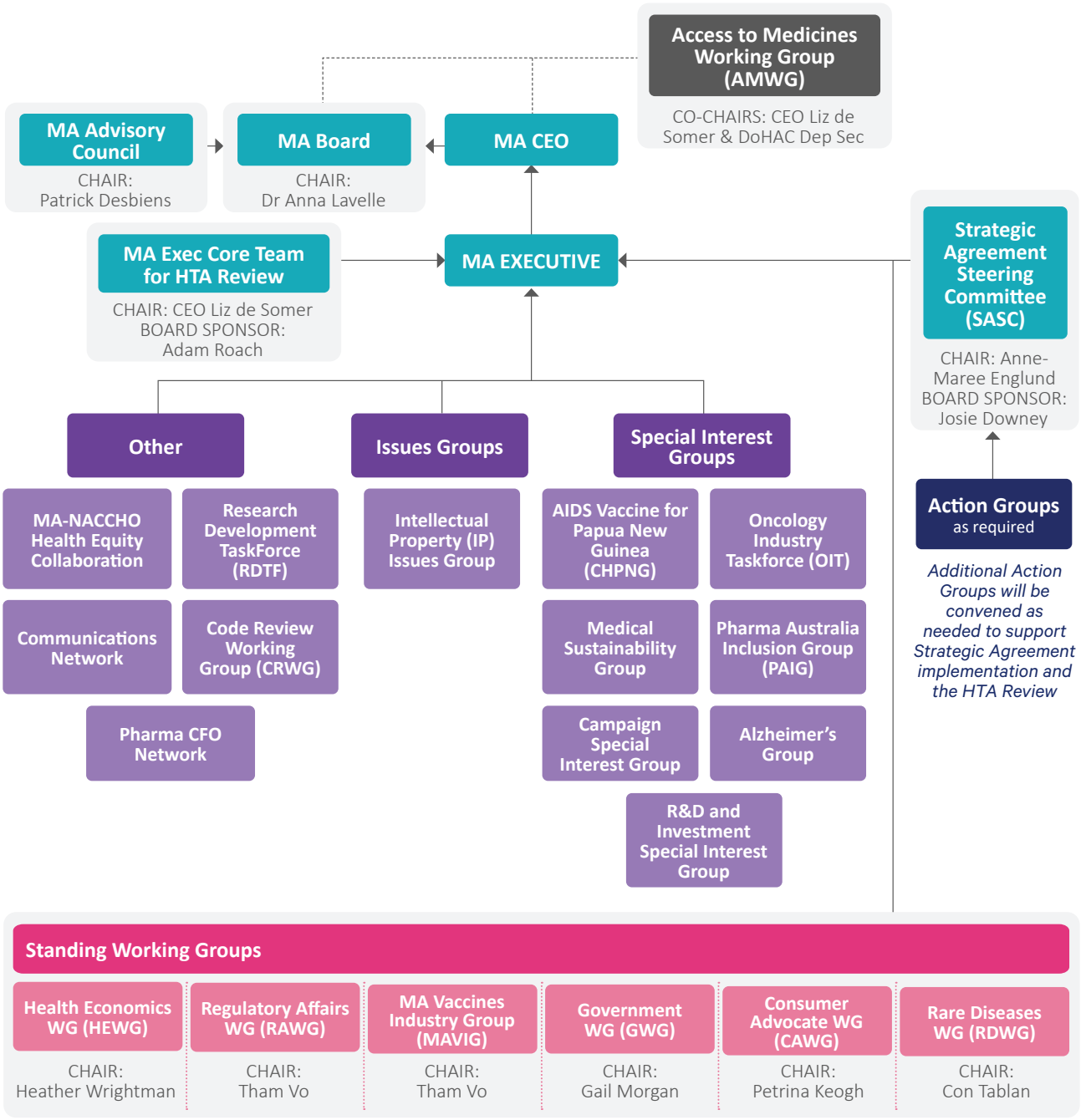
Anne continues to thrive at Shalom college, making strides both academically and personally. She is currently in her research year and is doing a psychology project. She is also a first aider at college and for John Ambulance Service NSW. Anne has also started flexing her artistic muscles and was recently extremely proud to have one of her artworks featured in a publication on Indigenous Health. Anne's confidence continues to develop in leaps and bounds: she gave the Acknowledgement of Country at the first formal dinner of the year, and she worked at the Medicine Review stall during O-week.

Medicines Australia has provided a total of $297,259 in funding for Shalom Gamarada since 2015.

