2009 2010

Medicines Australia Annual Report

2009–2010

MEDICINES Australia

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This Annual Report provides a summary of Medicines Australia's activities, initiatives and achievements for the financial year ending 30 June 2010. 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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Design Designers Wakefield Bevanda

MEDICINES AUSTRALIA

Vision + Mission

VISION

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

MISSION

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

Strategic Directions

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.

Chairman's report

Australia's medicines industry can reflect upon a year of significant progress on several policy fronts. Indeed, we can look ahead with a genuine sense of hope to a period of unprecedented stability and business certainty, notwithstanding the fact that two pieces of legislation crucial to industry's interests were still before the Parliament at the end of June 2010.

The primary focus of the past 12 months has been the protracted negotiations with the Federal Government to reach an agreement that would deliver enhanced and accelerated savings from the Pharmaceutical Benefits Scheme, in return for a period of pricing certainty and policy improvement.

On 6 May 2010 the Board of Medicines Australia and the Minister for Health and Ageing Nicola Roxon were joined at Parliament House by the then Prime Minister Kevin Rudd, who witnessed the signing of the Memorandum of Understanding. While this historic agreement will result in a considerable additional financial burden for Australia's pharmaceutical companies, it delivers a commitment from Government not to introduce any price-related PBS savings measures for four years. The stability that this commitment provides is paramount and will allow companies to continue to invest in Australia with confidence.

I look forward to the passage through Parliament of the legislation that gives effect to pricing changes delivered through the MoU. I also eagerly await the passage of the R&D Tax Credit Bill, which will introduce a new tax credit system, effectively lowering by 10 per cent the cost of conducting R&D and making Australia more competitive.

Over the past year I have continued to co-chair the Access to Medicines Working Group with David Learmonth, Deputy Secretary of the Department of Health and Ageing. The process improvements to the PBS agreed to in the MoU were the result of the considerable hard work by this group over the past three years in developing robust public health policy options. The AMWG will continue to explore further improvements to Australian patients' access to medicines.

I have also continued to chair the Pharmaceuticals Industry Council, which brings together AusBiotech, the Generic Medicines industry Association and Medicines Australia. The Council's aim to make Australia a more attractive location for global investment in clinical trials was advanced by the creation of the Clinical Trials Action Group, co-chaired by Mark Butler, the Parliamentary Secretary for Health, and Richard Marles, Parliamentary Secretary for Innovation and Industry. Perhaps for the first time, the Government acknowledged not only the social and economic value of maintaining industry investment in clinical research in Australia but also the growing international competition for global investment.

The Clinical Trials Action Group was established by the Pharmaceutical Industry Working Group, which is co-chaired by the Minister for Health and Ageing Nicola Roxon and the Minister for Innovation and Industry Senator Kim Carr. I look forward to continuing to engage with the new Government through the PIWG.

I particularly look forward to the publication of the Action Group's recommendations, which I hope will offer Australia a decisive pathway towards maximising our potential as a desirable destination for global clinical trials investment.

The 16th edition of the Medicines Australia Code of Conduct came into effect on 1 January 2010 and has enjoyed a smooth implementation. The new Code includes enhanced provisions concerning brand name reminders, prescribing software advertising and the disclosure of support for consumer organisations. These improvements will ensure the Code continues to set the highest ethical standard for the industry and remains aligned with the community's changing expectations.

There have been two additions to our membership this year. I am pleased to welcome to the association as Class 4 members, Andrew's Refrigerated Transport and Iris Interactive.

In September 2009 Ian Chalmers resigned as chief executive of Medicines Australia after three years in the role. I would like to acknowledge Ian's hard work, and significant contribution to the association and to the industry more broadly, in particular in overseeing the successful implementation of the PBS reforms.

The Board was delighted to appoint Brendan Shaw as the new chief executive in January 2010 and I would like to extend my thanks to Brendan for his astute advocacy for our Memorandum of Understanding and his determined and energetic leadership of the association over the latter half of the year.

Finally, I would like to thank my colleagues on the Board for their contribution and support this year. Their sound judgement and unswerving conviction have ensured a positive strategic direction for Medicines Australia.

We can embark upon the coming year with optimism.

Will Delaat

Chief Executive's report

The 12 months to June 2010 have been tumultuous for Australia's medicines industry and the member companies of Medicines Australia.

During the first half of the year the industry was confronted with significant commercial pressures from a range of policy and economic challenges.

The Federal Government's introduction of four new therapeutic pricing groups to cut money out of the Pharmaceutical Benefits Scheme came without any meaningful consultation with the industry. This generated enormous business uncertainty for Australia's medicines companies, making it difficult for them to plan realistically for the future and bring new medicines to Australian patients.

The demise of the Pharmaceutical Partnerships Program (P3) on 30 June 2009 meant that for the first time since the Hawke Government of the 1980s Australia has no industry program designed specifically to encourage the growth and development of Australia's medicines industry. We also had to accommodate the introduction of full cost recovery for the Government's evaluation process for listing new medicines on the PBS from 1 January 2010, placing a further cost burden on the business of helping Australians stay healthy.

Together with the aftermath of the global financial crisis, a deteriorating fiscal situation, increasing global rationalisation in the international industry and a government introducing major reforms to Australia's health system, the business environment for Australia's medicines companies became increasingly uncertain. To their credit, the member companies of Medicines Australia that make up the bulk of Australia's medicines industry responded to that environment in a resolute, united, positive and constructive manner and achieved a number of major changes.

For the first time in history the industry signed a Memorandum of Understanding (MoU) with the Commonwealth of Australia to achieve a more predictable and certain PBS policy environment. The MoU provides savings to government, improves the operation of the PBS for industry and patients, and provides a level of policy stability that industry needs to bring new medicines to Australians.

Medicines Australia members united behind a new, stronger Code of Conduct which came into effect on 1 January 2010 and which sets the standard for transparent, ethical behaviour for the broader health sector, both here and internationally.

The industry also responded to the Government's call for assistance in 'closing the gap' between the health of indigenous and non-indigenous Australians by partnering with the Jimmy Little Foundation, the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation and the Shalom Gamarada Ngiyani Yana Scholarship Program. Through these partnerships, Medicines Australia's members have committed over $1 million in financial support to these organisations' respective projects to improve indigenous health.

Through all of these activities, the member companies of Medicines Australia have shown that the majority of Australia's medicines industry is responding to changing community needs and partnering with the community to find solutions.

These solutions sometimes have adverse impacts on the industry. The bulk of the financial impact from the savings measures contained in the MoU, for example, will fall on Medicines Australia member companies, yet they have agreed to support the MoU. Medicines Australia member companies have demonstrated that they want to be solutions-oriented.

This constructive engagement, which has resulted in better outcomes for the industry and the wider community, would not have been possible without unity and collaboration within the membership of Medicines Australia. It has been a great pleasure to work with our member companies over the last 12 months. The leadership shown by the Medicines Australia Board in steering the industry through the often choppy policy waters of the past year has been instrumental to our success and I have much valued their wisdom and support.

It has been a particular pleasure to work with our Independent Chairman, Will Delaat, whose guidance and stewardship of the Board has been invaluable to the industry. The support and engagement of our member companies has been extremely encouraging, as has the hard work of all member company staff on our strategic committees and working groups.

