MEDICINES AUSTRALIA

ANNUAL REPORT 2008–09

MEDICINES AUSTRALIA VISION + MISSION STATEMENT

VISION

A leader in positive health outcomes, productivity and economic growth through the availability of innovative prescription medicines.

MISSION

In partnership with key stakeholders, drive the creation and development of an environment for the continued sustainable growth of the innovative research based prescription medicines industry.

STRATEGIC OBJECTIVES

1 Achieve credibility with, and obtain the trust of key stakeholders.

2 Continuously improve access to innovative medicines.

3 Achieve an optimal environment for sustainable innovation.

4 Maintain a high standard of ethical industry conduct through effective self-regulation.

5 Demonstrate leadership as a model pharmaceutical industry association.

ABOUT THIS REPORT

This Annual Report provides a summary of Medicines Australia's activities, initiatives and achievements for the financial year ending 30 June 2009. This report is provided to key stakeholders within Australia and overseas, including member companies, government, other industry and health professional associations, patient and consumer groups and the media.

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Will Delaat CHAIRMAN

CHAIRMAN'S REPORT

Medicines Australia member companies have not been immune from the global financial crisis and the ongoing structural changes that have dominated the pharmaceutical industry landscape internationally over the past year.

However, it is at times such as these that an industry association has most to offer, and I am very proud that the Board of Medicines Australia has provided the requisite leadership to ensure a viable operating environment is maintained for member companies locally.

Indeed, notwithstanding the tough economic climate and extreme fiscal constraints on Government, Medicines Australia has recorded some major achievements in key areas.

Member companies' swift and effective contribution to the global response to the swine flu pandemic has been indicative of the pivotal role of our industry within the broader healthcare sector. It has also shown how Government investment in medicines and vaccines can deliver substantial savings to other areas of public health.

The Access to Medicines Working Group (AMWG) has taken some important steps towards ensuring patients enjoy much quicker access to innovative new medicines. Not the least of these has been the start of pilot programs to streamline the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Scheme (PBS) listing processes.

There has been understandable frustration at the AMWG's sluggish rate of progress. However, there is an emerging consensus on a number of important issues. One is the role of coverage with evidence development as a tool for managing the challenges of listing complex medicines. Another is the growing recognition that the current methods of cost-effectiveness evaluation should be broadened.

The Pharmaceuticals Industry Strategy Group (PISG), which met monthly through the second half of 2008, presented a final report to the Minister for Innovation, Industry, Science and Research, Senator Kim Carr, in December 2008. Acting on the recommendations of the report, the Government announced in the 2009 Federal Budget a new R&D tax credit system.

The PISG report also recommended the establishment of a Government-supported strategic investment fund for industry, and a series of reforms to increase Australia's attractiveness as a location for clinical trials.

Disappointingly, these recommendations have not yet been implemented, although the Research and Development Taskforce is working closely with Government to improve the investment environment for clinical trials. Medicines Australia will continue to advocate for an industry investment incentive fund.

As chairman of the Code Review Taskforce, I was delighted that after an inclusive and transparent review process to which a broad range of stakeholders provided valuable input, the draft Edition 16 of the Code was unanimously accepted by the membership. An application for authorisation of Edition 16 was submitted to the Australian Competition and Consumer Commission (ACCC) on schedule, on 30 June 2009.

On several occasions throughout the year I have had the opportunity to speak in public forums about the tremendous contribution our industry makes to the health and wellbeing of Australians. In December I addressed the National Press Club of Australia, where I launched *Innovating for Life*, a publication which illustrates our contribution through real-life stories of patients whose lives have been dramatically changed by medicines or vaccines.

It is stories such as these which remind us all to be proud of the enormous difference that our work makes to the lives of ordinary Australians.

In May I contributed to SBS Television's *Insight* program which examined the relationship between pharmaceutical manufacturers and healthcare professionals. In this forum, the industry was able to present a balanced view of the commercial realities of bringing new medicines to the market within an ethical framework.

Medicines Australia was able to make two significant charitable donations this year. The first was a $100,000 contribution to the Victorian Bushfire Appeal as a response to the terrible disaster that unfolded in February. The second is a donation of more than $1 million, from the Special Purpose Fund, to the Jimmy Little Foundation.

There have been four additions to our membership in 2008–09. I am very pleased to welcome KMC Health, PricewaterhouseCoopers, Shire Pharmaceuticals and Stiefel Laboratories.

The Board of Medicines Australia has received a major injection of fresh talent over the past year with the election of five new directors filling casual vacancies. The Board has recognised the challenging business environment confronting member companies, and accordingly agreed to apply a 10 percent reduction in the annual member fees for 2009–10.

I thank all of those who served on the Board during the past year for the tremendous energy, conviction and wisdom that they have brought to the task of leading the industry and pursuing Medicines Australia's strategic goals.

We are well placed to meet the challenges of the year ahead.

On behalf of the Board I would like to take this opportunity to thank Ian Chalmers and his talented staff whose skill, professionalism and dedication ensure that Medicines Australia can continue to advance effectively the interests of its members, and those of Australian patients.

Will Delaat
CHAIRMAN

Ian Chalmers CHIEF EXECUTIVE

CHIEF EXECUTIVE'S REPORT

Despite an extremely difficult and uncertain business and policy environment, Medicines Australia can point to some significant achievements during 2008–09.

The overarching issue for industry has again been proactively and assertively managing the implementation of Pharmaceutical Benefits Scheme (PBS) reform. This will remain Medicines Australia's primary focus for the foreseeable future. I expect Medicines Australia to be closely engaged with the Government's scheduled review of PBS reform in 2009–10.

The establishment of a new Therapeutic Group Premium group announced in the Federal Budget was highly damaging to the industry and undermined the certainty on which the industry's support for PBS reform was predicated.

In the wake of this deleterious measure, Medicines Australia reiterated to Government the paramount importance of policy certainty and stability for our industry.

Indeed, speaking shortly after the Budget, the Minister for Health and Ageing, Nicola Roxon, publicly acknowledged the importance companies place on certainty in the policy arena, particularly with regard to PBS reform.

'I recognise that we are part way through this reform process and that industry desires the certainty that can be provided by sticking to the agreed reform timetable,' the Minister told an industry conference.

Government recognition of the need for policy certainty and stability remains a key factor in the industry's continuing ability to sustain financial viability in these times of economic weakness.

In 2008–09, Medicines Australia contributed to several of the numerous high-level reports commissioned by Government, including the National Health and Hospitals Reform Commission's Report, the Review of the National Innovation System, the Pharmaceuticals Industry Strategy Group Report, the Productivity Commission Review of Regulatory Burdens on Business, the Henry Tax Review, the Preventative Health Taskforce Review and the Health Technology Assessment Review.

While the progress of many of these reviews has been slowed by the deteriorating economic environment, the process of compiling submissions to these reviews, and the opportunity to evaluate policy options relevant to the industry and subsequent discussion with Government through the year, has of itself been beneficial.

The Access to Medicines Working Group (AMWG), another key PBS reform stabiliser, continues to examine ways to improve the listing of new medicines. Important progress has been made by the AMWG.

The Government agreed to publish the Pharmaceutical Benefits Advisory Committee's (PBAC) agenda six weeks in advance of its meetings. This measure is an important step in improving the transparency and accountability of the PBS listing process for new medicines and provides an avenue for patient input to PBAC decision making. This is another positive outcome of the Medicines Australia–Department of Health and Ageing 2006 Joint Medicines Policy Conference.

Through the AMWG, the Government embarked on two separate streamlining pilot initiatives to reduce the time to PBS listing for new medicines in Australia. Both pilots are expected to run until mid-2010.

Other work is under way to examine options to reduce uncertainty in the PBS submission evaluation process with the aim of reducing the number of resubmissions necessary before listing is achieved.

Medicines Australia remains concerned that major reductions in the price of comparator generic medicines could adversely impact on the listing of new medicines on the PBS in the future. This potentially serious problem is being closely monitored and the PBAC has indicated a willingness to consider the issue using options developed by the AMWG on a case by case basis. We will continue to pursue this issue resolutely.

Medicines Australia was successful in staving off PBAC cost recovery for another year. Although the measure was finally passed by Parliament in June 2009, cost recovery will not be implemented before 2010. This delay equates to a saving of at least $21 million to industry.

We welcomed the announcement by the Therapeutic Goods Administration (TGA) of wide-ranging business process redesign initiatives. These reforms aim to reduce maximum assessment times from 250 working days to at most 180 working days, with an aspirational target of 150 working days. Medicines Australia fully supports the work being undertaken by the TGA to bring about substantial increases in regulatory efficiency and effectiveness.

I have also been pleased with the TGA's undertaking to publish on its website up-to-date Consumer Medicine Information and Product Information—something we have been asking for some time.

The second Joint Medicines Policy Conference was held in Canberra in November, in partnership with the Department of Health and Ageing. This highly collaborative forum delivered a number of significant and meaningful outcomes. The explicit inclusion of health consumer groups and CHOICE representatives ensured some robust consumer-focussed policy dialogue throughout the conference and will shape the collaborative policy agenda for the years ahead.

Publication of the second and third six-monthly educational event reports was completed on time and in accordance with Australian Competition and Consumer Commission (ACCC) requirements. I have been pleased to note a continuing improvement in community and media understanding of the importance of regular dialogue between those who make medicines and those who prescribe them.

In June Medicines Australia concluded the formal Code of Conduct Review process, leading to an application to the ACCC for authorisation of Edition 16 of the Code. The review process was collaborative and inclusive, demonstrating a commitment by the industry to recognise and act on the concerns of healthcare professionals, health consumer groups and other interested groups.

We were also asked to provide advice and assistance to other associations in our region, particularly in the areas of functional structures, consultation arrangements and member engagement.

Medicines Australia's achievements reflect the leadership of a very industrious and diligent Board of Directors, led with commitment, passion and energy by our independent chairman Will Delaat. I thank Will for his guidance and support.

I am also very proud to acknowledge the energy and resolute commitment of Medicines Australia's loyal and very hardworking staff team, without which none of our successes would have been possible.

Ian Chalmers
CHIEF EXECUTIVE

MEDICINES AUSTRALIA BOARD 2008–09

DIRECTORS AS AT JUNE 2008

			APPOINTED
1	Mr Will Delaat	Independent Chairman	August 1998
2	Dr Graeme Blackman	Executive Chairman, Institute of Drug Technology Australia Ltd	June 1995
3	Mr Bruce Goodwin	Managing Director, Janssen-Cilag	12 May 2009
4	Mr Frederic Guerard	Managing Director, Novartis Pharmaceuticals Australia Pty Ltd	23 June 2009
5	Mr John Latham	Regional Director (Australia &New Zealand), Pfizer Australia	6 March 2007
6	Mr Jeremy Morgan	Managing Director, Eli Lilly Australia	6 March 2007
7	Mr Jez Moulding	Managing Director, sanofi-aventis Australia and New Zealand	1 January 2008
8	Ms Jane Orr	Managing Director, Merck Sharp & Dohme Australia Pty Ltd	18 December 2008
9	Ms Mary Sontrop	General Manager, CSL Biotherapies Australia & New Zealand	22 April 2008
10	Mr Ian Thompson	Managing Director, Amgen Australia Pty Ltd	1 May 2009
11	Mr Dieter Torheiden	General Manager, Solvay Pharmaceuticals	3 April 2007
12	Mr José Antonio T Vieira	Managing Director, AstraZeneca Pty Ltd	1 January 2008
13	Ms Deborah Waterhouse	Vice President and General Manager, GlaxoSmithKline Australia	9 December 2008

			APPOINTED	RESIGNED
14	Mr Udit Batra	Managing Director, Novartis Pharmaceuticals Australia Pty Ltd	12 June 2008	31 March 2009
15	Mr Richard Davies	Managing Director (Australia & New Zealand), Amgen Australia Pty Ltd	6 March 2007	7 October 2008
16	Ms Alison Finger	Managing Director, Australia & New Zealand Bristol-Myers Squibb (Australia) Pty Ltd	4 April 2008	8 April 2009
17	Ms Erica L Mann	Managing Director, Wyeth Australia Pty Ltd	26 September 2003	18 May 2009
18	Dr Steve Wooding	Managing Director Australia/New Zealand, Janssen-Cilag Pty Ltd	29 June 2007	18 December 2008

MEDICINES AUSTRALIA SECRETARIAT

1	Ian Chalmers	Chief Executive
2	Louise Collett	Executive Assistant to the Chief Executive
3	Dr Brendan Shaw	Executive Director Health Policy and Research
4	Donna Edman	Executive Director Public Affairs
5	Deborah Monk	Director Innovation and Industry Policy
6	Katie Whitehead	Director Corporate Services
7	Andrew Bruce	Reimbursement Strategies Manager
8	Michael Fitzsimons	Policy Manager
9	Elizabeth de Somer	Regulatory Affairs Manager
10	Amish Chaturvedi	Research Manager
11	Jamie Nicholson	Media Communications Manager
12	Diana Terry	Stakeholder Relations Manager
13	Heather Jones	Code of Conduct Manager
14	Di Phillips	Finance Manager
15	David Newman	Information Technology Manager
16	Jim Crompton	Health Economics Officer
17	Sam Shirley	Policy and Research Officer
18	Omar Khan	Innovation and Industry Policy Officer
19	Sue Elderton	Public Affairs Officer
20	Helen Cox	Policy Coordination Officer
21	Jennifer Delaney	Personal Assistant to Innovation and Industry Policy and Public Affairs Directors
22	Romina Bommes	Executive Officer
23	Joanne Toogood	Office Manager
24	Melissa Smith	Code of Conduct Administration Officer
25	Prya Sonah	Finance Assistant

STAFF DEPARTED MEDICINES AUSTRALIA 2008–09

26	Sophie Dunstone	Health Economics Officer
27	Jill Lindsay	Office Manager
28	Casey McDermid	Personal Assistant to Innovation and Industry Policy and Public Affairs Directors

→ KEY ISSUES

REFORMING THE ACCESS REGIME

The PBS, and Medicare of course, are Australian icons, and envied by countries around the world. They are part of our DNA—bedrocks of our universal health system, and at least a contributing factor to why we enjoy one of the world's highest life expectancies.