Harnessing the power of our members

The achievements described in this Annual Report could not have been made without the remarkable contributions of our members. Medicines Australia acknowledges and thanks the commitment of all members to furthering the collective position of the Australian medicines industry on important national and international issues.

In particular, 20 working groups/networks/Committees/Special Interest Groups have been critical in helping achieve the membership goals by working alongside Medicines Australia staff and other key stakeholders. These groups have worked tirelessly over this past year to assist the Medicines Australia team work towards achieving our desired industry objectives. Over 150 members have kept these groups active and achieving. A summary graphic of the standing working groups is provided below and the list of individuals within each group are provided at the end of this Annual Report.



Medicines Australia members

Class 1

Class 2

Class 3

Class 4

New members

In 2023-24 Medicines Australia welcomed two new members- Kyowa Kirin as a class 1 member and Pulse Economics as a class 4 member.

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, GSK
Tamara Dawson	Founder, Director Melanoma & Skin Cancer Advocacy Network
Glenys Beauchamp AO, PSM	Former Secretary, Department of Health
Greg Allen	Finance Manager, Epworth Freemasons Hospital
Renae Beardmore	Managing Director, EvoHealth
Dr Leigh Farrell	Executive Advisor, Certara C-Suite
Richard Vines	Founder and Chair, Rare Cancers Australia
Dr Kathryn Evans	Managing Director, BioMarin Pharmaceuticals Australia
Sergio Duchini	Non-Executive Director
Anne-Marie Perrett	Governance Advisor and Non-Executive Director
Former members serving during the year but ceased before 30 June 2024.	
Richard Tew	Pharma Country Head and Country President Australia and New Zealand

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.

Professor John Skerritt AM

Independent Selected Director

Professor John Skerritt AM was appointed to the Medicines Australia Board as an Independent Selected Director in December 2023.

Medicines Australia Board Chair, Dr Anna Lavelle AM, said she was delighted to welcome Prof Skerritt's provide strategic leadership, informed by decades of government experience, at a pivotal time for the pharmaceutical industry.

As a former Deputy Secretary of the Australian Department of Health and Aged Care and former head of the Therapeutic Goods Administration, Prof Skerritt's knowledge of the Australian therapeutics regulatory environment is unmatched.

His deep understanding of government, and policy development and implementation, will be invaluable as Medicines Australia builds on the work undertaken to date with the Government on the reforms needed to speed up patient access to new medicines.] In June 2024, Prof John Skerritt, was appointed as a Member of the Order of Australia (AM). He has been recognised for significant service to public health administration and governance, and to scientific research which includes joint roles as head of the TGA and Deputy Secretary from 2012 to 2023.

Indeed, all Australians have benefited from his contribution to the therapeutic regulatory environment, clinical trials system and broader health system.

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, cyber resilience, program delivery and reputation. Internal audit reviews are undertaken periodically at the direction of the Finance, Risk and Audit 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 a performance evaluation annually of the entire Board and Chair. In addition, governance training is provided each year in a number of areas such as competition and consumer law, AICD governance requirements, advocacy strategies and other selected topics.

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.

Ethics and compliance

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. Our Code Edition 19 is no longer new; our industry has embraced the principles approach and the risk-based decision-making it encourages.

Ethics and Compliance activities in 2023–2024 continued to focus on supporting members and the wider industry in interpreting the Code and applying its relevant principles to different contexts. This is demonstrated by providing educational opportunities that provide the industry with thought-provoking ethical dilemmas, designed to illustrate the principles of the Code and how they could apply in real world situations. Facilitated by our Ethics and Compliance team, these opportunities ensure the industry stays engaged with our Code, while also providing a safe space for members to learn from each other and remain at the forefront of ethical leadership. Engagement in these ethical dilemmas also illuminates the maturity and breadth of expertise we have in our membership.

In 2024, the review of Edition 19 began in earnest. It aims to build on, rather than reproduce, the work undertaken during the last Code review and in the subsequent five years since. The review provides an opportunity to take stock of the Code and make improvements where they are identified to ensure the Code remains relevant, coherent, useful, and credible to members, the wider industry, and external stakeholders.

Complaints Handling – an effective reactive compliance mechanism

Medicines Australia received three complaints in 2023–2024, as detailed in the table below.

All complaints were adjudicated by the independent Code of Conduct Committee, with full details available on our website.
Industry learns from the publication of complaint outcome summaries. We also received one self-reported breach by a member, and a small number of other concerns were raised which were not adjudicated by the Committee because the concern was not in the scope of the Code, the complainant was anonymous, or the complainant did not want to utilise the complaints mechanism to resolve their concern.