I would like to acknowledge the contribution of my predecessor Ian Chalmers, who left Medicines Australia in September 2009. Ian played an important role in growing the services delivered by Medicines Australia, reforming the Code of Conduct, leading the industry through the implementation of the original 2007 PBS reforms and driving Medicines Australia's international engagement on health technology assessment.

Finally, none of the industry's achievements in 2009–10 could have been possible without the unstinting efforts of the staff in the Medicines Australia secretariat. The staff are an exceptional team and have been outstanding in providing services to our members and representing an industry that is so important to Australia.

Australia's medicines industry makes a major contribution to Australia's social and economic wellbeing. It develops and provides the medicines and vaccines that treat Australian families, keep people out of hospitals, prevent a variety of diseases from affecting our children, help ageing Australians maintain a healthy lifestyle and ensure a productive population that can participate in growing our society and our economy. The Australian industry contributes over $4 billion in high-tech manufactured exports each year to Australia's trade balance. We invest $1 billion in research and development each year, directly employ over 14,000 Australians in high-skilled jobs, and deliver broader economic benefits to the research sector, hospitals and other industries like biotechnology.

It is an industry of which we can be enormously proud and, as this report shows, an industry that is making a major contribution to Australia and the broader global society. We at Medicines Australia look forward to working with our members to achieve more for the industry and the community over the next 12 months.

Dr Brendan Shaw

MEDICINES AUSTRALIA

Board members


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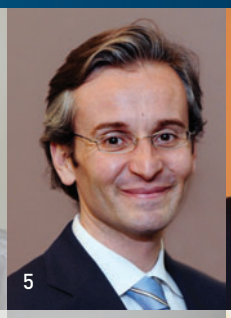
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Directors 2009–10

			APPOINTED TO BOARD
1	Mr Will Delaat	Independent Chairman	August 1998
2	Mr Klaus Abel	Managing Director, Lundbeck Australia Pty Ltd	1 January 2010
3	Dr Graeme Blackman	Executive Chairman, IDT Australia Ltd	June 1995
4	Mr Bruce Goodwin	Managing Director, Janssen-Cilag Pty Ltd	12 May 2009
5	Mr Fredric Guerard	Managing Director, Novartis Pharmaceuticals Australia Pty Ltd	23 June 2009
6	Mr John Latham	Regional Director (Australia & New Zealand), Pfizer Australia Pty Ltd	6 March 2007
7	Mr Jeremy Morgan	Managing Director, Eli Lilly Australia Pty Ltd	6 March 2007
8	Mr Jez Moulding	Managing Director, sanofi-aventis Australia Pty Ltd	1 January 2008
9	Ms Jane Orr	Managing Director, Merck Sharp & Dohme (Australia) Pty Ltd	18 December 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 Toledo Vieira	Managing Director, AstraZeneca Pty Ltd	1 January 2008
13	Ms Deborah Waterhouse	Vice President and General Manager, GlaxoSmithKline Australia Pty Ltd	9 December 2008

			APPOINTED	RESIGNED
14	Ms Mary Sontrop	General Manager, CSL Biotherapies Australia & New Zealand	22 April 2008	31 December 2009

MEDICINES AUSTALIA

Secretariat

LEADERSHIP


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ACCESS


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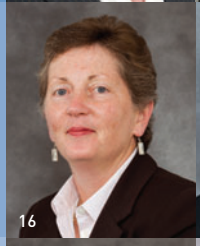
INNOVATION AND ETHICAL CONDUCT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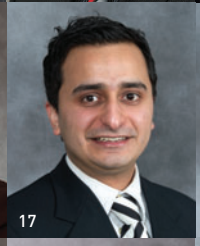
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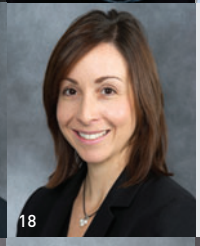
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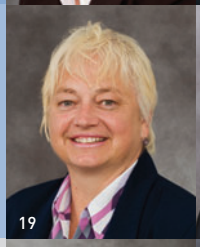
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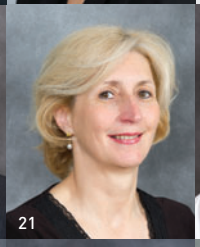
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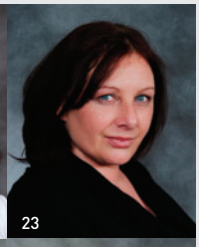
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Staff who departed in 2009–10


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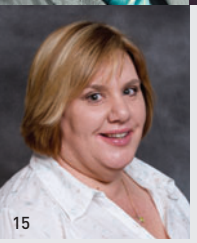
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LEADERSHIP

1	Brendan Shaw	Chief Executive
2	Louise Collett	Executive Assistant to the Chief Executive
3	Katie Whitehead	Director Corporate Services
4	Di Phillips	Finance Manager
5	David Newman	IT Manager
6	Joanne Toogood	Office Manager
7	Janelle Andre Morgan	Executive Officer
8	Prya Sonah	Finance Assistant

ACCESS

9	Andrew Bruce	Director Health Policy and Research
10	Jim Crompton	Reimbursement Strategies Manager
11	Elizabeth de Somer	Regulatory Affairs Manager
12	Michael Fitzsimons	Policy Manager
13	Amish Chaturvedi	Research Manager
14	Sam Shirley	Policy and Research Officer
15	Helen Cox	Policy Coordination Officer

INNOVATION AND ETHICAL CONDUCT

16	Deborah Monk	Director Innovation and Industry Policy
17	Omar Ali Khan	Senior Innovation and Industry Policy Officer
18	Romina Bognolo	Code of Conduct Administration Officer

IMAGE

19	Donna Edman	Executive Director Public Affairs
20	Jamie Nicholson	Media Communications Manager
21	Diana Terry	Stakeholder Relations Manager
22	Sue Elderton	Public Affairs Officer
23	Juanita Wenham	Personal Assistant to Innovation and Industry Policy and Public Affairs Directors

STAFF DEPARTED MEDICINES AUSTRALIA 2009–10

24	Ian Chalmers	Chief Executive
25	Heather Jones	Code of Conduct Manager
26	Romina Bommes	Code of Conduct Administration Officer
27	Jennifer Delaney	Personal Assistant to Innovation and Industry Policy and Public Affairs Directors
28	Alia Stanley	Executive Officer

Medicines Australia members 2009–10

Class One

Abbott Australasia Pty Ltd
Actelion Pharmaceuticals Australia Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
AMGEN Australia Pty Ltd
AstraZeneca Pty Ltd
Baxter Healthcare Pty Ltd
Bayer Australia Limited T/as Bayer Schering Pharma
Biogen Idec Australia Pty Ltd
Boehringer Ingelheim Pty Ltd
Bristol-Myers Squibb Australia Pty Ltd
Celgene Pty Limited
CSL Limited
Eli Lilly Australia Pty Ltd
Genzyme Australasia Pty Ltd
Gilead Sciences Pty Ltd
GlaxoSmithKline Australia Pty Ltd
Ipsen Pty Ltd
Janssen-Cilag Pty Ltd
Lundbeck Australia Pty Ltd
Merck Serono Australia Pty Ltd
Merck Sharp & Dohme (Aust) Pty Ltd
Mundipharma Pty Ltd
Novartis Pharmaceuticals Australia Pty Ltd
Novo Nordisk Pharmaceuticals Pty Ltd
Nycomed Pty Ltd
Pfizer Australia Pty Ltd
Roche Products Pty Ltd
sanofi-aventis Australia Pty Ltd
Schering-Plough Pty Ltd (now MSD)
Servier Laboratories (Aust) Pty Ltd
Shire Australia Pty Limited
Solvay (now Abbott Products Ltd)
Stiefel Laboratories Pty Ltd (now GSK)
UCB Australia Pty Ltd
Wyeth Australia Pty Ltd (now Pfizer)