Minister for Health and Ageing, **Nicola Roxon**, 19 May 2009

Improving the reimbursement environment

Medicines Australia undertakes a range of activities to improve the management and the reimbursement environment for its member companies.

The Access to Medicines Working Group's (AMWG) interim report to the Minister for Health and Ageing was released during 2008–09. The AMWG is a joint initiative of the Department of Health and Ageing (DoHA) and Medicines Australia, established to provide advice to the Government on issues surrounding the listing of new medicines on the Pharmaceutical Benefits Scheme (PBS).

The report examined several key issues. It addressed the impact of generic price reductions on the listing of new medicines, potential tools to manage uncertainty in submissions to list medicines, processes for more efficient assessment and listing processes, and measures to improve transparency of the Pharmaceutical Benefits Advisory Committee (PBAC) process.

The AMWG finalised and agreed the process for publishing the agenda of PBAC meetings six weeks prior to each meeting. This is a major step forward in the transparency of the PBAC process and allows companies, patients, clinicians and the broader community to see what new medicines are being assessed by the PBAC before each meeting. The new process includes provisions for members of the public, including patients and clinicians, to provide comments to the PBAC on upcoming medicines being considered.

During 2008–09 the Government also agreed, through the AMWG framework, to pilot two processes to streamline the listing process for PBS medicines with the aim of reducing the sometimes lengthy time to listing, and reducing the number of resubmissions. Those pilots will operate through 2009–10.

The Government did not accept Medicines Australia's recommendation to introduce policy tools in the evaluation process to manage the anticipated adverse impact of generic price reductions on the likelihood of new medicines being listed in the future. However, the Government has agreed that companies can highlight in their submissions where PBS reform may have adversely impacted on the cost-effectiveness of new medicines being assessed. The PBAC will use AMWG work in looking at these.

Medicines Australia continued its important work in representing the industry to the Department of Health and Ageing and the various PBS evaluation committees. Good dialogue continued with the Pharmaceutical Benefits Advisory Committee (PBAC) and the industry continued to be ably represented on the PBAC's Economic Subcommittee (ESC) and Drug Utilisation Subcommittee (DUSC). Throughout 2008–09, Medicines Australia and its member companies were involved in detailed PBAC methodological work on surrogate outcomes, indirect comparisons and patient compliance. Similarly, Medicines Australia represented the innovative industry on the Pharmaceutical Benefits Pricing Authority (PBPA). During this period, Medicines Australia worked with the PBPA on updating the PBPA policy manual and the manual for Weighted Average Monthly Treatment Cost (WAMTC).

Medicines Australia represented the industry on a range of government consultative bodies including the Paediatric Medicines Advisory Group, Medical Oncology Group of Australia's Roundtable, Palliative Care Medicines Working Group and the expert advisory group on Aboriginal and Torres Strait Islanders.

Securing long-term funding certainty

On 1 August 2008, the second phase of reforms to the PBS were implemented. (The implementation of PBS mandatory generic price reductions within the new F1/F2 formulary structure was introduced 12 months earlier.) These included a major 25 percent price cut for multiple brand PBS products in the F2T formulary and a 2 percent cut for similar products in the F2A formulary.

The first price cuts resulting from the operation of price disclosure on the PBS, where actual market pricing affects the Government reimbursement price, were announced late December 2008. On 1 August 2008, four molecules were expected to incur price reductions due to price disclosure of between 15 and 63 percent. However, the Government announced in late June that these price disclosure price reductions would be delayed due to administrative issues.

Medicines Australia has been monitoring the impact of PBS reform, assisting member companies to resolve issues as they arise, and advising the Government on the impact of reforms. Medicines Australia has also been working with the Department of Health and Ageing to establish a dispute resolution and audit process for price disclosure, enabling companies to have the opportunity to query a calculated price reduction.

In the lead up to the 12 May 2009 Federal Budget, there was much speculation that the Government would review its PBS reform policy and possibly make substantial changes to the policy. Medicines Australia supports PBS reform, but is acutely aware that insufficient time has elapsed to allow the savings from recent reforms to be delivered. Medicines Australia continues to regularly monitor data on the PBS and pharmaceutical sector.

During 2008–09 Medicines Australia, working with its member companies, advocated strongly that the Government should not implement additional savings measures for the PBS and, particularly, that no changes should be made to the architecture of PBS reform. The 2009 Federal Budget did contain unwelcome savings measures, creating a new therapeutic group and changes to reference pricing. These measures are opposed because they create significant uncertainty for future pricing of medicines which, in turn, makes it more difficult for companies to bring new medicines to Australia. However, the Budget did not contain a number of major savings measures which had been the subject of media speculation.

Medicines Australia made a major submission to the Federal Government's National Health and Hospitals Reform Commission. This submission highlighted the role the industry plays in working towards an effective health system and identified areas where the industry, government and the community can collaborate to further progress the principles of a good health system for Australia. The submission included a range of recommendations concerning the future of health policy: adopting an holistic approach to health funding; the role of the PBS; the quality use of medicines; efficiencies in financing health; and support for clinical trials.

Medicines Australia also made an initial submission to the Government's Preventative Health Taskforce. This submission highlighted the fact that medicines developed by the pharmaceutical industry are key tools of preventative health and help people to stay healthy and productive. The use of prescription medicines saves millions of dollars of taxpayers' money every year by preventing more costly hospitalisations and interventions in other parts of the health system. To date, the Taskforce has concentrated on the impact of alcohol, tobacco and obesity on our health system.

In 2008, Medicines Australia also made a submission to the Productivity Commission's Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades. This submission made a number of recommendations to alleviate the significant regulatory cost burden on Australia's pharmaceutical industry. Several of Medicines Australia's recommendations were adopted or acknowledged by the Commission and the Government is now in the process of implementing those recommendations, such as streamlining the interaction between the Therapeutic Goods Administration (TGA) and PBS listing process, and reviewing the administrative burden on companies of the WAMTC process.

Promoting an optimal regulatory environment

In 2008–09, Medicines Australia and its member companies worked very hard with the Government to secure reforms to the process of obtaining regulatory approval of prescription medicines through the TGA. During 2008–09 the TGA announced that it would be undertaking a major business process redesign program for prescription medicines. These reforms will improve the effectiveness of the TGA in its assessment of new medicines and improve the agency's efficiency . The reforms will shorten the time taken to register a new prescription medicine in Australia without compromising the TGA's well established rigour and standards.

The fact that these reforms are now being implemented, in some cases after being discussed and planned for 10 years, is a major milestone. Throughout 2008–09, Medicines Australia liaised with the TGA on the reform process and worked with member companies and the TGA to determine the detail of how such measures could be introduced. The Medicines Australia's Secretariat has been working closely with member companies through member briefings and Medicines Australia's Regulatory Affairs Working Group to develop its policy approach towards regulatory reform. Medicines Australia is looking forward to the rollout of the TGA reforms through 2009–10.

Aspirational targets to reduce the time to registration for important innovative prescription medicines will significantly enhance Australia's current regulatory system. Improved efficiencies and transparency of the decision making processes, as well as widespread public access to Product Information and Consumer Medicine Information, will greatly enhance the regulatory setting.

Medicines Australia maintained its good dialogue with the TGA through 2008–09 by ongoing involvement in the Therapeutic Goods Administration Industry Consultative Committee (TICC). This is a high-level forum engaging all the TGA's key stakeholders. The purpose of the biannual TICC meetings are to exchange information on industry trends and regulatory expectations, discuss the development of the TGA's corporate plan, annual business plans and budget, as well as consulting on fees and charges proposals. Medicines Australia also maintained regular direct dialogue with the TGA on its operations and progress.

Medicines Australia is represented on the Australian Government's Health Infrastructure Assurance Advisory Group (HIAAG). The HIAAG investigates a range of health related goods and services critical to maintaining the health and wellbeing of the Australian community; and which have a major impact on Australia's response to threats and vulnerabilities. In 2008–09, the HIAAG assisted the Government in monitoring the impact of the H1N1 pandemic influenza outbreak on health infrastructure and supply chains.

Supporting the quality use of medicines

During 2008–09 Medicines Australia stepped up its engagement on the quality use of medicines (QUM). The National Prescribing Service (NPS) met with the Medicines Australia Board in February 2009. This discussion identified a number of strategies the innovative pharmaceutical industry could pursue with the NPS. Medicines Australia also worked with the NPS on the National Medicines Symposium planned for 2010. Issues discussed included the proposed themes and program and industry's engagement.

Similarly Medicines Australia has been actively supporting the NPS' Medicines Industry Liaison Group and the activities it has been undertaking to improve knowledge of QUM activities within the industry, Government and the wider community. Medicines Australia had ongoing dialogue with the PBAC about how companies might better integrate QUM activities into their submissions for listing new medicines on the PBS.

The data in this section is the latest available at the time of compiling this report.

→ KEY ISSUES

KEEPING HEALTH COSTS DOWN: RESEARCH SNAPSHOT

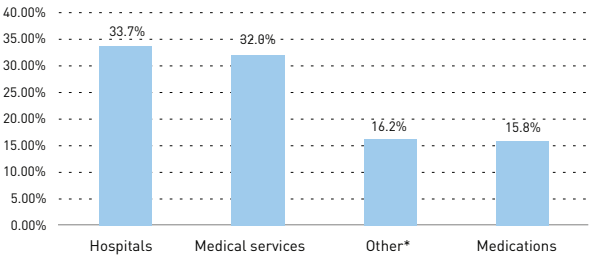
In 2008–09 Medicines Australia undertook considerable internal research into PBS growth.

Medicines continue to compare favourably to other areas of major health care in keeping Government expenditure down on the costs of illness and death. Not only do medicines prevent the deterioration of health to the point where other more serious and expensive health interventions are required, but the Pharmaceutical Benefits Scheme is the only health program which is subjected to routine rigorous assessment of cost effectiveness.

In 2006–07, Commonwealth Government expenditure on medicines constituted 15.8 percent of health expenditure, compared to 32.0 percent on hospitals and 32.7 percent on medical services. If both Commonwealth and state health expenditure are taken into account, medicines constitute 9.8 percent of the total.

CHART 1 Total Commonwealth Government Health Expenditure (minus capital and consumption expenditure) 2006–07

SOURCE Australian Institute of Health and Welfare, *Health Expenditure 2006–07*

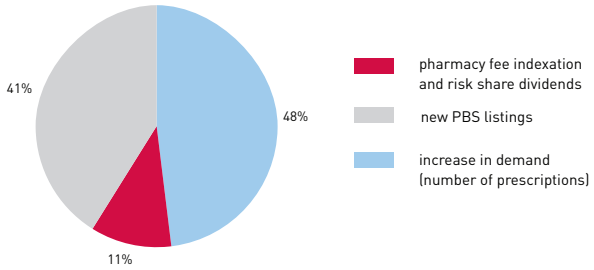


* Other incorporates categories of expenditure under 10 percent — i.e. dental, aids, research, administration, patient transport, community and public health.

In 2008–09, PBS growth increased by over 10 percent in nominal terms. This growth is attributed to a substantial increase in the number of scripts issued, a significant rise in the number of concession cardholders and the concessional free safety net, and some payments associated with the Fourth Community Pharmacy Agreement, which increased pharmacy remuneration. It was not exclusively, or even primarily, the result of increased payments to pharmaceutical companies. In fact the growth rate in pharmaceutical company sales for prescription medicines over the same period was only 6 percent.

CHART 2 Factors contributing to PBS growth 2008–09

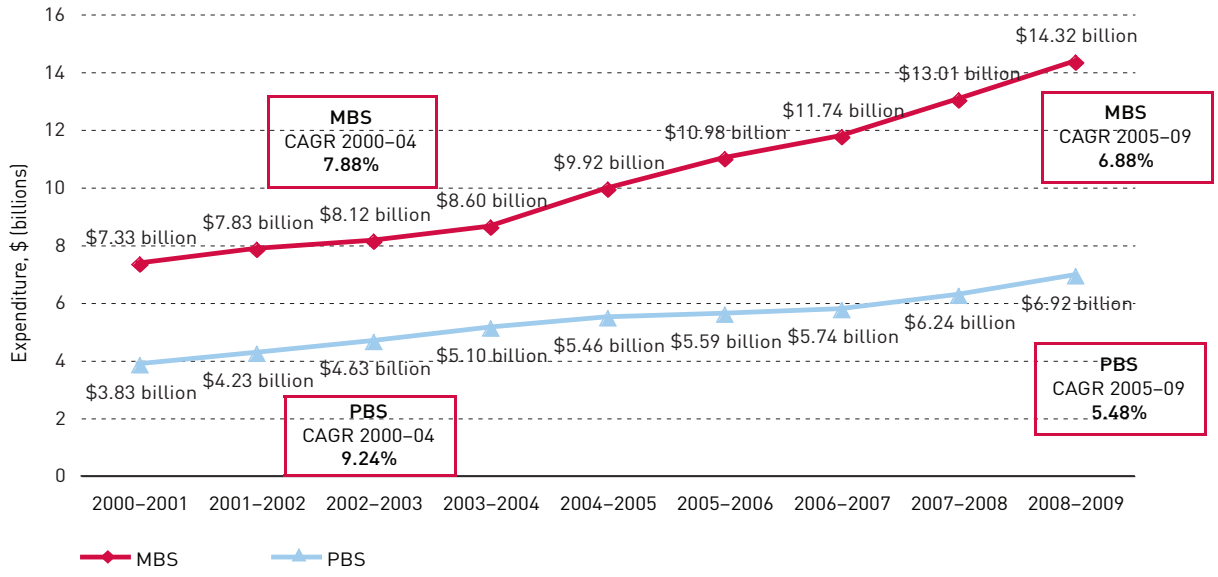
SOURCE Medicines Australia analysis of Medicare data for 2008–09



Moreover, the Compound Annual Growth Rate (CAGR) of the PBS over the past five years has been moderate in comparison to the Medical Benefits Scheme (MBS) growth.