Complaint	Subject Company	Complainant	Outcome	
1171	Member company	Member company	**No Breach** (Code Committee)	**Breach** (overturned by the Appeals Committee)
1172	Member company	Member company	**Breach**	**No Breach: Counter-complaint** (Abuse of the Code)
1173	Member company	Member company	**Breach** (Code Committee)	**Breach** (upheld by the Appeals Committee)

> **With Edition 19 of The Code being lean and principles-based, the complaints arising under Edition 19 are invaluable as learning opportunities; it's as though they act as case law or precedents to help us all understand how the principles are construed.**

Quote from Sarah-Jane Cozzi-Boyle, PhD MIPLaw, Medical Services Manager, Merck Sharp & Dohme (Australia) Pty Ltd

Monitoring Compliance – an effective proactive compliance mechanism

Medicines Australia received three complaints in 2023–24, as detailed in the table below.

Medicines 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. This year represents the full cycle of policies and procedure review; meaning that we now have reviewed the full cohort of our members approaches to Medical Representative Training.

The outcomes of reviews conducted by the Monitoring Committee in 2023–24 are as follows:

Review Activity	Subject area	Date	Number of members participating in the review	Outcomes
Policies and procedures	Hospitality provision to HCPs	July 2023	9	» 5 satisfactory » 4 were required to provide further clarification/information. On subsequent review, all were then satisfactory.
Promotional materials & HCP-only websites	Infections and Infestations	September 2023	7	» 4 satisfactory » 3 were required to make a change to the submitted material. On subsequent review, all were then satisfactory.
Policies and procedures	Interactions with non-HCP stakeholders	November 2023	11	» 7 satisfactory » 3 were required to provide further clarification/information. On subsequent review, all were then satisfactory.
Policies and procedures	Medical representative training (CEP)	March 2024	9	» 8 satisfactory » 1 was required to provide further clarification/information. On subsequent review, all were then satisfactory.
Promotional materials & HCO-only websites	Central Nervous System	May 2024	12	» 11 satisfactory » 1 was required to make a change to the submitted material. On subsequent review, all were then satisfactory.

There were no Code of Conduct complaints generated as a result of the above monitoring activities.

Transparency Reporting – building public trust

Interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. It is through making these interactions public that our membership meets societal expectations that interactions between corporations and society are not only conducted with integrity but are also transparent. Not only does it demonstrate our ongoing commitment to transparency, but it also enables our stakeholders to better understand the nature and extent of the programs we support – in the interest of increasing quality use of medicines, educating clinicians on the medicines we develop, and ultimately advancing patient care. This remains one of the key features that sets our members apart from non-members.

"Society has increasingly high expectations for transparency, none more so than in healthcare. Medicines Australia members meet those expectations and in doing so, strengthen the basis for increasing collaboration in the future" – Alison Bleathman – Medicines Australia.

Transfers of Value to Healthcare Professionals

All Members report payments and transfers of value made to healthcare professionals, available on www.disclosureaustralia.com.au. During this period, we published the 15th and 16th rounds of 6-monthly reporting since transparency measures commenced in 2015. The public remains interested in this data, with 95,415 searches undertaken since the launch of the searchable database in 2019, 23,287 of which were during this financial year.

- In terms of the number of interactions: 12,231 transfers of value reflecting an increase of 26% since the previous year.
- In terms of the cumulative value provided: $21 million, reflecting an increase of 46% since the previous year.

Virtual meeting attendance is diminishing, and payments/support extended to healthcare professionals to attend or speak at an educational meeting in person have bounced back significantly.

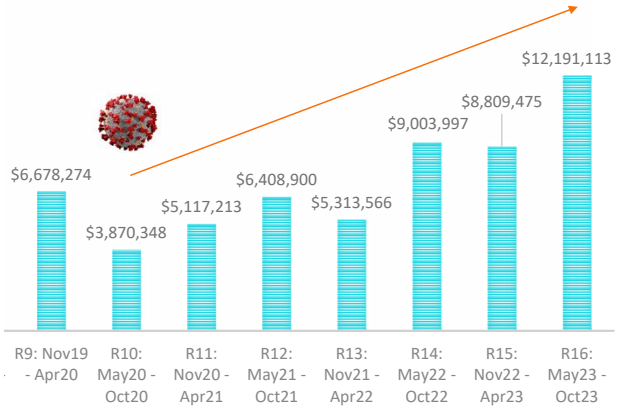
Third Party Meeting Sponsorship Reports

Our industry invests in the education of healthcare professionals through sponsorship of meetings and symposia organised by wholly and independently by third parties, such as colleges, universities and other recognised healthcare professional organisations. Companies ensure all sponsorship decisions are ethical and in line with the Code. Medicines Australia continues to publish sponsorships by members, available on our website.