Class Two

iNova Pharmaceuticals Pty Ltd
Invida Australia Pty Ltd
Norgine Pty Limited
Smith & Nephew Pty Ltd

Class Three

IDT Australia Ltd

Class Four

Andrew's Refrigerated Transport
Commercial Eyes Pty Ltd
Covance Pty Ltd
IMS Health Australia Pty Ltd
Iris Interactive Pty Ltd
Kendle Pty Ltd
KMC Health Care
KPMG
Pretium Pty Ltd
PricewaterhouseCoopers
Princeton Publishing Pty Ltd
Quintiles Pty Ltd

* *Italic type indicates companies which left Medicines Australia during 2009–10, through merger/acquisition or other reasons.*

KEY ISSUES

Improving timely access to medicines for Australians

2009–10 was an important year for the Australian medicines industry in terms of improving the timely access to medicines for consumers. Two developments, in particular, are noteworthy: the signing of a formal Memorandum of Understanding between Medicines Australia and the Commonwealth on the management of the Pharmaceutical Benefits Scheme; and the finalisation of the Therapeutic Goods Administration's Business Process Reforms which, from 1 November 2010, will reduce the time taken to evaluate and register new medicines. It is expected that both of these improvements will significantly lift business confidence in Australia's regulatory and reimbursement regime.

The Memorandum of Understanding

On 6 May 2010, Medicines Australia signed a four-year Memorandum of Understanding with the Commonwealth of Australia on the management of the PBS. By building on the 2007 PBS Reforms, the MoU provides the Federal Government with the confidence to include $1.86 billion in savings to the PBS in the forward estimates. The Commonwealth has agreed to introduce improvements to the PBS listing process and has formally acknowledged that a stable pricing environment is important for a viable and responsible medicines industry in Australia. The Commonwealth has undertaken not to implement any new policy to generate price-related savings from the PBS for the four-year term of the agreement. Importantly, this includes a four-year moratorium on the formation of new therapeutic groups, which is a welcome relief from a policy that Medicines Australia has long argued creates significant and unnecessary business uncertainty for its members.

Medicines Australia negotiated this agreement against the backdrop of growing uncertainty in Australia's economic outlook during the global financial crisis and unmistakable signals from the Commonwealth Government that it intended to make ongoing cuts to the PBS in order to fund its ambitious health reform agenda. The Government's desire to make cuts to the PBS was foreshadowed by the announcement of four new therapeutics groups in the second half of 2009; an announcement made without any meaningful consultation with affected parties.

Medicines Australia Board members, Chief Executive Brendan Shaw and Department of Health Secretary Jane Halton witness the formal signing of the Memorandum of Understanding between Medicines Australia and the Commonwealth by Medicines Australia Chairman Will Delaat, and Minister for Health and Ageing Nicola Roxon in May 2010.

Medicines Australia's objective during negotiations was simple: to provide its members with a predictable pricing and business environment and an improved PBS listing process. In addition to the four years of pricing policy certainty and the moratorium on new therapeutic groups, the MoU also provides Government with savings to the off-patent market (F2 formulary). While it was impossible to avoid some mandatory price cuts, most government savings will be delivered through strengthening existing pricing policies, in particular the price disclosure arrangements. Price disclosure policy uses companies' own decisions to drive efficiencies in PBS expenditure, thus minimising direct government intervention in the marketplace. Medicines Australia has long argued that market competition between multi-branded medicines will deliver the Government significant savings over the long term in the older off-patent market, thus providing substantial headroom to list new innovative medicines in the F1 formulary. This position is supported by independent modelling by Victoria University, the Pharmacy Guild of Australia, and PricewaterhouseCoopers.

The MoU also provides for important improvements in the PBS listing process. Most notably, from 1 January 2011, TGA and PBAC evaluation processes can be conducted in parallel, reducing the time it takes for some innovative medicines to become available to the Australian public. A new managed entry scheme for some innovative medicines for which there is a high, unmet clinical need will begin on 1 January 2011. As a form of 'coverage with evidence development', this scheme will potentially permit earlier listing with a commitment from the PBAC to re-value a medicine following the provision of more evidence at a later date.

The MoU also includes a commitment from the Government to improve the timely access to medicines that Australians need by setting a 'best-endeavours' six-month time limit on those PBAC-recommended medicines requiring Cabinet approval. While Medicines Australia welcomes this, it is one of the measures in the MoU which does not go far enough. Medicines Australia continues to argue that the threshold for medicines requiring Cabinet consideration should be increased from $10 million to $20 million and indexed to inflation to reflect the real value of the threshold as it was when it was established in 2001.

Many of the access improvements contained within the MoU were the result of more than three years of work by the industry and Government representatives on the Access to Medicines Working Group. These improvements could not have been negotiated as part of the MoU without the important groundwork of the AMWG and the substantial contributions of industry representatives including Medicines Australia Chairman Will Delaat, Steve Crowley (formerly Janssen-Cilag), David Grainger (Eli Lilly),

Ian Noble (Amgen), and Mendel Grobler (Pfizer). In turn, the AMWG has been supported by a larger industry policy forum under the aegis of the Access Strategic Committee and the PBS Reform Access Group. These industry groups will now turn their attention to ensuring that each of the negotiated access improvements is implemented in full and in a timely manner.

TGA Business Reforms

On 25 May 2010, the Therapeutic Goods Administration announced that the new Streamlined Prescription Medicines Submission Process would begin on 1 November 2010. This was the culmination of several years of work by Medicines Australia's Regulatory Affairs Working Group (RAWG) in building and consolidating an effective partnership with the TGA.

Following the demise of negotiations for the Australia New Zealand Therapeutic Products Authority, the TGA announced a broad range of legislative and business process reforms to begin in 2009. There was finally acknowledgement that the time taken by the TGA to evaluate and register a new medicine had become progressively longer than anticipated and increasingly unpredictable. Although the statutory timeframe of 255 working days remained intact, this was beset by multiple 'stopped clocks' and iterative 'section 31' questions. The net effect was extending evaluation times to an average 500 days. The inability to plan launching and post-registration activities further added to the uncertainty.

Sponsors will now be able to provide the TGA with prior notice of an impending submission and receive a timetable of evaluation milestones that the TGA will commit to meet. The pre-submission will include summary information in order that the TGA can assess the evaluation requirements and plan the workflow. The time from evaluation to decision under the new process will be nine calendar months including the time spent with the sponsor.

The TGA has committed to greater partnership with industry to provide predictability, business certainty, improved transparency of decision-making and other regulatory processes. This will ensure our industry is able to plan the timing of submissions and subsequent market launch activities and provide international colleagues with a benchmark for evaluation and decision-making.

Through the RAWG, Medicines Australia has worked closely with the TGA to develop a practical and achievable business process. We have negotiated hard to retain some flexibility in the system without compromising predictability. Although the streamlined submission process will begin in November 2010, there will be at least 12 months of transition. Industry should not lose sight of the gains this timely and predictable registration process will provide, not least for Australian patients, and we need to support the transition to the new system by continued partnership with the TGA.