CHART 3 Expenditure comparison: MBS-v-PBS

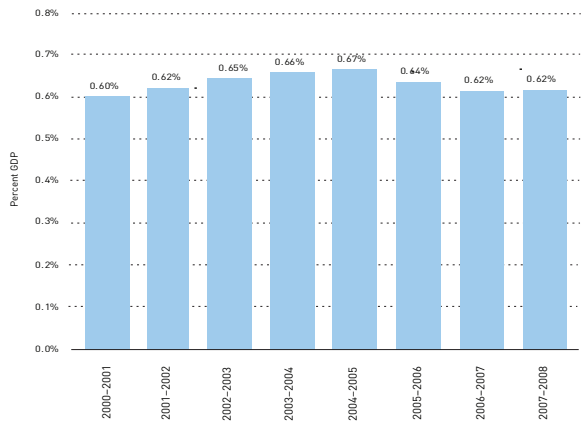
SOURCE Medicines Australia analysis of Medicare data for 2008–09



Between 2000–2001 and 2007–2008, the PBS has remained between 0.6 percent to 0.62 percent of gross domestic product (GDP).

CHART 4 PBS as a proportion of GDP 2007–08

SOURCE Australian Bureau of Statistics, *Australian National Accounts, Series 5206*. PBS expenditure data, Department of Health and Ageing Annual Reports: 2000–2001 to 2007–2008



Australia's total pharmaceutical expenditure as a proportion of health expenditure remains below OECD average.

The ageing population and inclusion of new preventative health, health enhancing and lifesaving medicines will continue to contribute to PBS growth. The impact of PBS reform will significantly ameliorate costs.

→ KEY ISSUES

THE QUEST FOR PHARMACEUTICAL INDUSTRY SUPPORT

Nicola Roxon and I have made a priority of reforming the operating environment for clinical trials, and the Government is always ready to talk about strategic investment proposals.

Minister for Innovation, Industry, Science and Research, **Kim Carr**, 27 July 2009

Pharmaceuticals Industry Strategy Group (PISG)

The PISG was formed in June 2008 by Senator Kim Carr, the Federal Minister for Innovation, Industry, Science and Research, to 'develop a plan to attract investment in R&D, clinical trials and manufacturing activity in Australia'. He noted that the 'pharmaceuticals industry is a cornerstone of the emerging global bio-economy and Australia must have a stake in it'.

PISG members represented all segments of the bio-pharmaceuticals value chain, including leaders from pharmaceuticals, biotechnology, and generic medicines industries and high-level Government and union representatives. Dr Brian McNamee (Chief Executive Officer and Managing Director of CSL) and Mr Craig Pennifold (then Head of the Innovation Division in the Department of Innovation, Industry, Science and Research) co-chaired the Strategy Group.

Between June and December 2008 Medicines Australia made five major and seven minor submissions to the PISG. In these, we broadly argued that:

- national industry policy must complement national health policy, and vice versa
- strategic industry support is vital to maintain investment in critical industries, and past programs to support the Australian pharmaceuticals industry have worked well, both for the industry and for Australia
- industry-specific tax incentives can provide a significant growth impetus to local companies as well as to subsidiaries of multinational corporations competing within their own companies to attract investment from headquarters to Australian business entities

- → a strong legislated framework to protect intellectual property rights is fundamentally important to the biomedical and innovator pharmaceuticals industries
- → clinical research must be regarded as a core function of the Australian healthcare system
- → growth in the pharmaceuticals industry is being hampered by the persistent shortage of skilled, 'job-ready' workers.

There was considerable debate among PISG members on whether certain activities are more likely than others to deliver net economic benefits to Australia. Several members argued that a Government program should only support major manufacturing projects, adding that tax incentives are sufficient to support R&D activities. Medicines Australia strongly advocated a more nuanced position. We argued that R&D (including clinical trials) must be regarded as a core Australian strength and future programs must be open to the possibility of supporting such activity, in addition to manufacturing.

In the clinical trials area, Medicines Australia worked closely with several industry experts to stress the considerable value of industry-sponsored clinical trials to Australia, and proposed reasonable and low cost measures to reverse Australia's declining competitiveness as a destination for clinical trials.

In December 2008, the PISG delivered its final report to Minister Carr. The report advised Government to establish a multi-million dollar fund to support major strategic investment in pharmaceuticals manufacturing and R&D infrastructure, but also cautioned that support must only be given to projects that are likely to deliver significant benefits to Australia.

The report also recommended measures to make Australia a more attractive location to stage clinical trials, including:

- → accelerating the establishment of a national system of ethics approval for multi-centre clinical trials
- → establishing coordinated national patient referral networks, especially in therapeutic areas of high trial activity
- → ensuring that systems of e-medical records in Australian public hospitals are compatible with industry needs, such as remote access to medical records of patients involved in clinical trials in Australia.

Minister Carr thanked the group for 'providing a thorough and balanced report'. He added that the 'Government is committed to setting the right conditions to boost the growth' of the pharmaceuticals industry in Australia, which 'delivers economic and social benefits to the community'.

The Government responded to the PISG Report, and other reviews in the innovation sphere, on 12 May 2009 (as part of the Federal Budget announcements) with the release of a White Paper *Powering Ideas: An Innovation Agenda for the 21st Century*. Regrettably, the Government did not announce the establishment of a Strategic Investment Fund. However, the White Paper provides a framework for Medicines Australia to continue to work with the Government to help ensure the long-term viability of one of Australia's most important industries.

Review of the National Innovation System

The Government commissioned a broad review of the national innovation system in February 2008. In his announcement of the review, Senator Kim Carr, the Federal Minister for Innovation, Industry, Science and Research, said that 'in today's economy, innovation policy is industry policy'. An expert panel, chaired by the noted innovation policy specialist, Dr Terry Cutler, conducted the review.

Medicines Australia lodged submissions with the review's expert panel and the R&D Tax Concession Working Group. The underlying aims of these submissions were to:

- highlight the socio-economic importance of the Australian pharmaceuticals industry, and its alignment with the national research and innovation priorities
- develop and assess ways in which Government policies can enable (and facilitate) growth in our industry.

The panel released *Venturous Australia: Building Strength in Innovation* in September 2008. Medicines Australia strongly supported several of the report's conclusions, including the need to:

- support industry-based research and development, especially by replacing the current R&D tax concession system with a simpler and more efficient R&D tax credit system
- reduce inter-institutional and cross-jurisdictional fragmentation in medical research
- facilitate commercialisation of innovative products and services
- increase the level of Government funding for research at Australian universities.

Medicines Australia asked that Government keep the industry's concerns in mind when drafting its response to *Venturous Australia*. For example, we argued that the report's proposal for an R&D tax credit system will have minimal impact on subsidiaries of multinational corporations if implemented improperly, and that the expert panel's report insufficiently addressed weaknesses in the Australian intellectual property system.

In its May 2009 response, the Government announced an ambitious policy agenda in *Powering Ideas: An Innovation Agenda for the 21st Century*. It added that reports by the PISG, the Review of Australian Higher Education and the Review of the Australian Textiles, Clothing and Footwear sector were closely consulted in drafting this agenda.

In accordance with earlier recommendations, the Government confirmed that the current R&D Tax Concession program will be replaced with a new R&D tax credit system in 2010. This represents the most significant overhaul of Australian tax-based incentives for business innovation in twenty years. Medicines Australia strongly supports the change and notes that the new system will offer a simpler, more predictable incentive for pharmaceutical businesses to invest in research and development in Australia.

In *Powering Ideas*, the Government also announced that it would invest (approximately):

- $100 million (as part of the Super Science—Future Industries Program) in research facilities and infrastructure to enable advances in drug discovery and health care
- $83 million in the new Innovation Investment Follow-on Fund to bolster the domestic venture capital market and assist small and start-up bio-pharmaceutical companies generate operational funds
- $200 million in the new Commonwealth Commercialisation Institute to assist companies transform laboratory science into profitable products and services
- considerable resources in facilitating connections between universities, the public sector and private companies.

As at June 2009 the Government had not released consultation papers to seek stakeholder input on these initiatives, including the details of the new R&D tax credit system. This process is likely to continue until December 2009.

Intellectual Property

The period between July 2008 and June 2009 saw Medicines Australia engaged on a number of fronts in the intellectual property space. In general, this engagement was informed by our belief in the fundamental importance of a strong, stable and predictable intellectual property system in sustaining innovation and in delivering faster access to innovative medicines.

In July 2008, the Productivity Commission released a draft research report in which it argued that Australia's current intellectual property system does not impose an unnecessary regulatory burden on the pharmaceuticals industry. To the contrary, Medicines Australia responded that the lack of sufficient data exclusivity, amendments to Section 26 of the *Therapeutic Goods Act 1989* in 2004, and more importantly, the lack of proper enforcement of exclusivity provisions, had increased patent litigation costs for the innovative pharmaceuticals industry. Companies are increasingly being forced to defend valid patents against infringements, which adds to the cost of doing business in Australia. In its final report, the Commission acknowledged that the operation of Section 26 amendments could create a 'significant burden for pharmaceutical patent holders'.

In October 2008 Medicines Australia made a detailed submission to the Advisory Council on Intellectual Property on its review of patentable subject matter. The submission responded to a series of technical questions such as:

- Can placing limits on inherently patentable subject matter be justified on economic grounds?
- Does the content of current Australian patent law meet the objectives of the system of determining inherent patentability of innovations?

In brief, Medicines Australia argued that, to the greatest extent possible, Australia should limit proscriptive exceptions to patentable subject matter and should also avoid creating new categories of exception, as these may have the undesirable effect of adversely affecting the incentives to invest in the development of existing and new technologies.

In December 2008, Medicines Australia issued a discussion paper on options for extending data exclusivity in Australia. The document argued that Australia's current data exclusivity provisions are below international best-practice, that this weakness undermines the relative strength of Australia's patent system. In the medium- to long-term, these shortcomings are likely to diminish Australia's ability to attract global investment in research and development.

In February 2009, Medicines Australia lodged a submission with the Australian Customs Service on proposed amendments to the Notice of Objection Scheme. These amendments would allow Customs to disclose additional information to objectors regarding infringers and country of origin (including for counterfeit medicines seized at Australian ports of entry). Medicines Australia strongly supported the amendments, but cautioned that one of the proposed safeguards—to allow infringers to forfeit goods prior to commencement of legal action—could undermine the opportunity for objectors to identify the source of infringing goods. In general, Medicines Australia argued that effective enforcement of intellectual property rights is crucial to respond to the growing challenge of protecting Australians from inadvertently accessing counterfeit goods, including medicines, the quality and efficacy of which cannot be guaranteed.

In March 2009, Medicines Australia lodged a submission with the Senate Community Affairs Committee in response to its inquiry into gene patents. Medicines Australia argued that Australia's current intellectual property legislation should not be changed to provide special rules for the patenting of genetic materials and gene derivatives. That is:

- patenting of gene-based technologies, so long as these are novel and useful, should continue to be allowed without restriction and without prejudice (in accordance with the regulations of the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property (TRIPS)
- patent term restoration provisions, as they apply to pharmaceutical products, should continue to be applicable to (gene) patents covering medical products for which regulatory approval is required
- patenting of techniques to isolate particular genes should continue to not be patentable unless a technique is of itself innovative
- patenting of genetic sequences per se should continue to be not permitted as these are mere 'discoveries' and not 'inventions'; that is, they should be excluded from patentability under 'prior art' considerations.

Between February and June 2009, Medicines Australia mounted a strong defence against proposals to amend the *Patents Act 1990* to either alter the method of calculating patent term extensions or allow manufacturers of generic medicines to produce patented medicines for export. In brief, Medicines Australia argued that such amendments would:

- undermine the rights of patentees in Australia
- contravene Australia's obligations under TRIPS and AUS–US FTA
- provoke retaliatory measures by Australia's trading partners
- harm multilateral efforts to implement globally harmonised standards of protection
- undermine efforts to boost research and development investment in Australia.

On 22 July 2009, the Minister for Innovation, Industry, Science and Research advised that the proposals put forward to amend the Patents Act could not be supported in light of Australia's international commitments on intellectual property and trade.

Tax Policy

Medicines Australia believes that the global competitiveness of Australia's future corporate tax system and its ability to appropriately adapt to changing global business environments will be crucial determinants of the ongoing ability of Australian companies—including Australian subsidiaries of multinational corporations—to attract investment in activities such as research and development and high value-add manufacturing.

This basic belief informed several significant engagements on tax policy issues between Medicines Australia and the Government during 2008–09.

For example, in October 2008, Medicines Australia lodged a major submission with the Treasury in response to the Government's comprehensive review of the Australian tax system. In this, we strongly encouraged the Government to significantly lower the tax burden on Australian businesses by:

- reducing the corporate income tax rate (but not at the expense of dividend imputation)
- implementing a system of R&D tax incentives that minimises compliance costs and maximises the administrative efficiency and the overall efficacy, utility and uptake of such incentives
- allowing a temporary acceleration of capital cost allowance to boost investment in manufacturing and/or research and development infrastructure
- lowering payroll taxes.

Medicines Australia lodged a follow-up submission in April 2009, in which we expanded on certain areas of critical concern for the industry and rearticulated the rationale for bold and urgent Government action to improve the global competitiveness of Australia's corporate tax system. We noted that many influential commentators argue that Australia should refrain from engaging in tax competition with other countries. Medicines Australia submitted that, as a general principle, we recognise that tax

competition may sometimes be harmful from a global perspective. Given the circumstances, however, we noted that a certain degree of tax competition is both justified and in Australia's best interests, especially because:

- → significantly reducing the aggregate tax burden is likely to attract new investment to Australia, with resulting positive effects on growth, employment and exports
- → there would be an opportunity for Government to take a share in any increase in revenue resulting from higher growth in the medium to long term
- → Australia has sovereign taxing powers which should not be constrained by international expectations
- → the spillovers from increased investment (in knowledge-intensive industries especially) are likely to be substantial, and far outweigh the cost of any forgone revenue in the short term.

Prior to this, in January 2009, Medicines Australia lodged a submission with the Board of Innovation Australia (AusIndustry) on the proposed 2009 Guidelines for R&D Plans, which are intended to replace the 2001 Guidelines. In general, Medicines Australia supported Innovation Australia's initiative to streamline and simplify these Guidelines, which will reduce the burden of compliance and encourage the (appropriate) utilisation of R&D tax incentives. Medicines Australia also made several suggestions to further clarify the proposed Guidelines.