During this period, we published the 15th and 16th rounds of 6-monthly reporting, reporting on a total of 2,934 sponsored independent events, delivering 20,845 hours of education to 616,150 healthcare professionals in those twelve months – an average increase across the board of 14% since the previous year.

Health Consumer Organisation Support Reports

In June 2024, Medicines Australia published the eleventh annual report of Members' financial support for Health Consumer Organisations (HCO). Members supported 130 different HCOs across Australia in calendar year 2023, ranging from national consumer organisations to small local groups, to the total value of $9,075,421.
This level of support represents the highest recorded and demonstrates the breadth of positive and beneficial relationships our industry has with the patient community.



Upskilling on Code- a year of educational opportunities

Medicines Australia supports the industry through educational activities so that members can understand and apply the Code in practice. These activities have been well attended, demonstrating not only a healthy engagement with the Code and also compounding its success as self-regulation.

1. Code Info Sessions x 4:
averaging 171 participants per session

Free, online and open to all and everyone, these webinars form an ongoing perpetual resource for our growing Code Resource Toolkit. 100% 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.

Pop up groups comprising members were responsible for developing the Balance Guidance.

2. New Code Guidance –by members, for members

Two pivotal Guidance documents were published in March 2024:

Communicating Ethically with patients and their representatives

Balance Guidance in product-related materials

Our members continue to drive and uphold our industry's ethical standards, including coming together to develop both sets of Guidance for pharmaceutical companies. They are fit for purpose because they link ethical conduct to the Code's principles, identify inherent risks, explore practical approaches to mitigate risks, and present decision-making checklists to help guide good decision-making.

Medicines Australia
Better health through research & innovation

Balance Guidance in product related materials

Edition 19 of the Code of Conduct requires that companies provide balanced information on products to support their appropriate use. This Guidance is designed to support and guide a company's ethical decision-making so they can achieve adequate balance in their product-related materials. However, this Guidance is not of equal standing to the Code, and each company has the responsibility to decide upon the appropriate level of information in their materials to ensure their materials are in line with the Code's principles and support proper assessment of a product's risks and benefits.

CONSIDERATIONS

- "Balanced" refers to "information presented in full, without bias". It is best thought of as providing equal importance to the benefits and risks of a product and recognizing that product and safety information are just as relevant as any claim*.
- The proportion of space available in the promotional material dedicated to the benefits versus the risks should be considered, however, there is no expectation that an equal amount of space needs to be dedicated to each.
- The **magnitude, number & type** of claims will alter balancing considerations.
- Rationale for selection of safety information should be guided by the relevance & recency of the safety balance to the claim being made and the objective of the piece. e.g. *If the claim is about prevention of worsening renal disease, then information that patients with severe renal impairment are contraindicated, should be included in the body of the piece.*
- Position and prominence of safety information should be considered relevant to the claim being made, the intention of the piece and it's audience.
- The age of the product: healthcare professionals will not be familiar with 'new' Australian products and therefore there are higher expectations to provide as much information as possible to support their appropriate use.
- The complexity of the medical condition being treated.
- Boxed Warnings/black triangle/safety concerns for the patient population.

* Claim refers to all types of claims, including therapeutic claims, promotional/non-promotional claims.

WATCH-OUT QUESTIONS

- Is the safety and risk information consistent with the medical condition?
- Is the safety information relevant to the claim?
- If viewed in isolation, would the claim be misleading?
- Does it emphasise the benefits whilst downplaying the risks?
- Is it misleading (by omission) or imbalance?

Taken as a whole, are we accurately representing the risks and benefits of the product?

Published March 2024

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3. Code Help Desk

Our team answered 340 Code-related questions and provided confidential non-binding guidance to the industry. This advice comes with no strings attached; it ensures industry is supported in navigating their application of Medicines Australia's principles-based Code. Advice is provided to all stakeholders: 55% of enquiries came from outside our membership. Providing this wider service beyond the membership helps ensure consistent compliance across the industry.

Member feedback:

"My sincerest thanks to the CodeHelpDesk for your comprehensive reply. I fully agree with your interpretation and approach. It's great to sanity check these things with you."

"Your advice is extremely useful and provides added nuance to how to interpret the Code. It is not easy!! But your explanation is very clear, it is also thought provoking and educational. Thank you so much for taking the time to help me with this query."