Access Strategic Committee and Working Groups

While the MoU and the TGA Business Reforms were the areas of primary focus, the Access Strategic Committee and its working groups continued to manage the many policy challenges facing Medicines Australia. In addition to its key advisory role during the MoU negotiations, the Access Committee oversaw the development of Medicines Australia submissions to the Federal Government's review of the 2007 PBS reforms and the Senate Inquiry into the formation of therapeutic groups. It also provided major policy input into Medicines Australia's submission to the Senate Inquiry into the legislation required to implement pricing policy changes agreed to in the MoU.

The RAWG played a key role in representing the industry to ensure that the TGA Business Process Reforms were implemented effectively and worked diligently to improve the transparency of the registration process by negotiating the final format and content of the Australian Public Assessment Reports (AusPARS). AusPARS are records of the TGA's decision-making process.

The adoption of a uniform clinical template in the writing of clinical evaluations will further enhance the industry's ability to analyse and respond to 'section 31' questions.

Additionally, RAWG assisted the TGA in the development of a simple and timely process for the uploading and publishing of Product Information and Consumer Medicine Information on the TGA website. The result is a single repository of accurate and up-to-date information maintained by the regulator responsible for approving these documents. This is another great move towards advanced transparency from the regulatory agency.

Health Economics Working Group

The Health Economics Working Group (HEWG) continued its work to improve the registration and reimbursement environment for pharmaceutical products in Australia.

Notably, the Working Group worked with the Council of Australian Therapeutic Advisory Groups (CATAG) to explore ways of managing the procurement of products which cause difficulty under capped budget systems. The group considered the process for products associated with a significant budgetary impact, by virtue of high unit cost, extensive utilisation or a combination of both. An issues paper was developed for CATAG.

HEWG worked with DoHA on implementation of cost-recovery measures to minimise the additional administrative pressures imposed by the introduction of fees for PBAC evaluation. HEWG will remain active in forthcoming reviews of cost-recovery.

In collaboration with RAWG, HEWG helped develop policy initiatives relating to the registration and reimbursement processes for biosimilar medicines (also referred to as Similar Biological Medicinal Products or SBMPs).

HEWG established a Health Technology Assessment Sub-Group to manage methodological issues in the PBAC process and provide support for any further investigative groups the PBAC may initiate.

Furthermore, HEWG has sought to learn from, and build relationships with important stakeholders in the PBS listing process. The Chair of the Economic Sub-Committee, DoHA Acting Assistant-Secretary, Policy and Analysis, and the PBPA Secretary attended HEWG meetings throughout the year.

During the year, the International Policy Scanning Working Group (IPSWG) provided international evidence and advice to the Access Committee on priority issues. IPSWG also conducted an international policy scan which captured the various policy developments internationally pertaining to the provision of medicines.

Medicines Australia Vaccines Industry Group

This year the Medicines Australia Vaccines Industry Group (MAVIG) was re-established under the auspices of the Access Strategic Committee. MAVIG's priorities include promoting a favourable policy environment for the growth of the vaccine industry in Australia, and supporting initiatives to improve vaccine protection and coverage in the interests of public health.

MAVIG has worked closely with government and non-government stakeholders, including the Public Health Association of Australia (PHAA) and the National Centre for Immunisation Research and Surveillance (NCIRS) to meet these objectives.

Significantly, MAVIG has engaged DoHA to ensure the new national vaccines procurement regime does not adversely impact the industry or inhibit access to vital vaccines.

MAVIG collaborated with the NCIRS to produce a *Value of Childhood Vaccines* DVD for healthcare clinics and schools. The group also sponsored a plenary session titled *New Vaccines* at the PHAA's biannual Immunisation Conference.

KEY ISSUES

Improving the investment environment

Medicines Australia congratulates the Federal Government for taking the important step to improve and update Australia's tax based incentives to encourage private R&D investment. We are confident that the new system will make Australia a more competitive location for R&D investment.

DR BRENDAN SHAW

CHIEF EXECUTIVE, MEDICINES AUSTRALIA

Official Committee Hansard • SENATE • ECONOMICS LEGISLATION COMMITTEE
Reference: Tax Laws Amendment (Research and Development) Bill 2010

Thursday, 20 May 2010 • CANBERRA

R&D Tax Credit

On 13 May the Federal Government introduced to Parliament a Bill to replace the existing R&D Tax Concession program with a new R&D Tax Credit program.

Earlier versions of the exposure draft legislation were of concern, particularly with respect to: the 'object' clause; the definition of 'core' and 'supporting' R&D; the list of excluded activities; feedstock; and 'expenditure not-at-risk' provisions (the last being problematic to the extent that Australian research would be made ineligible for the credit if reimbursed by companies' overseas head offices).

Many of Medicines Australia's concerns were shared by other industries, which made vocal, public objections through the media. However, Medicines Australia took a more considered and constructive approach, seeking to support the Government's intentions of providing a valuable incentive to industry, while identifying the flaws in the way the legislation had been drafted.

Medicines Australia, with the assistance of member companies and the Innovation Strategic Committee, commented on two early versions of the Bill in February and April 2010, as well as on the Treasury's consultation paper issued in October 2009. We also engaged with key Federal politicians and representatives from Treasury and the Department of Innovation, Industry, Science and Research to ensure that the program would deliver tangible benefits for member companies.

The version of the Bill introduced to Parliament largely addressed our concerns, although some of the detail in the design of the proposed new program was not ideal.

On balance, however, Medicines Australia strongly supports the implementation of the R&D Tax Credit program. The existing R&D Tax Concession program has failed to help Australian companies attract a larger share of the global pharmaceutical industry's R&D investment budget, which is worth approximately $120 billion annually. The existing tax concession is outdated, unpredictable and over-complicated and does not provide a globally competitive incentive to companies conducting R&D in Australia. The implementation of the proposed R&D Tax Credit legislation will make access to tax benefits more predictable and help reduce the cost of conducting eligible R&D in Australia by up to 10 per cent. This will allow Australian companies to better demonstrate to global investors the advantages of sending R&D investment to Australia.

The current legislation for the R&D Tax Credit was reviewed by the Senate Economics Committee. Brendan Shaw and Deborah Monk appeared before the Committee on 20 May 2010. In his opening statement, Dr Shaw said the existing tax concession program 'simply isn't working' and that the new program will deliver a greater, more stable and more predictable benefit to companies conducting R&D in Australia.

The Senate has yet to vote on the Bill to implement the new R&D Tax Credit, despite being advised by the Senate Economics Committee to do so before 30 June 2010. Medicines Australia will continue to strongly encourage all political parties to support the implementation of this important new program.

Clinical Trials Action Group

In October 2009, the Minister for Health and Ageing Nicola Roxon and the Minister for Innovation, Industry, Science and Research Kim Carr announced the creation of the Clinical Trials Action Group, to be co-chaired by the Parliamentary Secretary for Health Mark Butler and the Parliamentary Secretary for Innovation Richard Marles. Other members of the Action Group included Chief Medical Officer of the Australian Government Professor Jim Bishop, Executive Director of the 'HoMER' initiative of the National Health and Medical Research Council Dr Tim Dyke, and Mitch Kirkman of Novartis.