→ KEY ISSUES

THE VALUE OF CLINICAL TRIALS CONDUCTED IN AUSTRALIA: RESEARCH SNAPSHOT

In March 2009 the Research and Development Task Force (RDTF) of the Pharmaceuticals Industry Council (PIC) undertook two surveys on sponsored clinical research in Australia. The first was an industry benchmarking study. The second was a survey of institutional researchers to evaluate the diverse contributions of Australian conducted clinical trials to the economy, to patients and to Australian researchers and research institutions.

Benchmarking Survey of Industry Sponsored Clinical Research in Australia in 2008

The benchmarking survey involved 23 multinational and 10 Australian innovative pharmaceutical corporations operating in Australia.

The survey revealed that the pharmaceutical industry directly or indirectly supported at least 1498 clinical research jobs in 2008.

- → Thirty three companies reported having 870 employees involved in trial/direct support.
- → One hundred and twenty nine investigator and 699 study coordinator positions were funded via industry trials.
- → More than $285.52m was expended on research in 2008 by the responding companies.
- → More than 1388 trials/projects were reported in 26 therapeutic areas.

Multinational companies funded the vast majority of expenditure on trials in Australia and the majority of trials per se—$262.52m versus $22.33m of the responding companies.

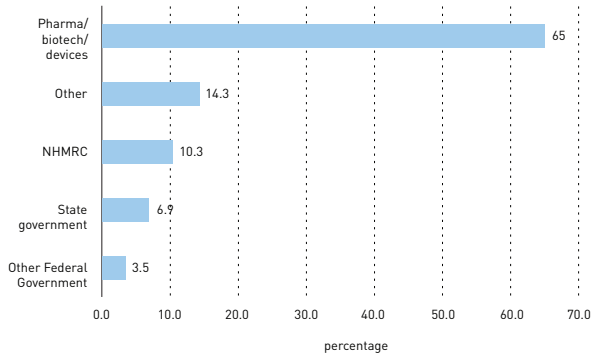
All multinational corporations reported that set-up costs in Australia have increased over the previous two years, with higher institutional overheads identified as the primary source of increased costs.

Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research

This was the first formal survey to assess the impact of pharmaceutical industry sponsored research in Australia. One hundred and eighty seven researchers responded (of whom 88 percent were principal investigators with an average of 16.5 years of research experience).

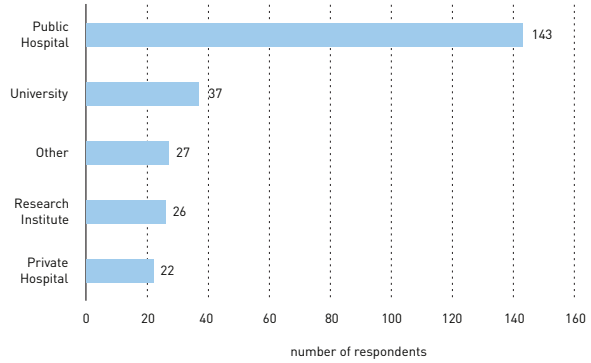
Participants in the investigator survey identified the diverse public and private sources of funding which supported their research. Funding came predominantly from pharmaceutical, biotechnology and medical devices companies with the majority of the remainder coming from government sources.

CHART 5 Source of funds for research: Average percentage by source in 2008



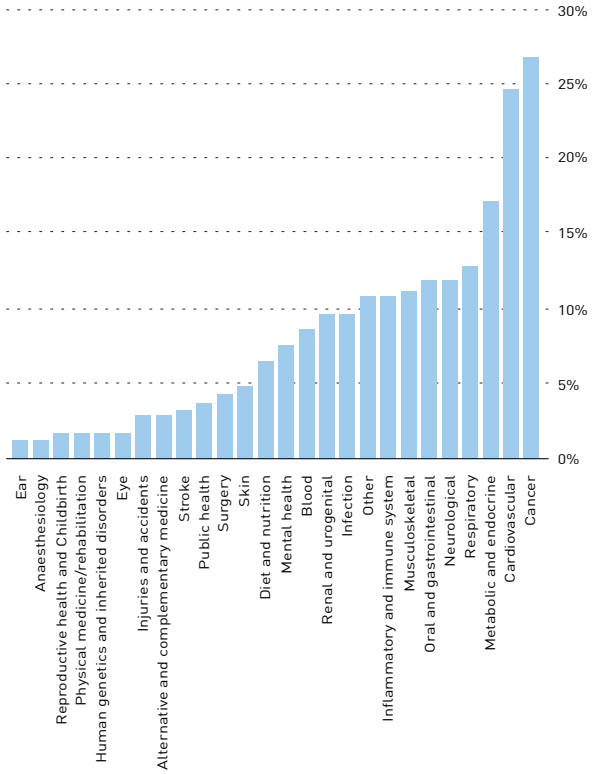
The study centres in which the respondents were located were also identified. Over 56 percent of the study centres were in private hospitals.

CHART 6 Type of Study Centre



Respondents reported activities in 26 therapeutic areas.

CHART 7 Clinical trials by therapeutic areas



Respondents were asked to evaluate the effectiveness of clinical trials for a diverse range of potential beneficiaries. Benefits to patients were rated very highly, as were benefits to researchers and academic institutions in providing experience, supplementary funding for research interests and global recognition of Australian expertise.

Benefits to patients

CHART 8 Providing early access for Australian patients to new therapies

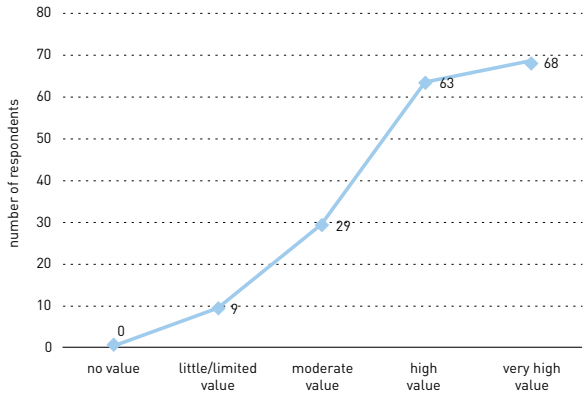
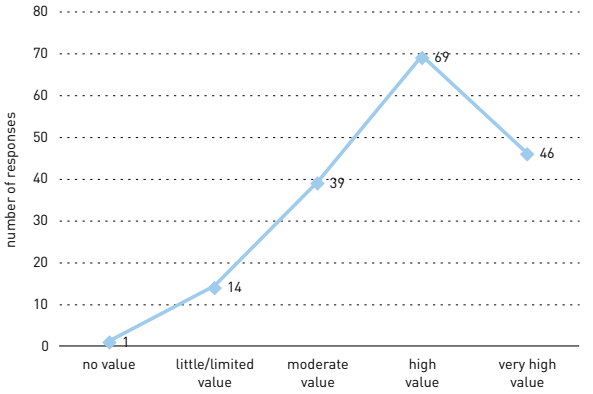
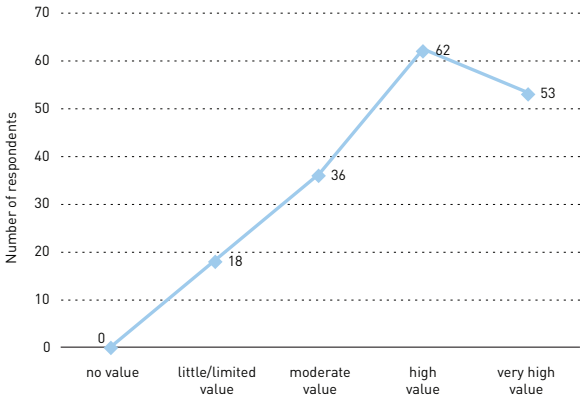


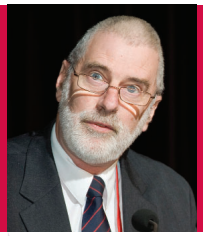
CHART 9 Assisting the uptake of new evidence-based findings into clinical practice



Benefits to Australian researchers and research institutions

CHART 10 Global recognition of the expertise of Australian researchers





→ KEY ISSUES

PROMOTING ETHICAL CONDUCT

I believe Medicines Australia deserves congratulations for making further incremental improvements to the 16th edition of their Code.

Dr Ken Harvey, Senior Lecturer in Health Studies at Latrobe University and member of Healthy Skepticism in his submission to the ACCC on the authorisation of Edition 16th of the Code of Conduct, 28 July 2009

Promoting ethical conduct

2008–09 has been another year of significant achievements in relation to promoting ethical conduct within the industry. The Medicines Australia Board recognises the significance of the ethical conduct of members by including it in the Strategic Plan.

The Code is an important platform for the pharmaceuticals industry to articulate and demonstrate an ethical culture through a committed, self-regulatory approach. Medicines Australia has continued to work with our stakeholders during 2008–09 in pursuit of this goal.

Code of Conduct Review

One of the major activities throughout 2008–09 was the wide-ranging and comprehensive review of the Code of Conduct. Medicines Australia is very grateful for the input and contributions by many stakeholders to the review, including over 46 written submissions and participation in seminars, workshops and meetings.

Detailed information on the full terms of reference for the review and the review process can be found in the Code of Conduct Review Panel Report which is available on the Medicines Australia website.

Independent Audit

In its initial submission, CHOICE recommended to Medicines Australia that the review of the Code be conducted by an independent reviewer. The Board agreed that the review process could be enhanced by the appointment of an independent auditor to oversee the Code review and ensure that it is comprehensive, effective, responsive and

transparent. Medicines Australia appointed Dr Simon Longstaff, Executive Director of the St James Ethics Centre as independent auditor. The final report on the Independent Audit of the Code Review is available on the Medicines Australia website.

Medicines Australia has listened and responded to our stakeholders' written submissions, comments made at workshops held with consumers and meetings with a range of individuals and organisations. Through our engagement with them we have developed the new edition of the Code, which continues to step up to the challenge of ensuring the Code meets the highest standard of self-regulation.

The following significant improvements in Edition 16 are highlighted. It will:

- raise the already high standard required for medical and promotional claims to prohibit advertising in prescribing software
- restrict brand name reminders only to items that are directly relevant to the practice of medicine or pharmacy (that is, items that will not be used outside the practice)
- specifically require additional training for member company representatives on privacy legislation and the Explanatory Notes recommend that Code compliance forms a specific part of the performance reviews of member company representatives
- explicitly deal with new forms of 'social media' (for example, Facebook, YouTube, MySpace, Twitter, blogs and wikis)
- clarify that the general rules restricting the provision of benefits by companies to healthcare professionals also apply in the context of research and clinical trials
- specifically regulate relationships between pharmaceutical companies and health consumer organisations
- increase consumer representation activities directed to the Code Committee where the complaint is in relation to the general public or patients
- substantially increase fines for breaches of the Code.

Timeframe for the introduction of Edition 16

Edition 16 was unanimously adopted by Medicines Australia members on 15 June 2009. The application for authorisation of the new Code was made to the Australian Competition and Consumer Commission (ACCC) on 30 June 2009. If the ACCC determines by the end of December 2009 that the Code should be authorised, Edition 16 will become effective on 1 January 2010.

Medicines Australia is proud of its achievements in reviewing, revising and reporting under the Code. Our stakeholders in ethical conduct can expect continuous and demonstrable improvement in ethical conduct under the new Code of Conduct.

Communicating about the Code and ethical conduct

A cooperative approach is key to effectively promoting understanding of the Code and ethical conduct. Medicines Australia regularly works with pharmaceutical companies, healthcare professional organisations, consumers and agencies and businesses working with the industry (advertising and public relations agencies, suppliers, event organisers) to raise awareness, aid understanding of and promote compliance with the Code.

In 2008–09 Code Secretariat staff conducted or participated in 70 events communicating about the Code, with a combined audience of 1570 people. These events included meetings, briefings, workshops and presentations at third party seminars and conferences.

In May 2009 the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) hosted the Seventh International Code Compliance Network Conference (CCN) in Washington. The aim was to stimulate an informed debate among code experts from around the world on the challenges and potential of self-regulation in the field of ethical promotion of pharmaceutical medicines. The two-day conference was attended by compliance officers involved in daily ethical promotion from 15 different countries. Medicines Australia was represented by Ms Deborah Monk.

Educational Event Reporting

The Code requires that each member company will provide a full report on all educational meetings and symposia, as defined in Sections 6, 7 and 10 of the Code, held or sponsored by that company.

Companies are required to report on a six-monthly basis:

- July–December, with reports required by 14 January and publication on the Medicines Australia website by 30 March
- January–June, with reports required by 14 July and publication on the Medicines Australia website by 30 September.

The Monitoring Committee will, at the end of each financial year, review the information provided by member companies in accordance with Section 16.3 of the Code. The review will be of information for three months selected by the Committee at random for the preceding 12-month period.

In September and October 2008, the Monitoring Committee reviewed 100 percent of educational event reports for three months randomly selected by the Committee from the 12 months to 30 June 2008. The months selected were October 2007, March 2008 and May 2008.

At the same time the Committee reviewed approximately five percent of all educational events held between January and June 2008, assisted by the independent auditor Deloitte Touche Tohmatsu.

As a result of this review the Monitoring Committee forwarded 26 educational events to the Code of Conduct Committee. Twelve of those events were subsequently found in breach of the Code.

Of the 30,469 events reported in the 12 months to June 2008, 33 were found in breach of the Code. This represents a compliance rate of 99.0 percent.

Having engaged Deloitte to independently review the educational event reports for the first two six month reporting periods and the extensive review by the Monitoring Committee, the Medicines Australia Board accepted that with a compliance rate of 99.0 percent, additional assistance with auditing is not required.

The Monitoring Committee will continue with its annual review of three months of the preceding 12 months of events. The outcomes of all complaints forwarded to the Code of Conduct Committee will continue to be published in the Code Quarterly Report and Code Annual Report.