Over the year, a snapshot of Medicines Australia educational & engagement activities include:

NOTES FROM THE HELP DESK ARTICLES X 13

each article averages **93** unique views from our membership

an increase of over **50%** from the previous year.

OPPORTUNITIES TO JOIN THE MONITORING AND CODE COMMITTEES

19 invitations accepted by members

A RESPONSIVE CODE HELP DESK

over **340** pieces of considered advice given

CODE COMPLIANCE NETWORK

3 meetings with an average of **50 members** attending each session.

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 2023–2024, 909 individual students enrolled in one or more programs offered under the CEP. Of this total, almost 600 enrolled in Program 1 – Code of Conduct, consistently the highest performing program. Forty three members attended the updated Bridging Course.

Surveys indicate that overall program satisfaction was exceptionally high across both semesters for all six core programs (range 87–95%), and students strongly felt that assessments supported their ability to apply knowledge to real situations (agreement rate 80–95%).

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 2024 we announced the 2023 Award winners, which was well-reported in trade media and remains one of our most widely shared social media posts.

The following students achieved outstanding results and demonstrated in-depth understanding of the pharmaceutical industry during their 2023 CEP studies:

Alexander Moore, PhD- UTAS Active Learning Prize (Semester 2) and a CEP Achievement Award (The Janssen Pharmaceutical Companies of Johnson & Johnson)

Ethan Ward- UTAS Active Learning Prize (Semester 1) and a CEP Achievement Award

Audrey Lee- Code of Conduct Achievement Award (Bristol Myers Squibb)

Hanson Lee- CEP Achievement Award (GSK)

Karen Lee- CEP Achievement Award (Gilead Sciences)

Elissa Loughnan- CEP Achievement Award (Allergan Aesthetics, an AbbVie Company)

Esme Munro- CEP Achievement Award (Servier Australia)

Matthew Nicolaides- CEP Achievement Award

Jay Randhawa- CEP Achievement Award (GSK)

Ivanka (Vanja) Ruvarac- CEP Achievement Award (GSK)

Anthea Wainwright- CEP Achievement Award

"The MA CEP course was so valuable for everyday execution of my professional role, the content was thorough, well thought out and has added to my confidence when engaging with medical professionals."

2023 CEP Award Winner
Alexander Moore (Janssen-Cilag)

Governance & Code Review

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. It is through the committees that 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 IFPMA's Ethics and Business Integrity Committee (eBIC), we contribute feedback to emerging advice. Further to this, we also played a key role as the IPMA started a review of their Code of Practice, leading one of the working groups which undertook a gap analysis of their Code and other global Codes.

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.

Review of Code Edition 19

Reviewing Edition 19 started in January 2024 and provides a timely opportunity to take stock of the principles-based Code and make improvements, should they be identified.

Expert guidance is provided by a Code Review Working Group made up of members, and with assistance by Deborah Monk, who returns in the capacity of Code Consultant for this review.

A published Consultation Paper kicked off the broad and inclusive consultation phase in April. It outlined 7 key questions to guide the first feedback round, to which we received over 50 written submissions. These informed the development of key recommendations to guide the first stage of drafting changes to Code Edition 19, which were shared with members in a series of Code Review Member Forums in June.

Code of Conduct Committee members

These Committees provide a robust and independent mechanism to hear and manage complaints made under the Code of Conduct, and to proactively monitor Member Company conduct. Authority is delegated to these Committees under the constitution. They are known colloquially as the Code, Appeals and Monitoring Committees, and their composition is dictated by the Code in ***Section 17.***

Code/ Appeals Committee	
Mr Michael Daniel	Independently appointed Chair
Ms Catherine Bembrick	Independently appointed Chair
Mr Jason Korke	Independently appointed Chair
Assoc Prof John Gullotta AM	Nominated by the AMA
Prof Arduino A. Mangoni	Nominated by the RACP
Dr Catherine Streeton	Nominated by the RACP
Prof Christian Gericke	Nominated by the RACP
Mr Peter Martin OAM	Nominated by the CHF
Ms Maryanne Maher	Nominated by the CHF
Ms Tara Le Flohic	Nominated by the CHF
Prof Ric Day AM	Nominated by the ASCEPT
Dr Joel Iedema	Nominated by the ASCEPT
Ms Tara Le Flohic	Nominated by the CHF
Prof Ric Day AM	Nominated by the ASCEPT
Dr Joel Iedema	Nominated by the ASCEPT
Dr Rod Pearce	Nominated by the AGPN
Ms Rowena Love	Observer from the TGA
Dr Michael Tam	Nominated by the RACGP
Dr Kelly Chenlei Li	Nominated by the RACGP
Dr Martine Walker	Nominated by the RACGP
Monitoring Committee	
Sarah Hyde	Independently appointed Chair
Mrs Helen Maxwell-Wright AM	Independently appointed Chair
Mr Paul Murdoch	Nominated by the CHF
Mr John Stubbs AM	Nominated by the CHF
Dr Rashmi Sharma AOM	Nominated by the RACGP
Dr Brian Morton AM	Nominated by the AMA