The Action Group, which was supported by five sub-committees drawn from industry, academia, and health consumer organisations, was asked by Minsters Roxon and Carr to recommend ways to improve Australia's competitiveness as a destination for global investment in clinical trials. Its work focused on five key areas:

- developing a clinical trials roadmap;
- developing key performance measures for clinical trials;
- ensuring the rapid uptake of streamlined ethics, scientific and governance review processes;
- strategies to improve patient recruitment; and
- developing an ICT strategic plan for clinical trials.

The formation of the Clinical Trials Action Group was a major achievement for Medicines Australia and the Australian medicines industry. It was the direct result of at least 10 months of vigorous advocacy, notably by Mitch Kirkman (Novartis), Dr Melissa Grady (AstraZeneca), Dr Jan Twomey (formerly Schering-Plough), Dr Jane Frost (Pfizer), Dr Carlo Maccarrone (GSK), Dr Kaylene O'Shea (Celgene), and Dr Linda Nielsen (sanofi-aventis). It demonstrated that the Federal Government, perhaps for the first time, acknowledged not only the social and economic value of maintaining industry investment in Australian clinical research but also the growing threat that countries in Asia, South America and eastern Europe pose as Australia's competitors for global clinical trial investment.

The Action Group submitted its final report to Ministers Roxon and Carr in June 2010. However, before making the report public, the Ministers said they would seek the approval of the Australian Health Ministers' Advisory Council, whose members will have jurisdiction over the implementation of many of the Action Group's [anticipated] recommendations. This has yet to occur.

Over the next 12 months, Medicines Australia will work with Government to ensure the timely implementation of the Action Group's recommendations. We will also continue to pursue regulatory reforms directly with state and territory governments, particularly in New South Wales, Queensland and Victoria.

Intellectual Property

Medicines Australia engaged on a number of fronts on intellectual property issues during 2009–10. This engagement continued to be informed by our strong belief in the fundamental importance of a strong, stable and predictable intellectual property system in sustaining innovation and delivering faster access to innovative medicines.

In August 2009, Medicines Australia's Director of Innovation and Industry Policy Deborah Monk appeared before the Senate Community Affairs Committee as part of its inquiry into gene patents. She argued that Australia's 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 not to be patentable unless a technique is of itself innovative and useful; and
- patenting of genetic sequences *per se* should continue not to be permitted as they are mere 'discoveries' and not 'inventions', that is, they should be excluded from patentability under 'prior art' considerations.

In September 2009, Deborah Monk and the then Medicines Australia Chief Executive Ian Chalmers appeared before the Joint House and Senate Committee on Foreign Affairs, Defence and Trade to explain why Medicines Australia opposed a proposal to amend the *Patents Act 1990* to allow non-patent holders to manufacture patented medicines for export to countries where the relevant patent had expired. They argued that such an amendment would be in contravention of Australia's international trade obligations, including under articles 28 and 33 of the WTO TRIPS Agreement and Article 17.9.8(b) of the Free Trade Agreement between Australia and the

United States. They also noted that the concept of patent term restoration, which the proposed amendment was designed to undermine, is an integral part of providing sufficient time for innovators to recover the enormous cost of bringing new medicines to market. The Government has notified Medicines Australia that it will not amend the Patents Act.

In October 2009 Medicines Australia wrote to the Australian Government's Advisory Council on Intellectual Property (ACIP) in response to its interim report on post-grant patent enforcement strategies. Among other measures, the ACIP's interim report recommended the formation of several new administrative bodies that would be vested with the authority to issue non-binding rulings on different elements of future cases involving patent disputes. Medicines Australia responded that:

- it does not support the establishment of a separate Validity and Infringement Opinion Service to be administered by IP Australia, because it would impose additional costs and administrative burdens, without obvious gains for the large majority of patent holders in Australia;
- it does not support the establishment of a Patents Tribunal to administer a non-binding determinative alternative patent dispute resolution process because it too would create additional steps in patent enforcement without significantly reducing the overall burden of patent enforcement in Australia; and
- the process of patent dispute resolution in Australia should be streamlined by reforming case management processes in existing courts.

In addition, Medicines Australia expressed its disappointment at the absence from the ACIP's interim report of any mention of 'patent linkage' or of unfair and inequitable penalties that may be imposed on pharmaceutical patent holders in Australia for attempting to enforce their patent rights.

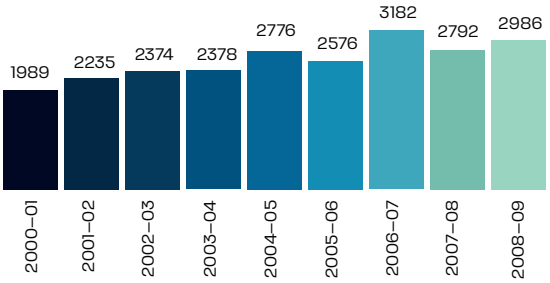
In a submission to IP Australia made in June 2010, Medicines Australia strongly supported the implementation in Australia of measures consistent with the principles of the *Doha Declaration on the TRIPS Agreement and Public Health*, which would make it easier in the future for Australian companies to play a role in responding to critical health emergencies in the world's least developed countries. Under the proposed system, the Federal Government would be able to issue compulsory licences for the manufacture and export of generic copies of patented medicines to the world's least developed countries facing specific public health emergencies. However, strict conditions would have to be met before a compulsory licence may be issued, and safeguards such as distinctive packaging and labelling to prevent re-direction of exported medicines would be put in place to protect the rights of patent holders.

Medicines Australia's top recommendation to IP Australia was that the authority to issue compulsory licences under the new system should be vested in the Federal Court of Australia, instead of the Commissioner of Patents. Medicines Australia also reminded IP Australia, and other stakeholders who support the implementation of the TRIPS Protocol, that the global pharmaceuticals industry is already at the forefront of the effort to bring life-saving medicines to the world's poorest countries. Globally, the industry has already invested over US$10 billion since 2000 in health programs in some of the world's least developed countries, and donated over 1.3 billion doses of vaccines and medicines for infectious and chronic diseases.

KEY ISSUES

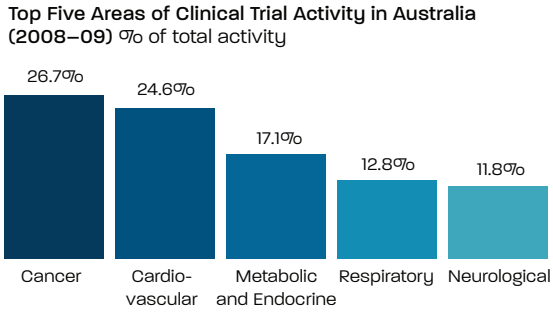
Clinical research in Australia: Key facts

Since 2000, more than 7,000 clinical trials have been conducted in Australia, involving 23,000 clinical trial notifications to the TGA.



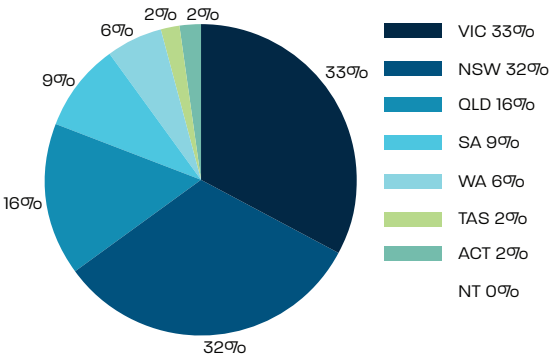
SOURCE: Clinical Trial Notifications, Therapeutic Goods Administration

The medicines industry conducts clinical trials in over 20 therapeutic areas in Australia.