→ KEY ISSUES

CODE OF CONDUCT PERFORMANCE 2008–09: SNAPSHOT

CHART 11 Reported breaches of the Code of Conduct 2008–09: Determinations

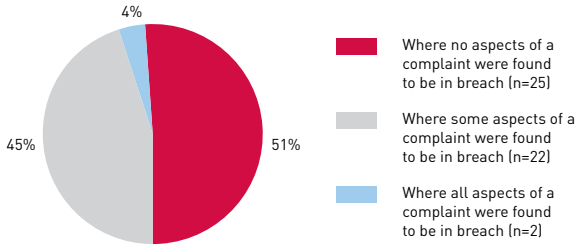


CHART 12 Sanctions imposed by the Code of Conduct and Appeals Committees 2008–09

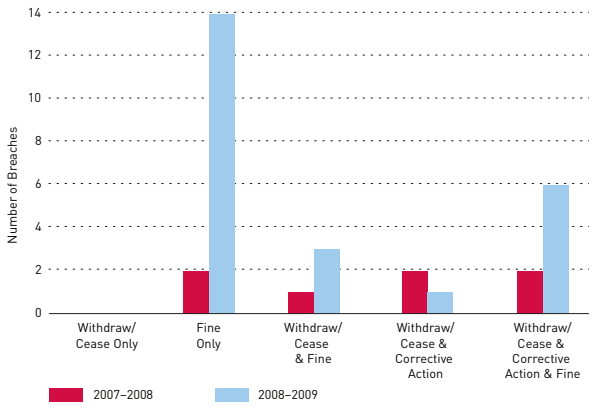


CHART 13 Fines imposed by the Code of Conduct and Appeals Committees 2008–09

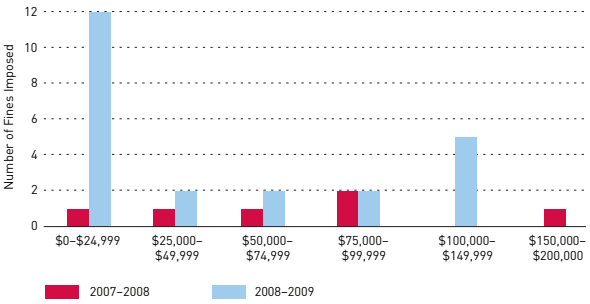
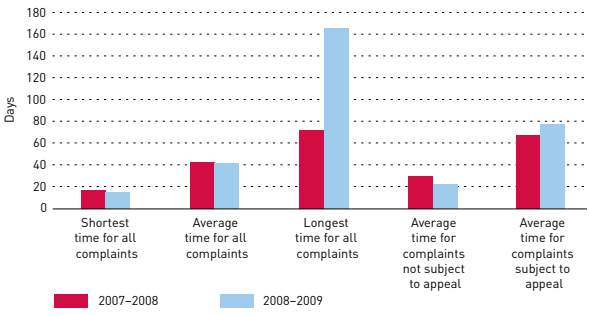


CHART 14 Length of time to resolve all finalised complaints: comparison 2007–08 and 2008–09



EVENTS DIARY: 2008–09

JULY

- First meeting of the Pharmaceuticals Industry Strategy Group (PISG)
- Medicines Australia replied to the Productivity Commission's Draft Report on the *Annual Review of Regulatory Burdens on Business—Manufacturing and Distributive Trades*
- Medicines Australia appeared before the Senate Committee Inquiry on Cost Recovery
- *2007–08 Code of Conduct Annual Report* published

AUGUST

- Medicines Australia Board Retreat
- TGA consultations on regulatory reforms and improvement of business processes
- Medicines Australia-sponsored National Press Club Health Excellence in Health Journalism Awards
- First meeting of the Pharmaceuticals Industry Working Group (PIWG) under the new Federal Government
- *National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008* decided in the negative in the Senate (36 for and 36 against)
- Medicines Australia met with the NHMRC Research Integrity Section to discuss the implementation plan for the national harmonised multi-centre ethics review system
- Member briefings on PBS reform and the Code of Conduct (Sydney/Melbourne)

SEPTEMBER

- Call for submissions to the Code of Conduct Review
- Senate Community Affairs Committee Inquiry into of the Draft Regulations under the proposed PBAC Cost Recovery Bill—Medicines Australia made a submission and appeared before the Committee
- Productivity Commission released its *Annual Review of Regulatory Burdens on Business* recommending: parallel TGA/PBAC assessment of medicines; increase of the cost threshold requiring Cabinet consideration of PBS listings; reducing the time and cost of TGA processes; harmonised national system of multi-centre clinical trials and other measures of benefit to the industry
- PBAC agenda published six weeks in advance of the next meeting for the first time
- Medicines Australia published the 2nd Educational Event Report

OCTOBER

- Senate Community Affairs Committee tabled its report on PBAC Cost Recovery Draft Regulations
- Medicines Australia made a submission to the Advisory Council on Intellectual Property's Review of Patentable Subject Matter
- Mitch Kirkman received Medicines Australia's 2008 Pat Clear Award
- Medicines Australia Annual General Meeting (18 October 2008)

NOVEMBER

- Medicines Australia/DoHA Second Joint Medicines Policy Conference
- Interim Report of the Access to Medicines Working Group (AMWG) published
- Medicines Australia made a submission on the 2009–10 Federal Government Budget
- Member briefings on Health Consumer Organisation (HCO) and Government stakeholders perception audits (Sydney/Melbourne)

DECEMBER

- Pharmaceuticals Industry Strategy Group (PISG) finalised its report to the Minister for Innovation, Industry, Science and Research
- Medicines Australia Board hosted dinner for the Federal Parliamentary Press Gallery
- Medicines Australia Chairman, Will Delaat, gave a nationally televised address at the National Press Club
- *Innovating for Life* launched
- Medicines Australia made a submission to DoHA on dispute resolution in relation to PBS price disclosure decisions
- Government announced the Health Technology Assessment (HTA) Review
- Joint Medicines Australia/PEB/PBAC workshop on the PBS listing process (Canberra)

JANUARY

- Code of Conduct Review consumer workshops held

FEBRUARY

- Medicines Australia donated $100,000 to the Red Cross Victorian Bushfire Appeal Fund
- Medicines Australia circulated a benchmarking survey of industry-sponsored clinical trials to members and biotech and generic companies
- Mediciines Australia forwarded *PBS Growth—What is the optimal for an ageing population?* to the Prime Minister, the Treasurer, the Finance Minister and the Minister for Health and Ageing
- Medicines Australia's Code of Conduct Review Consumer Workshop (Sydney/Melbourne)

MARCH

- Medicines Australia attended the Federal Liberal Party Council Business Observers Forum
- Medicines Australia made a submission to the Senate Community Affairs Committee Inquiry into Gene Patents
- 4th Pharmaceutical Industry Council (PIC) R&D Taskforce Forum
- Access to Medicines Working Group (AMWG) agreed to a TGA/PBAC streamlining pilot project
- Medicines Australia published the 3rd Educational Event Report
- Medicines Australia made a submission to the National Preventative Health Taskforce

APRIL

- Medicines Australia Code Review Panel finalised the 16th Edition of the Code of Conduct

MAY

- Medicines Australia began compiling an assessment of the industry's contribution to the Swine Flu pandemic
- Medicines Australia Board approves Special Purpose Funds (SPF) to the Jimmy Little Foundation of $1.08m
- Federal Budget for 2009–10 handed down
- Medicines Australia made a submission to the Government's Health Technology Assessment (HTA) Review
- Medicines Australia distributed its biannual economic survey to member companies
- Member briefing on PBS reform, AMWG, TGA and Budget issues (Sydney/Melbourne)
- Member/stakeholder briefing on the Code of Conduct Review—(Sydney/Melbourne)

JUNE

- Senate passes PBAC Cost Recovery Bill
- Medicines Australia General Meeting (15 June 2009)
- Second Therapeutic Goods Bill addressing a number of ANZTPA-negotiated amendments introduced to the House of Representatives
- 16th Edition of the Code of Conduct was unanimously adopted by members

CONFERENCES + EVENTS

Second Joint Medicines Policy Conference

Medicines Australia, together with the Department of Health and Ageing, hosted the Second Joint Medicines Policy Conference (JMPC), themed *The Future of Medicines Policy in Australia*, at the Hotel Realm, Canberra on 25 and 26 November 2008.

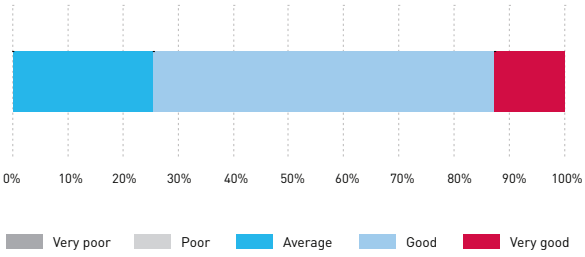
The event attracted 326 delegates, of whom 28 were from health consumer organisations sponsored by Medicines Australia.

The Conference was opened by the Minister for Health and Ageing, Nicola Roxon, and international speakers Professor Sir Michael Rawlins (United Kingdom), and Dr Durhane Wong-Rieger (Canada) addressed the delegates. In addition, five panel discussions were conducted over the two-day event, involving a significant number of key stakeholders in the area of medicines policy in Australia.

Feedback from delegates praised the content and organisation of this event.

Nearly all survey respondents (94 percent) rated the Joint Medicines Policy Conference highly as a forum to gain information relevant to delegates.

CHART 15 Second Joint Medicines Policy Conference: Participant Satisfaction Rating



Particular mention should go to the Conference Planning Committee:

- Professor Lloyd Sansom, Chair Pharmaceutical Benefits Advisory Committee
- Ms Diana MacDonnell, Department of Health and Ageing
- Mr Andrew Mitchell, Department of Health and Ageing
- Mr Paul Storey, Department of Health and Ageing
- Mr David Grainger, Eli Lilly Australia Pty Ltd
- Dr Brendan Shaw, Medicines Australia
- Mr Michael Fitzsimons, Medicines Australia
- Ms Romina Bommes, Medicines Australia

PHOTO 1: *Panelists David Learmonth (Deputy Secretary, Department of Health and Ageing), Lloyd Sansom (Chairman, Pharmaceuticals Advisory Committee), Professor John Gullotta (Chairman of the AMA'sTherapeutic Goods Committee) and Will Delaat (Chairman Medicines Australia) addressing the Second Joint Medicines Policy Conference*

PHOTO 2: *Secretary of the Department of Health and Ageing, Jane Halton, toasting the PBS's 60th Anniversary, Second Joint Medicines Policy Conference Dinner, 25 November 2008*

The actions which it was agreed are to be progressed by the Department of Health and Ageing and Medicines Australia and other willing stakeholders in 2009–10 are as follows.

- → Improved speed of access to new medicines through:
  - TGA process improvements
  - TGA/PBAC overlap
  - Post-PBAC processes.
- → Ongoing review of appropriateness of evidence:
  - ensure fitness for purpose of Health Technology Assessment decisions (incorporating targeted therapies, quality of life considerations, social value considerations and horizon scanning).
- → Integration of health technology within and beyond medicines:
  - better integration of processes (Medical Service Advisory Committee, Pharmaceutical Benefits Advisory Committee and Therapeutic Goods Administration).
- → Opportunities to improve consumer input and engagement with respect to:
  - decisions about individual medicines
  - medicines policy
  - development of consumer capability in Health Technology Assessment.
- → Improve industry participation in relation to the:
  - structure of Health Technology Assessment committees
  - visibility of Pharmaceutical Benefits Advisory Committee processes.

Celebrating 60 years of the Pharmaceutical Benefits Scheme

The Department of Health and Ageing, together with Medicines Australia, hosted a special gala dinner on 25 November 2008 to celebrate 60 years of the Pharmaceutical Benefits Scheme.

Guests reflected on the success of the PBS in providing life enhancing and life saving, affordable medicines to the Australian community.

PHOTO 1: *Medicines Australia Chairman, Will Delaat, addressing the National Press Club*

PHOTO 2: *Chairman's National Press Club Address*

PHOTO 3: *Dr Rohan Hammett, Therapeutic Goods Administration*

PHOTO 4: *Anne O'Riordan, Accenture Global Products*

The Chairman's National Press Club Address

Medicines Australia Chairman Will Delaat gave a televised address to the National Press Club in December, in which he spoke about the value of medicines, the importance of access to medicines and the compelling reasons why the Government should not wind back its investment in the PBS.

The address focussed on the important partnerships between the industry and Government in bringing new medicines onto the PBS, and between industry and prescribers in helping to ensure appropriate use of medicines.

The occasion was also used to launch *Innovating for Life*, an account of the benefits which innovative new medicines provide in this country.

Managing Directors' Dinners

Managing Directors' dinners provide a unique opportunity for the leaders of our member companies to come together to discuss issues of mutual interest and to meet and hear from influential opinion leaders and key stakeholders on matters of direct interest to the operating environment of the industry.

During 2008–09 Medicines Australia hosted six Managing Directors' dinners.

15 JULY 2008

Dr Rohan Hammett, Therapeutic Goods Administration

Dr Rohan Hammett is the National Manager of the Therapeutic Goods Administration (TGA). He is also a member of the Steering Committee of the Global Harmonisation Taskforce for Medical Services and the Council for International Organisations of Medical Science (CMIOS) Working Group on Signal Detection in Pharmacovigilance. The dinner was an opportunity for Dr Hammett to provide an early indication of TGA's Business Process Reform.

10 SEPTEMBER 2008

Guest Speaker: Ms Anne O'Riordan, Accenture Global Products

Ms O'Riordan is head of the Hong Kong Division of Pharmaceuticals and Medical Products Group for the consulting company Accenture. The dinner offered an opportunity for Medicines Australia managing directors to participate in a discussion around strategic global directions for our industry, informed by perspectives from a well regarded international consulting company.

18 FEBRUARY 2009

Senator Kim Carr, Minister for Innovation, Industry, Science and Research

Managing directors were able to hear directly from the Minister regarding his views on the current policy issues impacting on the innovative pharmaceutical industry in Australia. In particular, the dinner gave managing directors the opportunity

PHOTO 5: *Senator Kim Carr, Minister for Innovation, Industry, Science and Research*
PHOTO 6: *Deborah Monk and Ian Chalmers, Medicines Australia*
PHOTO 7: *Dr Christine Bennet, NHHRC*
PHOTO 8: *Glenn Milne, News Limited*

to discuss the Final Report of the Pharmaceuticals Industry Strategy Group, released in December 2008. The Minister met with all managing directors at the pre-dinner drinks, providing a mutually valuable opportunity for informal discussion.