Medicines Australia Team

Elizabeth de Somer

Gail Morgan

Alison Bleathman

Anne-Maree Englund

Geraldine Rossiter

Gary Butcher

David Newman

Tham Vo

Constantine Tablan

Sophie Seck

Lucy O'Brien

Heather Wrightman

Clare Mazitelli

Kate McKeown

Petrina Keogh

Brent Weston

Staff As At 30 June 2024

Standing Working Groups

Working groups are essential to achieving our goals as a membership, they are a critical way in which members actively contribute and work together with Medicines Australia staff and stakeholders.

Strategic Agreement Steering Committee (SASC)

The SASC was formed in 2021 to assist Medicines Australia to deliver the ongoing Strategic Agreement commitments in accordance with the Board's strategic priorities, including the HTA Review.

Members of SASC as at 30 June 2024:	
Anne-Maree Englund (Co-Chair)	Medicines Australia
Ian Noble (Co-Chair)	Amgen
Colman Taylor	HTAnalysts
Gabbie Reppen	Lilly
Greg Cook	Bristol Myers Squibb
Julie Ellis	Menarini
Louise Graham	Pfizer
Megan Bohensky	BeiGene
Sarah Bridge	Bayer
Wade McMonagle	AbbVie

Health Economics Working Group (HEWG)

The 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 2024:	
Heather Wrightman (Co-Chair)	Medicines Australia
Julia Lewis (Co-Chair)	AbbVie
Megan Bohensky	Beigene
Sarah Bridge	Bayer
Lucas Tocchini	Biogen
Peter Germanos	Boehringer Ingelheim
Louise Larkin	Eli Lilly
Brandon Jones	Janssen
Allan Wu	Merck
Louise Graham	Pfizer

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 2024:	
Petrina Keogh (Co-Chair)	Medicines Australia
Genelle Jessup	MSD
Hayley Andersen	Bristol Myers Squibb
Jamie Nicholson	Roche
Katherine Tocchini	Novo Nordisk
Libby Noble	Alexion
Fiona Savio	Amgen
Gabrielle Bietola	Sanofi
Paula Dry	Takeda
Vanessa Stevens	Vifor

Government Working Group (GWG)

The 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 2024:	
Gail Morgan	Medicines Australia (Chair)
Alison Crosweller	Janssen
David Thomson	Amgen
Fiona Tigar	Biogen
James McAdam	Bristol Myers Squibb
Josh Bihary	Pfizer
Martin Snoke	Roche
Monica Saba	Bayer
Sam Howes	Organon
Kieran Schneeman	AstraZeneca

Regulatory Affairs Working Group (RAWG)

The 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 2024:	
Tham Vo (Co-Chair)	Medicines Australia
Helen Critchley (Co-Chair)	Sanofi
Michael Parker (Co-Chair)	AstraZeneca
Ailsa Surman	Amgen
Brian Hewitt	Pfizer
George Lillis	Novartis
Kirpal Kaur	Bristol Myers Squibb
Marina Gebara-Coghlan	Boehringer Ingelheim
Mary Flannery	Bayer
Mitch Green	BeiGene
Sean Abel	Menarini

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 2024:	
Kathryn Evans (Co-Chair)	BioMarin
Constantine Tablan (Co-Chair)	Medicines Australia
Nicole Gaupset	Alexion
Warren Brooks	Ipsen
Anne-Maree Englund	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

Medicines Australia Vaccination Industry Group (MAVIG)

The 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 2024:	
David Pullar (Co-Chair)	GlaxoSmithKline
Tham Vo (Co-Chair)	Medicines Australia
Andrew Thirlwell	Pfizer
Candice Burch	AstraZeneca
Crissa Kyriazis	Biointelect
Jerome Higgins	MSD
Penelope Kaltzis	GlaxoSmithKline
Sarah Lindeman	Sanofi
Valda Struwig	Pfizer
Vanessa Xavier	Sanofi

Code Review Working Group (CRWG)

The CRWG is responsible for providing advice and support to MA staff and the Code Review Consultant, Deborah Monk, throughout the review of Edition 19. Formed through an Expression of Interest in February 2024, it is anticipated it will remain until Code Edition 20 comes into effect (2025).