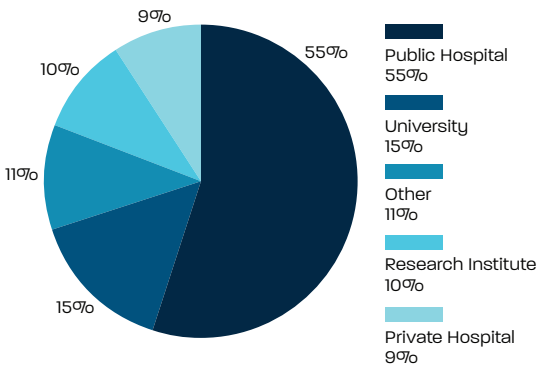
SOURCE: Pharmaceuticals Industry Council

Eighty per cent of clinical trials in Australia are conducted in New South Wales, Victoria and Queensland.



SOURCE: Pharmaceuticals Industry Council

Most industry-sponsored clinical trials in Australia are conducted in public hospitals and university research centres.

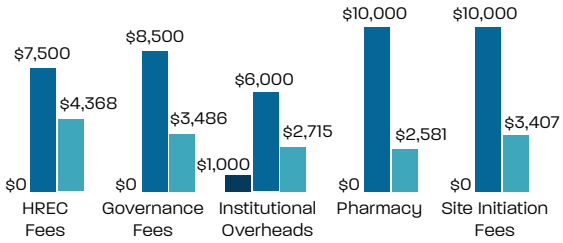


SOURCE: Pharmaceuticals Industry Council

KEY ISSUES

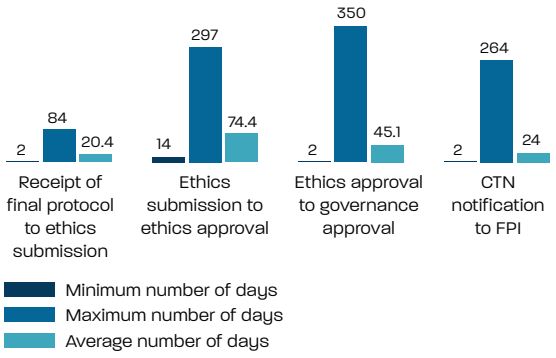
Clinical research in Australia: Key challenges

COST: The cost of setting up a clinical trial in Australia is high by international standards—about $16,500 per site.



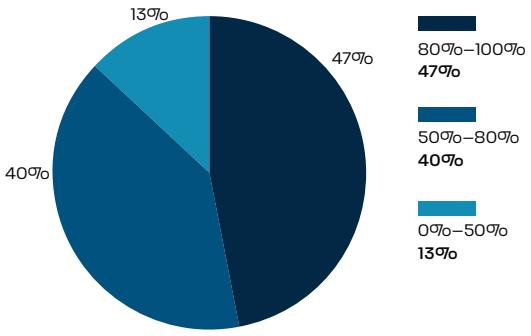
SOURCE: Pharmaceuticals Industry Council

SPEED: The average time it takes companies to set up a clinical trial in Australia is about 164 days.



SOURCE: Pharmaceuticals Industry Council

PATIENT RECRUITMENT: Over half of all Phase III clinical trials conducted in Australia have trouble meeting patient recruitment targets.



SOURCE: Pharmaceuticals Industry Council

KEY ISSUES

Beyond the Medicines Australia Code: Levelling the playing field for ethical conduct

The Medicines Australia Code of Conduct (Code) is in its 16th edition and continues to provide an exemplary ethical framework for companies when they interact with health professionals and consumers. Medicines Australia members have continued to demonstrate their commitment to ensuring their conduct remains of the highest ethical standard and that their self-regulatory Code sets the benchmark for the industry.

Highlights

The new edition of the Code of Conduct was authorised by the Australian Competition and Consumer Commission (ACCC) and is deserving of its reputation as a world leader in codes of conduct for the medicines industry.

Medicines Australia has delivered on its commitment that, once administrative costs of the Code program have been covered, surplus revenue from fines would be put to worthy causes. This has allowed Medicines Australia to donate:

- $1m to the Jimmy Little Foundation to help improve indigenous health outcomes in remote communities.
  - The Uncle Jimmy *Thumbs Up!* campaign will deliver healthy eating messages to indigenous communities, to encourage children and parents to make more nutritious food and drink choices.
  - The establishment of a mobile renal dialysis unit for the Western Desert region, to be managed by the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation based in Alice Springs.
- $150,000 to the Shalom Gamarada Ngiyani Yana Scholarship Program to sponsor two indigenous medical students at the University of New South Wales.

Levelling the Playing Field

There is no reason for there to be one standard of ethical conduct for Medicines Australia members and another, lesser, standard for non-member companies supplying prescription medicines. There must be a consistent ethical standard for all companies when they interact with health professionals and consumers. We are encouraged by the Government's commitment to pursue a level playing field for promotional activities within the prescription medicines sector and more broadly in the therapeutic goods industry. Medicines Australia cannot require generic or other companies to become Medicines Australia members. However, we very firmly believe that every prescription medicine company should adhere to the high ethical standards embodied in the Medicines Australia Code of Conduct.

On 30 June 2010 the Parliamentary Secretary for Health Mark Butler issued the Australian Government's Position Paper on the Promotion of Therapeutic Goods. The Government has proposed that the therapeutic goods industry strengthen and standardise self-regulation through developing universal adherence to consistent industry-wide codes based on a common set of high-level principles. It is expected that these principles will create a level playing field within the sector, which will meet

the Government's objective of ensuring that health professionals' management choices for patients are based on clinical evidence rather than incentives or other influences.

Medicines Australia will be an active participant on the Working Group that is developing the high-level principles for industry conduct. It is pleasing that the Government has demonstrated leadership by initiating this process and supporting industry self-regulation. If the Australian medicines industry is unable to step up to the challenge of consistent and effective self-regulation, government regulation could be imposed. This would be a backward step from Medicines Australia's perspective.

Social Responsibility

Medicines Australia's sponsorship of the Jimmy Little Foundation, the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation and the Shalom Gamarada Ngiyani Yana Scholarship Program reflects the pharmaceutical industry's commitment to practical, on-the-ground initiatives to improve the lives of indigenous Australians and making a real, long-term difference to indigenous health. While this is a relatively modest contribution compared with the vast challenge in closing the gap between indigenous and non-indigenous Australians' health and life expectancy, it is a positive and responsible step forward in effecting change.

If this donation can encourage young indigenous Australians to choose more nutritious food, and if indigenous Australians on renal dialysis in the Western Desert can travel home and have treatment while they are there with their family, this money will have been put to great use.

Medicines Australia sponsorship of the Shalom Gamarada Ngiyani Yana Scholarship Program will enable two talented indigenous Australians to realise their dreams and become qualified and successful medical practitioners. Medicines Australia recognises the urgent need to improve indigenous health outcomes and fully supports the recruitment and training of more indigenous doctors.

Code of Conduct Edition 16

The ACCC's authorisation of Edition 16 of the Code was a very pleasing outcome from the 18-month consultation process during which Medicines Australia and the ACCC sought input from industry, patient groups, consumer organisations, healthcare professionals, colleges and societies, professional associations, academics and other stakeholders.