17 MARCH 2009

Ms Deborah Monk and Mr Ian Chalmers, Medicines Australia

Deborah Monk, Director Innovation and Industry Policy, Medicines Australia, and Ian Chalmers, Chief Executive of Medicines Australia, provided an update briefing on the current review of the Medicines Australia Code of Conduct. This was followed by a 'round table' discussion on aspects of the operation of our Code, facilitated by Medicines Australia Chairman, Will Delaat.

28 APRIL 2009

Dr Christine Bennett, Chair, National Hospitals and Health Reform Commission (NHHRC)

The dinner provided an opportunity to discuss contemporary health policy options explored in the NHHRC Interim Report, released on 16 February 2009. Discourse between managing directors and Dr Bennett was lively and engaging.

15 JUNE 2009

Mr Glenn Milne, Political Editor for News Limited

This dinner immediately followed the Medicines Australia General Meeting. Glenn Milne provided managing directors with some candid views on his perceptions of the first 18 months of the Rudd Government, how it has performed, or failed to perform, and the likely nature of political leadership for the foreseeable future.

Member Briefings

Among the services offered to members in 2008–09 were 13 special member briefings on issues of importance.

- 8 October 2008 (Sydney) and 9 October 2008 (Melbourne): *PBS reform and the Code of Conduct*
- 6 November 2008 (Sydney) and 7 November 2008 (Melbourne): *HCO and Government stakeholders perception audits*
- 2 December 2008 (Canberra): *Joint Medicines Australia/PEB/PBAC workshop on the PBS listing process*
- 4 February 2009 (Sydney) and 5 February 2009 (Melbourne): *Medicines Australia's Code of Conduct Review Consumer Workshop*
- 1 April 2009 (Sydney) and 2 April 2009 (Melbourne): *Proposed amendments to the Code of Conduct*
- 6 May 2009 (Sydney) and 7 May 2009 (Melbourne): *PBS reform, AMWG, TGA and Budget issues*
- 19 May 2009 (Sydney) and 21 May 2009 (Melbourne): *Code Review—members/stakeholder briefing*

AWARDS

PHOTO 1: *Ian Chalmers, (Chief Executive of Medicines Australia) presenting the 2008 Pat Clear Award to Mitch Kirkman (Novartis Pharmaceuticals) at the Annual General Meeting*

PHOTO 2: *Will Delaat (Chairman of Medicines Australia), Paul Smith (Award Winner), Nicola Roxon (Minister for Health and Ageing), and Ian Chalmers (Chief Executive of Medicines Australia) at the Excellence in Health Journalism Awards*

2008 Pat Clear Award

The Pat Clear Award recognises outstanding contributions to the pharmaceuticals industry in Australia. The 2008 winner is Mr Mitch Kirkman from Novartis.

Mr Kirkman has had a long and meritorious history of service to our industry. In particular, he has helped to secure much needed improvement to the regulatory investment environment for clinical trials in Australia.

Excellence in Health Journalism Awards

Mr Paul Smith of *Australian Doctor* was the overall winner of the Medicines Australia 2008 Health Journalist of the Year Award which was presented by Will Delaat at the National Press Club on 13 August. The Award was followed by an address by the Minister for Health and Ageing, Nicola Roxon. Mr Smith won the award for his story 'Inside Out' which explored the high personal cost of the failure of the prison system to deal with drug abuse and mental illness.

Category winners were:

- Will Storr: *Fairfax Good Weekend*, 'TB or Not TB' (Best News Feature/Article or Presentation)
- Emma Cook: *SBS TV*, 'A Hollow Vision' (Best Documentary or Documentary Series)
- Maryanne Demasi: *ABC Catalyst*, 'Magic Bullet or clever con?' (Best Feature/Article or Presentation)

PHOTO 3: *Will Delaat (Chairman, Medicines Australia) Dr Lynn Robinson (University of Queensland) and winners of the 2008 CEP Awards at the Awards dinner*

Continuing Education Program Awards

Medicines Australia's Continuing Education Program is designed to educate medical representatives to a recognised industry standard.

The Continuing Education Program is primarily directed at medical representatives working within the prescription medicines industry, and recommended to those who may not be currently employed within the industry, but would like to pursue a career as a medical representative. It is also available to personnel working for organisations interacting with the pharmaceutical industry. The program is offered by distance learning and online modalities through UQ Health Insitu, which is backed by the resources of the University of Queensland.

UQ Health Insitu Active Learning Prize

The Continuing Education Program Awards for 2008 (students enrolled between January and December 2008) were presented at an Awards dinner in May 2009.

The UQ Health Insitu Active Learning Prize for semester 1 was awarded to Wendy Russell-Reed from Alcon Laboratories and the Prize for semester 2 was awarded to Matthew Ryan from Nycomed.

2008 CEP Certificate of Excellence

The winners of this award are the students who achieve the 10 highest aggregate marks for the five programs (out of a possible total aggregate of 500). The awards were presented to:

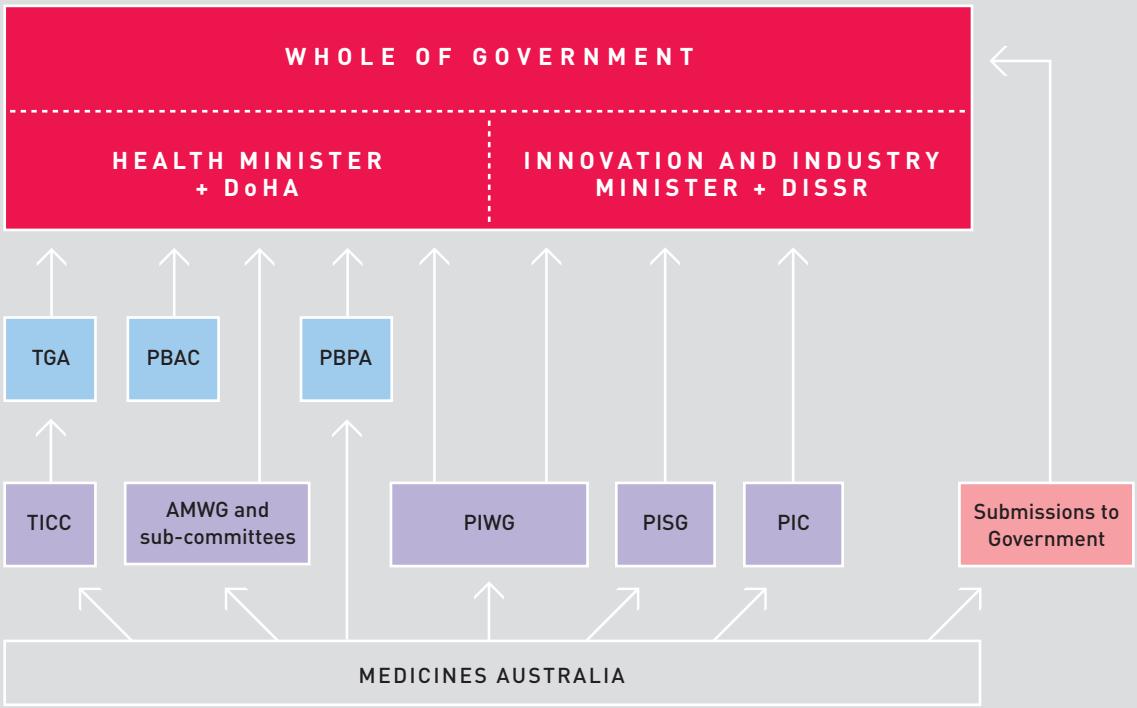
- Luke Beeby, Pfizer Australia
- Jennifer Byrne, Genzyme Australasia
- Megan Cashman, CSL
- Adrian Desfontaines, Merck Sharp & Dohme (Australia)
- Liz-Anne D'Souza, sanofi-aventis
- Amanda Hughes, GlaxoSmithKline Australia
- Nicky Johnson, Pfizer Australia
- Ann Johnstone
- Rebecca Shaw, Novo Nordisk Pharmaceuticals
- Tanja Wells, Boehringer Ingelheim

2008 Code of Conduct Award

To be eligible for this award a student must achieve a final mark of 100 percent for the Code of Conduct Program. In 2008, this award was won by Marian Garcia from Boehringer Ingelheim.

WORKING WITH GOVERNMENT

GOVERNEMENT COMMITTEE STRUCTURE CHART



The prescription medicines industry is one of the most highly regulated, if not the most regulated, industry in Australia.

New medicines must pass through a formidable series of clinical trials before they can be considered for market access and governments impose strict conditions on standards of evidence and the ethical parameters permitted in such clinical trials. Such medicines are subjected to rigorous and intensive safety and effectiveness testing by the Therapeutic Goods Administration (TGA) before they can be placed in the market.

Government subsidisation of the medicines to make them accessible to all Australians at affordable prices is subject to a second round of scrutiny by the Pharmaceutical Benefits Advisory Committee (PBAC) and the price at which they will be made available under the Pharmaceutical Benefits Scheme (PBS) is then determined by the Pharmaceutical Benefits Pricing Authority (PBAC). Unlike nearly any other product, prescription medicines cannot be promoted directly to the consumers and a rigorous code determining what may or may not be claimed in

PHOTO 1: *Will Delaat (Chairman of Medicines Australia), Nicola Roxon (Minister for Health and Ageing) and David Learmonth (Deputy Secretary of the Department of Health and Ageing) at the joint DoHA/Medicines Australia Medicines Policy Conference, 25 November 2009*

PHOTO 2: *Kim Carr, Minister for Innovation, Industry, Science and Research talking to managing directors at the Medicines Australia dinner, 18 February 2009*

terms of their benefits is in place. Breaches of these promotion conditions are subject to punitive damages by both the Therapeutic Goods Administration and Medicines Australia's own Code of Conduct.

In addition to these regulatory conditions placed on the availability and sale of the medicines themselves, the sustainability of the industry in Australia is also subject to industry support, patent and other intellectual property laws and taxation law.

As a consequence, the industry must work closely with Government in the regulatory and policy-making spheres to secure sensible outcomes for both the industry and consumers. As noted elsewhere in this report, Medicines Australia made 11 submissions to Government inquiries in 2008–09 to provide evidence in response to proposed or desired policy changes affecting the industry and to represent the interests of its member companies.

Medicines Australia is also a member of a number of key policy and regulatory committees dealing with access to medicines and the business parameters required for the industry to continue to prosper and invest in Australia. Membership of each of these committees provides real value for the innovative pharmaceutical industry to have its interests and aspirations taken into account.

Access to Medicines

Access to Medicines Working Group (AMWG)

The first meeting of the AMWG took place in April 2007. AMWG was formed to help the Department of Health and Ageing (DoHA) and Medicines Australia to work effectively together and provide advice on access to new medicines to the Minister for Health and Ageing for the consideration of the Government. It is jointly chaired by David Learmonth (Deputy Secretary of DoHA) and Will Delaat (Chairman of Medicines Australia).

The terms of reference for the AMWG are:

- providing strategic oversight of ongoing joint activities undertaken by the Department of Health and Ageing and Medicines Australia to enhance the Pharmaceutical Benefits Scheme (PBS) processes

→ as a result of the reforms to the PBS announced in 2006, consider issues relating to the timely and appropriate access to effective new medicines on the Pharmaceutical Benefits Scheme (PBS).

Pharmaceutical Benefits Pricing Authority (PBPA)

The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent non-statutory body established in 1988 which is required to:

→ review the prices of products supplied under the Pharmaceutical Benefits Scheme (PBS) and, since 2006, the vaccines on the National Immunisation Program (NIP)

→ recommend prices for new items that are recommended for listing on the PBS and, since 2006, NIP.

PBPA includes two industry representatives (one from Medicines Australia and one from the Generic Medicines Industry Association), a consumer nominee, two Department of Health and Ageing representatives, a representative from the Department of Innovation, Industry, Science and Research (DIISR); and an independent Chair.

The Economic Sub-committee (ESC) of the PBAC

ESC (established in 1993) is charged with:

→ reviewing and interpreting economic analyses of drugs submitted to PBAC

→ advising the PBAC on these analyses

→ advising the PBAC on technical aspects of requiring and using economic evaluations.

The Drug Utilisation Sub-committee (DUSC) of the PBAC

DUSC (established in 1988) is required to:

→ collect and analyse data on drug utilisation in Australia for use by the PBAC

→ make inter-country comparisons of drug utilisation statistics

→ assist in generating information relating to rational use and prescribing of medicines.

The Therapeutic Goods Administration Industry Consultative Committee (TICC)

TICC meets twice yearly as a consultative forum to obtain input on corporate planning, budgeting processes and TGA performance.

The Health Infrastructure Assurance Advisory Group (HIAAG)

The HIAAG's primary role is to highlight specific private sector issues that impact upon the safety and security of the health of the community and promote strategies for private sector business continuity in the event of a health emergency. HIAAG's membership includes representation from ten health and medical organisations (including Medicines Australia) and six Federal Government departments or authorities.

Pharmaceuticals Industry Strategy Group (PISG)

The PISG was established by the Minister for Innovation, Industry, Science and Research in May 2008 to examine the drivers and barriers to attracting new internationally competitive and sustainable manufacturing and R&D investment in the pharmaceuticals sector. It reported to the Minister in December 2008. The Government released the final report in February 2009.

Pharmaceutical Industry Working Group (PIWG)

The PIWG provides a forum for industry to engage strategically with Government to ensure an environment that encourages investment in innovation in Australia.