Members of the Code Review Working Group as at 30 June 2024:	
Sophie Seck (Chair)	Medicines Australia
Alan Paul	GlaxoSmithKline
Alina Hughes	Sanofi
Ben Poole	Bayer
Christina Koniaras	MedWise Consulting
Elle Bontzouklis	Pfizer
Goli Zarshenas	Roche
Grant Villanueva	AbbVie
Hashmine Sidhu	BeiGene
Milagros Vernango	Bristol Myers Squibb
Sophie Hibburd	Takeda

Chief Financial Officer (CFO) Network

The CFO Network is an open group for member company representatives. Two meetings were convened during the year to consider topical issues including: generative AI for finance, international tax updates, corporate tax changes to thin capitalisation rules, OECD's Pillar Two Global and Domestic Minimum Taxes, royalties, taxation of intangible assets for large multinationals and critical infrastructure reporting. The network also assisted with a submission to the Department of Defence during the year.

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

Communications Network

The Communications Network is an open group for member company representatives that meets monthly to discuss topical media and reputation issues, Medicines Australia events, campaigns and other initiatives that require communications support or engagement. The network has assisted with amplifying the Stronger PBS campaign and sharing background information to support media responses.

Code Compliance Network (CCN)

The CCN is a 'community of practice'; a network of people who share a similar knowledge of the Code, and work in roles that are influenced heavily by the Code. The Network comprises nominated personnel from Medicines Australia companies, numbering 70 people.

Four meetings were convened during the year, during which the regular 'ethical crunch' session provided a membership perspective to some of the trickier and more complex issues arising from the Code. In addition, the Network gave active input into the Code review and the development of key Code Guidance.

The CCN is chaired by Medicines Australia's Senior Manager of Ethics and Compliance, Sophie Seck.

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. During 2023–24 there were three Action Groups: the Horizon Scanning Forum; HTA; and cell and gene and rare input to the HTA Review.

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.

Three Action Groups were active during 2023–24:

Horizon Scanning Forum

The Horizon Scanning action group facilitated the delivery of the second Horizon Scanning Forum held on 22 March 2024 in Canberra.

Members of the Horizon Scanning Action Group as at 30 June 2024:	
Tham Vo (Co-Chair)	Medicines Australia
Constantine Tablan (Co-Chair)	Medicines Australia
Eric Johnsson	GlaxoSmithKline
Greg Cook (SASC sponsor)	Bristol Myers Squibb
Christine Pollicino	Roche
David Thomson	Amgen
Stephen Richardson	Sanofi
Katrina Lapham	Biointelect

HTA

The HTA Action Group was formed to focus on championing the HTA Review and advocating for desired outcomes and reforms with external stakeholders.

Members of the HTA Action Group as at 30 June 2024:	
Matt Britland	Medwise
Andrew Thirwell (Co-Chair)	Pfizer
Petrina Keogh (Co-Chair)	Medicines Australia
Ben Gommers	Novartis
Giao Tran	Sanofi
Fiona Tigar	Biogen
Hayley Andersen	Bristol Myers Squibb
Tham Vo	Medicines Australia
David Thompson	Amgen
Ian Black	Independent
Sam Pearson	AbbVie
Libby Noble	Alexion
Stephen Richardson	Sanofi
Emma St Clair-Pearce	AbbVie

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 2024:	
Anne-Maree Englund (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)

The OIT was formed in 2012 with a vision to drive the change toward embracing innovative and personalised medicine with an urgency to shape policy because cancer patients do not have time to wait. In 2024, a refreshed OIT is urgently driving policy changes to embrace innovative and personalised medicine, recognising that patients cannot afford to wait.

OIT has set clear objectives: to be the industry's voice on oncology treatment access, ensure a sustainable industry, build a reputation for collaboration and proactivity, accelerate equitable access to innovative medicines through policy change, and lead globally in providing the right medicine to the right patient at the right time.

This year, OIT has funded three key projects to tackle new challenges:

- A Combinations Therapies Subgroup advocating for reforms to improve access to combination regimens.
- Support for the Medicines Access Portal, allowing clinicians to find medicines available outside PBS reimbursement.
- A patient voice survey through All.Can to gain insights into patients' experiences with cancer treatment and medicine access in Australia.