Medicines Australia is proud of its achievements in reviewing, revising and reporting under the Code.

Areas in which the Code has been strengthened include:

- Brand name reminders: a ban on brand name reminders that are ordinarily used outside the surgery (eg pens, coffee mugs, notepads);

- Prescribing software: a ban on advertisements for prescription medicines in prescribing software used by doctors;
- Transparency of support for consumer groups: any support provided to consumer groups must be disclosed on a company's website; and
- Fines: the maximum fine for breaching the Code is increased to $300,000.

Educational Event Reports

Pharmaceutical companies take very seriously their responsibility to provide doctors with current, accurate and balanced information and provide a wide variety of educational opportunities throughout the year. These engagements are legitimate, appropriate and, in the case of Medicines Australia members, transparent. Doctors continue to vote with their feet by attending these events because they derive genuine professional benefit from their engagement with pharmaceutical companies. It is also evident from the reports that member companies support a wide range and large number of independently organised educational meetings for health professionals.

Member companies continue to report their educational events, which are published every six months on the Medicines Australia website. There continues to be a high level of transparency and compliance with the Code requirements for the provision of high-quality education and appropriate hospitality.

How we performed

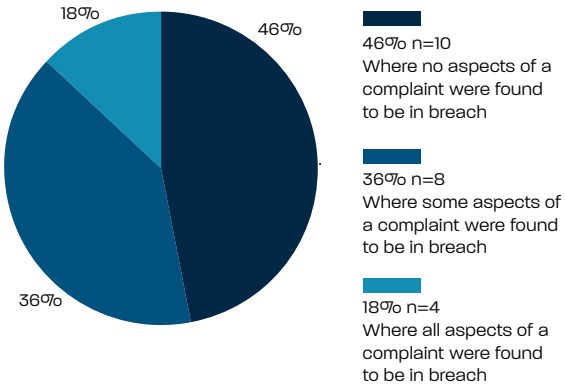
There was an increased level of compliance by member companies with respect to adherence to the Code in 2009–10. Thirty-nine new complaints were received, which is a decrease from 2008–09 when 59 complaints were submitted to Medicines Australia. Of the 22 new complaints finalised in 2009–10, 45 per cent were found not to be in breach of the Code. Details of the complaints considered in 2009–10 and the outcomes are reported in the Code of Conduct Annual Report, on the Medicines Australia website.

The Monitoring Committee continued to provide extensive reviews of company promotional material and activities. In 2009–10 the Committee reviewed 548 different items and 18,300 educational events with six events referred to the Code of Conduct Committee for its consideration.

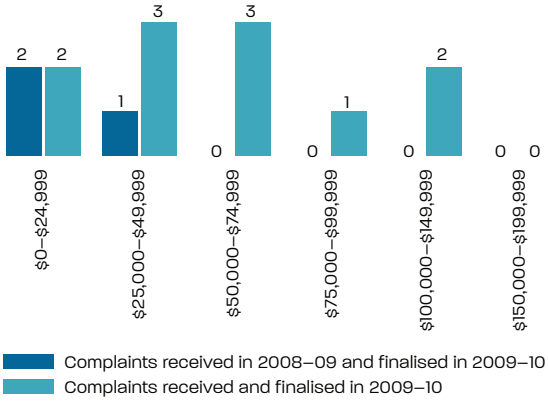
KEY ISSUES

Code of Conduct performance in 2009–10: A snapshot

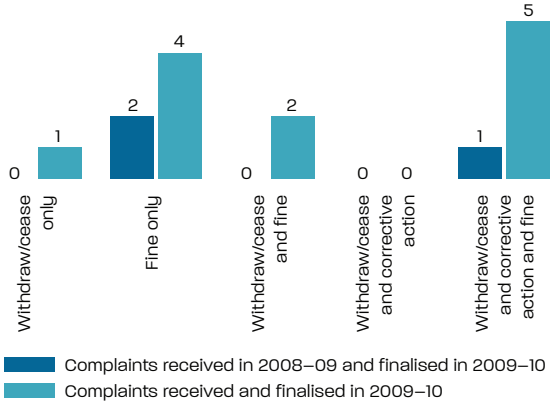
Outcomes of complaints received and finalised in 2009–2010



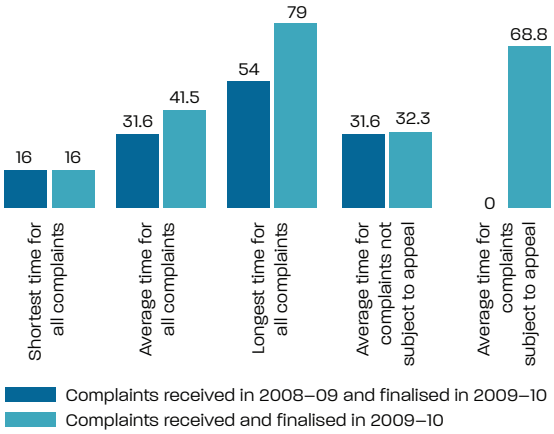
Fines imposed by the Code and Appeals Committees on companies found in breach of the Code



Sanctions imposed by the Code and Appeals Committees on companies found in breach of the Code



Length of time to resolve all finalised complaints (days)



KEY ISSUES

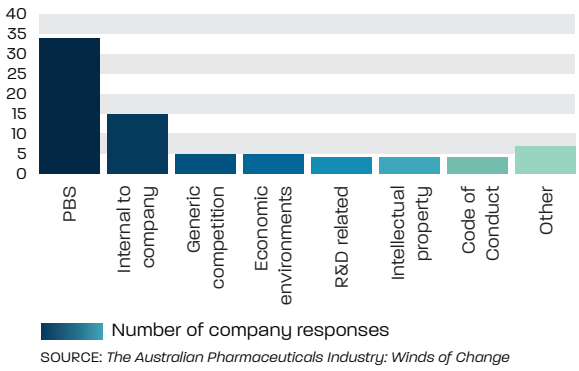
Members' perceptions of the operating environment: Research snapshot

In 2009 Medicines Australia distributed an economic survey to member companies to seek information on key economic activities and indicators for 2008. Thirty-two of 48 companies completed the survey. Those companies accounted for 75 per cent of total pharmacy sales of prescription medicines in Australia. The results were published in *The Australian Pharmaceuticals Industry: Winds of Change* which is available on the Medicines Australia website. The survey also incorporated a number of in-depth, open-ended questions designed to elicit member company views on key policy concerns, important opportunities and business confidence for the coming calendar year, some of the results of which are presented here.

The insights provided by this qualitative section of the survey provide great reassurance that Medicines Australia's priorities are aligned with those of members, and securing a stable policy environment over the long term through the Memorandum of Understanding between Medicines Australia and the Commonwealth is a significant step in meeting members' needs.

With respect to the identification of the areas of most concern affecting the business environment, respondents were asked to identify the top three areas of concern for the coming year.