Among its responsibilities PIWG is charged with:

→ discussing identified constraints/impediments to the industry's competitiveness and expansion and identified opportunities for growth

→ discussing a strategic direction for the sector, including the work undertaken by the Pharmaceuticals Industry Council (PIC)

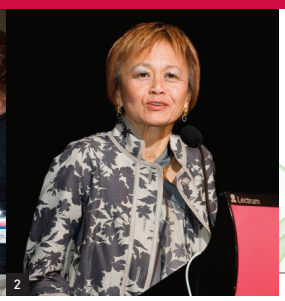
- → facilitating communication and providing linkages among Australian players involved in the discovery, development, production and supply of pharmaceuticals
- → as necessary, contribute to resolving policy conflicts so both the objectives of industry and Government are satisfied and consistent policy signals are sent to industry
- → monitoring the progress in forums addressing issues of the sustainability and processes of the Pharmaceutical Benefits Scheme (PBS).

PIWG is chaired jointly by the Minister for Innovation, Industry, Science and Research and the Minister for Health and Ageing. Members include Medicines Australia, the Generic Medicines Industry Association (GMiA), AusBiotech and the National Health and Medical Research Council (NHMRC).

The Pharmaceuticals Industry Council (PIC)

The Pharmaceuticals Industry Council (established 2006) is the peak body for the Australian pharmaceutical and biotechnology industries. It brings together the innovative, generic and biotechnology industries to present a whole-of-sector approach to addressing opportunities and threats to investment in the sector. PIC is chaired by Will Delaat, the Chairman of Medicines Australia's Board. Chief Executive, Ian Chalmers, represented Medicines Australia's interests and perspectives on the Council in 2008-09.

WORKING WITH HEALTH CONSUMERS



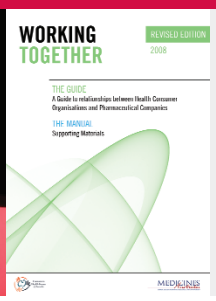


PHOTO 1: *Anne McKenzie (Health Consumers Council, WA), Joy Russo (Consumer Health Forum), Sally Crossing (Cancer Voices NSW), Helen Hopkins (Consumers Health Forum) and Diane Walsh (Top End Division of General Practice) at the Second Joint Medicines Policy Conference*

PHOTO 2: *Dr Duhane Wong-Rieger (Founder and Head of the Consumer Advocare Network) speaking at the Second Joint Medicines Policy Conference*

Medicines Australia has a number of multi-industry collaborations with consumer organisations, such as the National Heart Foundation, Mental Health Council of Australia, and Arthritis Australia. By bringing together members of leading pharmaceutical companies, Medicines Australia supports initiatives aimed at improving the health outcomes for Australians.

The collaborations operate in accordance with the principles in the *Working Together Guide* jointly developed by the Consumers Health Forum of Australia and Medicines Australia. The Guide was reviewed in 2008. The Guide recognises the increasing number of relationships between health consumer organisations and the pharmaceutical industry, and the need for both parties to work together in an appropriately transparent and accountable way. The framework of the Guide concentrates on guiding principles: respect for independence; achieving and maintaining public trust; fairness; openness and transparency; and accountability. It also includes examples of good joint partnerships.

Medicines Australia recognises and values the perspectives of, and participation by, consumer representatives in our various committees. The Consumers Health Forum of Australia provides consumer representatives for a range of Medicines Australia committees—the Code of Conduct Committee, the Code of Conduct Appeals Committee, the Code of Conduct Monitoring Committee and the *Working Together Guide* Review Steering Committee.

In November, the day prior to the Joint Medicines Policy Conference, Medicines Australia convened a workshop on consumer participation in medicines policy, in collaboration with Consumers Health Forum. The facilitator for the day was international consumer advocate, Dr Durhane Wong-Rieger. The workshop included discussions around broad topics such as optimising health outcomes through improving access to, availability of and understanding of good quality health information; integrated health management for consumer and health professionals; and best international models of health consumer advocacy.

WORKING WITH THE COMMUNITY

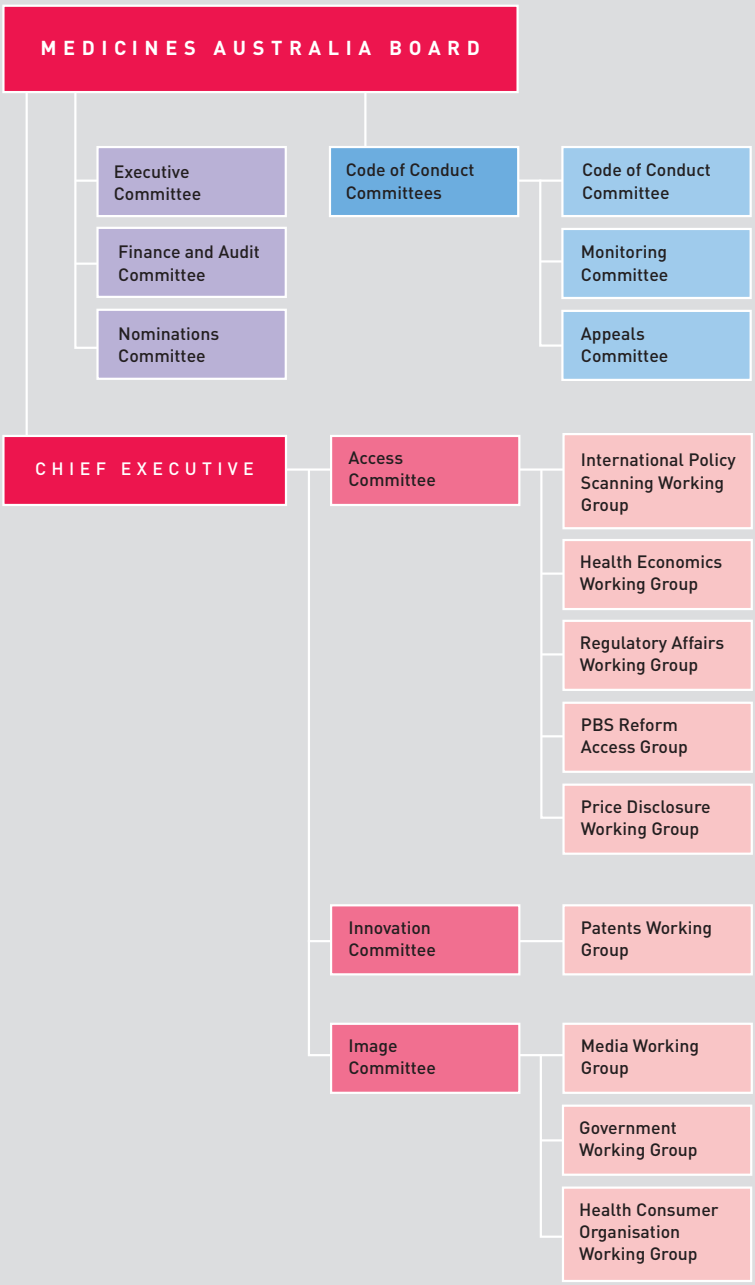
PHOTO 3: *A number of Medicines Australia members have formed the Collaboration for Health in Papua New Guinea (CHPNG) which aims to address the growing HIV health crisis by building in-country healthcare capacity through training and mentoring healthcare workers. The CHPNG is working with the Australasian Society for HIV Medicine (ASHM) and the PNG Catholic HIV Health Service*

Medicines Australia and its member companies provided sponsorship or other support to the following initiatives and projects in 2008–09:

- training of HIV healthcare teams in Papua New Guinea
- healthcare training and resource provisions in East Timor
- the development of programs to improve access to medicines in Papua New Guinea
- health and education programs for young indigenous Australians in Alice Springs
- the expansion of nutrition programs for indigenous children in remote areas of South Australia
- a prestigious award in scientific and intellectual excellence to promote achievement in science
- a national program to enable Year 12 school students to test-drive a wide range of universities and careers in the sciences
- a flagship program to provide university undergraduates with the opportunity to join biomedical research teams as casual employees
- Stewart House holiday and education centre for children from country NSW
- Mission Australia's program to assist homeless people and raise awareness of homelessness
- the Red Cross Victorian Bushfire Appeal
- World Vision sponsorship of children
- the Australian Science Olympiads
- the Rural Health Education Foundation
- Salvation Army Christmas drive
- Men's Health Week
- Canteen NSW
- Community Youth Counselling Services in Ryde, NSW.

WORKING WITH OUR MEMBERS

MEDICINES AUSTRALIA COMMITTEE CHART



The expertise, information and sense of strategic direction contributed by our member companies is of great significance to the success of Medicines Australia's endeavours. In 2008–09 the major forums for such contributions came through the Board, Medicines Australia's three strategic committees, its ten working groups and the Budget Taskforce. The Code of Conduct Committees which, for obvious reasons, are not primarily comprised of member companies, also provided advice and direction to Medicines Australia and member companies in addition to regulatory work undertaken on behalf of the industry.

Medicines Australia Strategic Committee and Working Group Membership: 2008–09

Access Strategic Committee

- Brendan Shaw (Medicines Australia), co-Chair
- Michelle Burke (Bristol-Myers Squibb Australia), co-Chair
- Jez Moulding (sanofi-aventis), Board sponsor
- Ian Thompson (Amgen Australia), Board sponsor
- Sue Alexander (Roche Products)
- David Grainger (Eli Lilly Australia)
- Mendel Grobler (Pfizer Australia)
- David Garmon-Jones (Merck Serono Australia)
- Nick Kursteins (Novartis Australia)
- Paul Lindsay (sanofi-aventis)
- Michael Nobes (Wyeth Australia)
- Sara Pantzer (Amgen Australia)
- Andrew Carter (Commercial Eyes)

HEALTH ECONOMICS WORKING GROUP (HEWG)

- Dell Kingsford-Smith (Janssen-Cilag), Chair
- Andrew Bruce (Medicines Australia)
- Greg Cook (Bristol-Myers Squibb Australia)
- Jim Crompton (Medicines Australia)
- Richard de Abreu Lourenco (Covance)
- Sheryl Dunlop (Schering-Plough)
- Sophie Dunstone (Medicines Australia)
- Diana Edwards (Abbott Australasia)
- Peter Germanos (Boehringer Ingelheim)
- Michael Haberi (GlaxoSmithKline Australia)
- Gary Hamann (Servier Laboratories)
- Ian Noble (Amgen Australia)
- Martin O'Rourke (Eli Lilly Australia)
- Michael Ortiz (Solvay Pharmaceuticals)
- Trish Palmer (Wyeth Australia)

PBS REFORM ACCESS GROUP (PRAG)

- Brendan Shaw (Medicines Australia), co-Chair
- David Grainger (Eli Lilly Australia), co-Chair
- Sue Alexander (Roche Products)
- Andrew Bruce (Medicines Australia)
- Karen Barfoot (Bristol-Myers Squibb Australia)
- Jim Crompton (Medicines Australia)
- Dell Kingsford-Smith (Janssen-Cilag)
- Paul Lindsay (sanofi-aventis)
- Michael Nobes (Wyeth Australia)
- Ian Noble (Amgen Australia)
- Sara Pantzer (Amgen Australia)
- Mike Smith (AstraZeneca)
- Michael Wonder (Novartis Australia)

PRICE DISCLOSURE WORKING GROUP (PDWG)

- Michelle Burke (Bristol Myers Squibb Australia), Chair
- Diana Edwards (Abbott Australasia)
- Michael Fitzsimons (Medicines Australia)
- Peter Germanos (Boehringer Ingelheim)
- Suzanne Lyon (Novartis Australia)
- Duncan O'Brien (Janssen-Cilag)
- Brendan Price (Merck Sharp & Dohme Australia)
- Mark Rohrlach (Novartis Australia)
- Phillip Spiers (AstraZeneca)
- Vanessa Xavier (Wyeth)

INTERNATIONAL POLICY SCANNING WORKING GROUP (IPSWG)

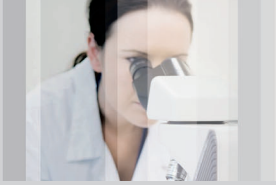
- Amish Chaturvedi (Medicines Australia), Convener
- Bruce Goodwin (Janssen-Cilag)
- Elizabeth Arnold (Bristol-Myers Squibb Australia)
- Michael Burkin (Actelion)
- Geoffrey Chin (Novartis Australia)
- Sheryl Dunlop (Schering Plough)
- Paul Lindsay (sanofi-aventis)
- Angelika Maerz (Wyeth Australia)
- Beth O'Leary (Covance)
- Brendan Shaw (Medicines Australia)
- Sam Shirley (Medicines Australia)
- Rob Wiseman (Pfizer Australia)

REGULATORY AFFAIRS WORKING GROUP (RAWG)

- Sue Alexander (Roche Products), Chair
- Stuart Armstrong (sanofi-aventis)
- Warren Back (Merck, Sharp & Dohme Australia)
- Helen Critchely (Abbott Australasia)
- Elizabeth de Somer (Medicines Australia)
- Rory Graham (CSL)
- Mary Flannery (Eli Lilly Australia)
- David Herd (GlaxoSmithKline Australia)
- Karen James (Wyeth Australia)
- Kirpal Kaur (Bristol-Myers Squibb Australia)
- George Lillis (Novartis Australia)
- Andrew Notley (Gilead Sciences)
- Duncan Purvis (Janssen-Cilag)
- Sylvia Roins (Pfizer Australia)
- Mark Rowland (Amgen Australia)
- Tony Whittaker (Commercial Eyes)

VACCINES WORKING GROUP

- Lauren Conyer (Wyeth Australia), Chair
- John Anderson (CSL)
- Christine Apostopoulos (Novartis Australia)
- Helen Concilia (CSL)
- Grant Duff (Solvay Pharmaceuticals)
- Alex Gosman (GlaxoSmithKline Australia)
- Brent MacGregor (sanofi-aventis)
- Glen Mason (sanofi-aventis)
- Sheryl Page (GlaxoSmithKline Australia)
- Caroline Pilot (Solvay Pharmaceuticals)
- Tony Skelton (Baxter Healthcare)
- George Weber (Novartis Pharmaceuticals Australia)