Petrina Keogh	Medicines Australia
Heather Wrightman	Medicines Australia
Gillian Sharratt	AbbVie
Jan Lewis	AbbVie
David Thomson	Amgen
Heather Cahill (Co-Chair)	AstraZeneca
Tanya Holloway	AstraZeneca
Annie Quan	Bayer
James McAdam	Bristol Myers Squibb
Matt Douglas	Bristol Myers Squibb
Katrina Vanin (Co-Chair)	GlaxoSmithKline
Daniel Gregory	GlaxoSmithKline
David Kop	Janssen
Nicole Woodhill	Merck
Julie Ellis	Menarini
Eddie Lam	Menarini
Isabelle Ryder	MSD
Kate Applegarth	MSD
Shabnam Valiya	Novartis
Sarah Greenbaum	Pfizer
Jacqui Youseff	Pfizer
Natalie Betts	Roche
Jennifer Lam	Roche

Pharma Australia Inclusion Group (PAIG)

The 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.

Prajni Sadananda (Co-Chair)	Eli Lilly
Jenn Jones (Co-Chair)	Takeda
Anne Harris (Steering Committee)	Pfizer
Nathalie McNeil (Steering Committee)	AbbVie
Alison Bleathman (Steering Committee)	Medicines Australia
Urs Voegeli (Steering Committee)	Johnson & Johnson

Member Companies
Biogen
MSD
Abbvie
Takeda
Astellas
Bristol Myers Squibb
Boehringer Ingelheim
Janssen
Organon
Eli Lilly
Pfizer
Roche
Merck
Healthcare Logistics
Sanofi
Ipsen
AstraZeneca
Beigene
Novo Nordisk

R&D Special Interest Group (R&DSIG)

The R&DSIG was established in 2023 to evaluate the case for new government incentives to attract pharmaceutical industry R&D in Australia (including clinical trials) and recommend incentives that would deliver increased global investment in Australia.

Constantine Tablan (Co-Chair)	Medicines Australia
James McAdam (Co-Chair)	Bristol Myers Squibb
Ryan Clarke (Co-Chair)	Bristol Myers Squibb
David Pullar (Co-Chair)	GlaxoSmithKline
Lindsay Grant	AbbVie
David Thomson	Amgen
Hugo Robinson	MSD
Ben Gommers	Novartis
Tracy Jones-Bower	Roche

Alzheimer's Disease Special Interest Group (ADSIG)

The ADSIG was established in 2022 to understand the healthcare infrastructure and workforce capacity roadblocks to patients being diagnosed with Alzheimer's disease and accessing treatment and identify areas of priority where industry can play a role. The Group also seek to encourage government focus on the needs of people with Alzheimer's and the anticipation of potential medicines in this area (formation and delivery of National Dementia Strategy).

Fiona Tigar (Co-Chair)	Biogen
John Bower (Co-Chair)	Eisai
Katherine Burchfield	Eli Lilly
Terese Cole	Eli Lilly
Mark Scott	NovoNordisk
Alison Bleathman	Medicines Australia

Medicines Australia Medical Sustainability Group (MAMSG)

The MAMSG is committed to driving industry change and ensuring the medicines industry is a leader in sustainability across all aspects of its operations. The Group aims to investigate and collaborate across five areas: Emissions reduction, Waste reduction, Sustainability of supply chains, Supporting the Australian Government in achieving its targets under the Paris Agreement, Partnering with the Australian Government Department of Health and Aged Care.

Ben McDonald (Chair)	AstraZeneca
Kate McKeown	Medicines Australia

Member companies
AbbVie
Alexion
Amgen
AstraZeneca
Bayer
Bristol Myers Squibb
Eisai
Merck
Novartis
NovoNordisk
Organon
Pfizer
Roche
Sanofi

Stronger PBS Campaign Special Interest Group (Campaign SIG)

The Campaign SIG comprises member companies that have contributed financially to amplify the Stronger PBS campaign. In 2023-24 this activity included radio advertisements, paid and earned media coverage, and targeted social media posts.

Stuart Englund (Co-Chair)	Johnson & Johnson
Gail Morgan (Co-Chair)	Medicines Australia
Kate Richards	AbbVie
Penny George	AstraZeneca
Candice Burch	AstraZeneca
Rebecca Mojsin	Boehringer-Ingelheim
Helena Sfelagis	GlaxoSmithKline
Angela Hill	GlaxoSmithKline
Simon Higgins	Ipsen
Warren Brooks	Ipsen
Lisa Julian	Lilly
Kate McKeown	Medicines Australia
Hugo Robinson	MSD
Jackson Busse	MSD
Anne Harris	Pfizer
Andrew Thirlwell	Pfizer
Francesca Bianco	UCB
Val Staikou	Novo Nordisk

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