Innovation Strategic Committee

- Deborah Monk (Medicines Australia), co-Chair
- Rod Whittington (Janssen-Cilag), co-Chair
- Graeme Blackman (IDT Australia), Board sponsor
- Erica Mann (Wyeth Australia), Board sponsor
- Dieter Torheiden (Solvay Pharmaceuticals), Board sponsor
- Jose Vieira (AstraZeneca), Board sponsor
- Candice Braithwaite (Wyeth Australia)
- Mike Kabos (Bristol-Myers Squibb Australia)
- Bill Ketelbey (Pfizer Australia)
- Omar Ali Khan (Medicines Australia)
- Angelika Maerz (Wyeth Australia)
- John C. Reid (Abbott Australasia)
- Linda Swan (Merck Sharp & Dohme Australia)

PATENTS WORKING GROUP (PWG)

- Deborah Monk (Medicines Australia), Chair
- Rebecca Allsopp (sanofi-aventis)
- Sally Glover (Pfizer Australia)
- Shahnaz Irani (Spruson & Ferguson)
- Omar Ali Khan (Medicines Australia)
- Angelika Maerz (Wyeth Australia)
- Cate Martin (Eli Lilly Australia)
- Sara Pantzer (Amgen Australia)
- Alison Roy (Eli Lilly Australia)
- David Walker (GlaxoSmithKline Australia)

Image Strategic Committee

- Donna Edman (Medicines Australia), co-Chair
- Alex Gosman (GlaxoSmithKline Australia), co-Chair
- John Latham (Pfizer Australia), Board sponsor
- Jeremy Morgan (Eli Lilly Australia), Board sponsor
- Jane Orr (Merck Sharp and Dohme Australia), Board sponsor
- Gillian Adamson (Pfizer Australia)
- Karen Barfoot (Bristol-Myers Squibb Australia)
- Alan Brindell (sanofi-aventis)
- Paul Cross (Astra Zeneca Australia)
- Libby Day (Roche Products)
- Grant Duff (Solvay Australia)
- Peter Mayrick (i-Nova Australia)
- Ian McKnight (Wyeth Australia)
- Glenn Montgomery (Merck Serono Australia)

GOVERNMENT WORKING GROUP (GWG)

- Donna Edman (Medicines Australia), co-Chair
- Michael Riley (Servier Laboratories), co-Chair
- Karen Barfoot (Bristol-Myers Squibb Australia)
- Rowena Cowan (sanofi-aventis)
- David Hungerford (AstraZeneca)
- Tim James (Janssen-Cilag)
- Natasha Maclaren-Jones (Novartis Australia)
- Ian McKnight (Wyeth Australia)
- David Miles (Pfizer Australia)
- Sara Pantzer (Amgen Australia)
- Patrick Tung (Merck Serono Australia)

HEALTH CONSUMER ORGANISATION WORKING GROUP (HCOWG)

- Diana Terry (Medicines Australia), co-Chair
- Sarah Tennent (GlaxoSmithKline Australia), co-Chair
- Peter Murphy (Novartis Australia), co-Chair
- Gillian Adamson (Pfizer Australia)
- Fiona Bailey (Eli Lilly Australia)
- Kellie Howe (Eli Lilly Australia)
- Holly Kania (Roche Products)
- Ian McKnight (Wyeth Australia)
- Monique McLoughlin (Amgen Australia)
- Jennifer Stevenson (Abbott Australasia)
- Jude Tasker (Pfizer Australia)

MEDIA WORKING GROUP (MWG)

- Jamie Nicholson (Medicines Australia), co-Chair
- Libby Day (Roche Products), co-Chair
- Bernadette Basell (GlaxoSmithKline Australia)
- Adrian Dolahenty (Bayer Schering Pharma)
- Lisa Julian (Eli Lilly Australia)
- Paul de Leon (Merck Sharp & Dohme Australia)
- Michael Moore (Bristol-Myers Squibb Australia)
- Simone Prideaux (AstraZeneca)
- Peter Poggioli (Wyeth Australia)
- Rachel Reyna (Merck Sharp & Dohme Australia)
- Adam Roche (Janssen-Cilag)
- Claire Russell (sanofi-aventis)
- Maida Talhami (Pfizer Australia)

Budget Taskforce (a combined Access/Image group)

- Donna Edman (Medicines Australia), co-Chair
- Brendan Shaw (Medicines Australia), co-Chair
- Michelle Burke (Bristol-Myers Squibb Australia)
- Amish Chaturvedi (Medicines Australia)
- Rowena Cowan (sanofi-aventis)
- Paul Cross (Novarits Australia)
- Libby Day (Roche Products)
- Adrian Dolahenty (Bayer Schering Pharma)
- Sue Elderton (Medicines Australia)
- Michael Fitzsimons (Medicines Australia)
- Alex Gosman (GlaxoSmithKline Australia)
- Mendel Grobler (Pfizer Australia)
- Paul Lindsay (sanofi-aventis)
- Ian McKnight (Wyeth Australia)
- David Miles (Pfizer Australia)
- Jamie Nicholson (Medicines Australia)
- Sara Pantzer (Amgen Australia)
- Kieran Schneemann (AstraZeneca)
- Charles Waterfield (AstraZeneca)

Code of Conduct Committees

Code of Conduct Committee Membership

PANEL OF INDEPENDENT CHAIRMEN OF COMMITTEES

- Michael Daniel (PricewaterhouseCoopers)
- Michael Gorton (Russell Kennedy)
- John Kelly (John Kelly & Associates)
- Alan Limbry (Strategic Resolution)
- Bernard O'Shea (Deacons)
- Ian Tonking (Barrister)

INDEPENDENT MEMBERS OF THE CODE OF CONDUCT AND APPEALS COMMITTEES

- Peter Bird (Therapeutic Goods Administration)
- Sharon Caris (Consumers Health Forum of Australia)
- Associate Professor David Champion (RACP)
- Dr Ray Cook (Therapeutic Goods Administration)
- Dr Marcela Cox (RACGP)
- Professor Richard Day AM (ASCEPT)
- Dr John Gullotta (Australian Medical Association)
- Dr Avi Lemberg (RACP)
- Anne McKenzie (Consumers Health Forum of Australia)
- Judith Maher (Consumers Health Forum of Australia)
- Dr Harry Nespolon (RACGP)
- Dr Ruth Ratner (AGPN)
- Professor Paul Seale (ASCEPT)
- Patti Warn (Consumer Health Forum of Australia)
- Associate Professor Ken Williams (specialist pharmacologist)

Code of Conduct Monitoring Committee Membership

INDEPENDENT CHAIRMEN OF THE MONITORING COMMITTEE

- Russell Edwards
- Dr Michael Wyer

INDEPENDENT MEMBERS OF THE COMMITTEE

- Henry Ko (Consumers Health Forum)
- Dr Robyn Napier (Australian Medical Association)
- Sheila Rimmer AM (Consumers Health Forum)
- Dr Sue Wicker (RACGP)

INSIDE MEDICINES AUSTRALIA

GOVERNANCE

Summary of strategic priorities

The Medicines Australia Board Annual Strategic Retreat was held between 31 July and 1 August 2008.

The Retreat focused on ensuring that Medicines Australia is adequately resourced and appropriately focused to serve the requirements of member companies.

The Board reviewed the Medicines Australia Strategic Plan 2007–10, particularly focusing on the relevance of the Vision and Mission of Medicines Australia and key priorities:

- achieve credibility with, and obtain the trust of key stakeholders
- continuously improve access to innovative medicines
- achieve an optimal environment for sustainable innovation
- maintain a high standard of ethical industry conduct through effective self regulation
- demonstrate leadership as a model pharmaceutical industry association.

Member meetings

There were two member meetings during 2008–09.

Annual General Meeting

18 October 2008

- Mr John Latham chaired the meeting and presented both the Annual and Financial Reports to the Board.
- Medicines Australia announced the establishment of the Special Purpose Fund.
- Mr Mitch Kirkman, Novartis Pharmaceuticals, was the recipient of the Pat Clear Award for 2008.

Special Member Meeting

15 June 2009

- Medicines Australia Chairman Will Delaat chaired the meeting. The purpose of the meeting was to pass a Special Resolution of the Members in relation to adoption of Edition 16 of the Code of Conduct.
- Adoption of Edition 16 of the Code of Conduct was carried unanimously.

Board meetings

There were 13 Board meetings throughout the course of the year. Seven occasions were scheduled in-person meetings and the remainder were conducted out of session.

- 1 July 2008—Medicines Australia, Canberra
- 12 August 2008—Medicines Australia, Canberra
- 16 September 2008
- 14 October 2008—Pfizer Australia, West Ryde
- 9 December 2008—National Press Club, Canberra
- 9 February 2009
- 17 March 2009—AstraZeneca Conference Centre, North Ryde
- 7 April 2009
- 28 April 2009
- 12 May 2009—Medicines Australia, Canberra
- 15 May 2009
- 22 May 2009
- 23 June 2009—Hilton Airport, Melbourne

Medicines Australia acknowledges and thanks the Directors for their tireless commitment to the industry.

Throughout 2008–09 there were five Casual Vacancies arising on the Board. Medicines Australia also acknowledges the commitment and expertise of Board members who resigned throughout 2008–09.

CORPORATE POLICIES

Medicines Australia Policy on Political Donations

For the purposes of formally ratifying the Medicines Australia position in relation to political donations and in anticipation of the Commonwealth Electoral Act amendments with respect to political donations (and recognition of amendments to state legislation), the Medicines Australia Board approved a policy on political donations in October 2008.

- The policy recognises the validity of all legitimate and reasonable opportunities to engage with political and government stakeholders, including through legal and transparent donations to political parties.
- Medicines Australia will abide by all relevant Australian Commonwealth and State laws pertaining to contributions or donations to political parties, including all public disclosure requirements.
- While cash donations are ruled out, fee-paying engagement is authorised for policy discussions through attendance at conferences, policy workshops, round table discussions and other opportunities which may arise.

The full policy is available on the Medicines Australia website.

Medicines Australia Policy and Remuneration Schedule for Consumer Representatives on Medicines Australia Committees

Medicines Australia values the perspective of and participation by consumer representatives on its various committees and acknowledges that consumer representatives frequently forgo their paid employment in order to prepare for and attend meetings. In October 2008 the Medicines Australia Board endorsed a formal policy in relation to the remuneration of consumer representatives. A schedule incorporating an hourly fee, transport and accommodation is included in the policy. The full version can be found on the Medicines Australia website.

Establishment of the Medicines Australia Special Purpose Fund

The establishment of the Special Purpose Fund was announced at the AGM in October 2008. The Special Purpose Fund is derived from the Code of Conduct fine income, minus costs incurred in running the Code of Conduct and associated activities.

At the 9 December Board meeting, the Board endorsed in principle the allocation of funds from the Special Purpose Fund to not more than two not-for-profit charitable organisations which focus on indigenous health.

On 12 May 2009, the Medicines Australia Board approved funding of $1,081,000 to the Jimmy Little Foundation.

The Medicines Australia Finance and Audit Committee will oversee the Fund activities:

- Mr John Latham (Pfizer Australia), Chair
- Mr Jeremy Morgan (Eli Lilly Australia)
- Mr Dieter Torheiden (Solvay Australia)

SECRETARIAT

Office refurbishment

The decision of the Board in 2007 to grow the Medicines Australia Secretariat to fulfil the key priorities identified in the 2007–10 Strategic Plan was fully realised in 2008. During 2008–09 Medicines Australia undertook a refurbishment of its premises to accommodate the expanded Medicines Australia team. The refurbishment of the Medicines Australia offices took place from 18 August–23 December 2008.

Medicines Australia thanks all members for their patience and understanding for any inconvenience while the refurbishment was in progress.

IT Strategy

Medicines Australia invested in new IT infrastructure during 2008–09. The new infrastructure will enable a redevelopment of the Medicines Australia website that best serves our Board, our members, stakeholders and the general public.

Image

Promoting the Value of Medicines

In 2008 Medicines Australia worked with Ogilvy Healthcare to produce *Innovating for Life*. *Innovating for Life* tells the story of the value of medicines. Seven people shared their personal experiences with chronic and sometimes life-threatening diseases, and explained how their lives have been enhanced or saved by medicines. Covering asthma, stroke, rheumatoid arthritis, depression, HIV/AIDS, cancer and vaccination against infectious disease, *Innovating for Life* charts the journey of improvements in medicines from the perspective of the people who are dependent on them while providing details of their impact on the overall health of Australians.

Over 20,000 copies of *Innovating for Life* were ordered by member companies and a number were requested by members of the public, research organisations and other industry organisations. Every member of the Commonwealth Parliament was sent a copy as were over 20 consumer healthcare organisations.

MEDICINES AUSTRALIA PUBLICATIONS

PUBLICATIONS AND REPORTS

- *2007–08 Medicines Australia Annual Report* (October 2008)
- *Working Together Guide: a guide to relationships between Health Consumer Organisations and Pharmaceutical Companies* (Revised Edition) (November 2008)
- *Working Together Manual Supporting Materials: a guide to relationships between Health Consumer Organisations and Pharmaceutical Companies* (Revised Edition) (November 2008)
- *Innovating for Life* (December 2008)

SUBMISSIONS

- July 2008—*Medicines Australia submission to the Productivity Commission on Regulatory Burdens—Manufacturing and Distributive Trades*
- September 2008—*Medicines Australia submission to the Community Affairs Senate Committee—Draft National Health (Pharmaceutical Benefits—Charges) Regulations 2008*
- October 2008—*Medicines Australia submission to the Advisory Council on Intellectual Property on Patentable Subject Matter*
- October 2008—*Medicines Australia initial submission to the Treasury's Review of the Australian Tax-Transfer System*
- November 2008—*Medicines Australia submission to the 2009–10 Federal Budget*
- January 2009—*Medicines Australia submission to AusIndustry and Innovation Australia on amendments to Guidelines for R&D Plans for Claiming R&D Tax Benefits*
- February 2009—*Medicines Australia submission to the Australian Customs Service on amendments to the Notice of Objection scheme* (Trade Marks Act 1995 *and* Copyright Act)
- March 2009—*Medicines Australia submission to the Preventative Health Taskforce*
- March 2009—*Medicines Australia submission to the Senate Community Affairs Committee Inquiry on Gene Patents*
- April 2009—*Medicines Australia follow-up submission to the Treasury's Review of the Australian Tax-Transfer System*
- May 2009—*Medicines Australia submission to the Health Technology Assessment (HTA) Review*

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