Business Environment Concerns 2009 (78 responses)



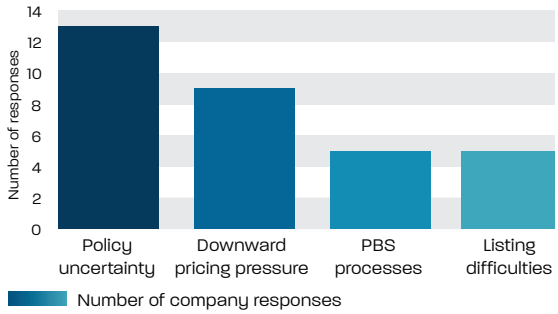
SOURCE: *The Australian Pharmaceuticals Industry: Winds of Change*

Of 78 responses, 34 (44 per cent) identified PBS policy as the area of most concern. Internal company concerns were identified in 11 (19 per cent) responses (including four mentions of difficulties in attracting and retaining skilled staff). The economic environment, especially the impact of the global financial crisis, emerged as a concern in five responses, and competition from generic companies also attracted five responses (although it can be extrapolated that the four respondents expressing concern about the IP environment were also concerned about generic competition). There were four explicit

mentions of Australia's IP regime as an area of concern, the same number that referred to limitations on marketing as a result of Code of Conduct regulation. Shortcomings in the national system of ethical approvals for clinical trials and the negative impact on R&D investment were mentioned three times. Seven responses were too difficult to classify (largely because they were unclear/ambiguous).

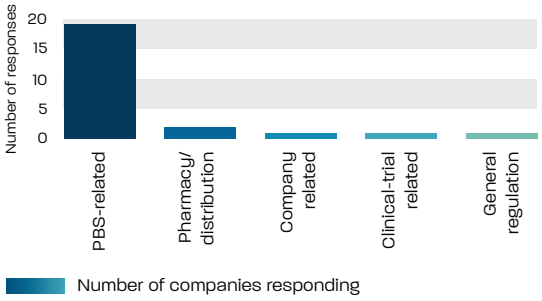
When concerns about the PBS are broken down, 41 per cent nominated policy uncertainty, followed by downward pricing pressure, PBS processes and listing difficulties.

Source of PBS concerns, 2009



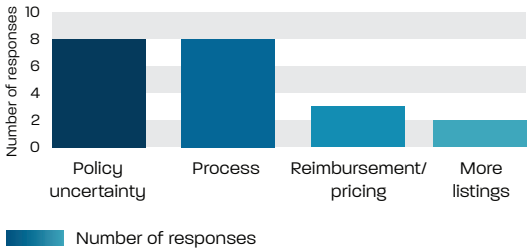
Not surprisingly, when asked in a separate set of questions to identify the one aspect relating to the current environment which respondents would like changed, 19 out of 24 responses were PBS-related.

Most important change to business environment, 2009
(Number of responses = 24)



When the nature of the desired changes to the PBS was broken down, policy certainty and process improvements were on a par (38 per cent each), followed by reimbursement improvements (14 per cent) and more listings (10 per cent).

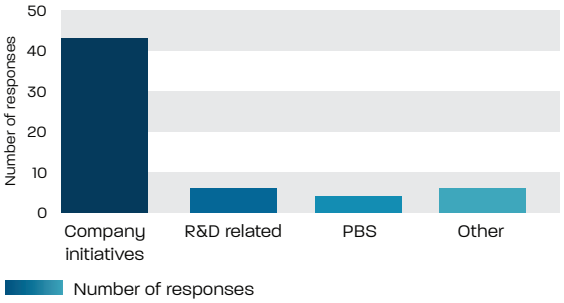
Nature of improvements to PBS identified, 2009
(Number of responses 21*)



* *While there were only 19 responses identifying PBS-related improvements, in two cases both listing and reimbursement were mentioned. Hence there were 21 responses overall.*

Respondents were also asked to nominate three factors which they expected to have a positive impact on their businesses in the following 12 months.

Business environment opportunities for 2010
(59 responses)

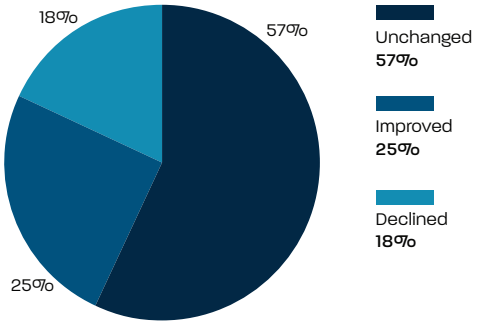


Most identified factors which were internal to the company's business environment.

When these internal factors were broken down by areas of opportunity, 40 per cent of answers were related to new product launches, 14 per cent to R&D-related opportunities and 14 per cent to PBS performance. Twenty-three per cent of responses could not be classified because they were either unique or too ambiguous.

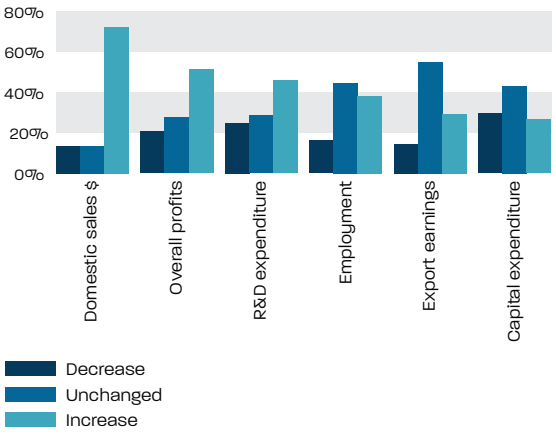
Respondents were also asked to provide their views on the likely performance of their businesses to July 2010. Fifty-seven per cent expected performance to remain unchanged; 25 per cent expected it to improve.

Overall business confidence in 12 months to July 2010



They were then asked to identify which aspects of their business were likely to improve, decline or remain unchanged. The majority (73 per cent) projected that their sales revenue would grow. Approximately half also anticipated that their overall profits and R&D expenditure would increase. A minority (39 per cent) predicted a growth in employment and export earnings (30 per cent). Respondents who anticipated capital expenditure change were more likely to see it decreased (30 per cent) than increased (27 per cent).

Business confidence to performance indicator in 12 months to July 2010



When these results are broken down by size of company, the trends were as follows:

- Smaller companies (turnover of less than $100 million) predicted an increase in sales revenue, R&D expenditure, employment and overall profits—but no change in export earnings or capital expenditure.
- Medium companies (turnover of more than $100 million but less than $400 million) predicted increases in domestic sales revenue, R&D expenditure and overall profits, but no change in export earnings and employment, and a mixed response to capital investment.
- Large companies (turnover of more than $400 million) predicted growth in domestic sales revenue, unchanged capital expenditure, export earnings, employment and overall profit, and a decrease in R&D expenditure.

Key events diary

JULY

- Medicines Australia made submissions to IP Australia's consultations on *Getting the Balance Right* and *Exemptions to Patent Infringement*.
- Medicines Australia was notified that the Government accepted Medicines Australia's arguments against a proposal that Australia's IP laws should be amended to allow generic companies to manufacture, for export, medicines still under patent in Australia. The proposal was formally rejected.

AUGUST

- The Medicines Australia Board reviewed current priorities at its strategic retreat and determined key areas for action in 2009–10.
- Medicines Australia appeared before the Senate Inquiry into 'gene' patents.

SEPTEMBER

- Medicines Australia hosted a members workshop for the proposed R&D Tax Credit program to identify improvements to the design of the measure.
- The Medicines Australia Chairman, Chief Executive and Board members met with Minister Roxon to discuss the Federal Budget environment and potential implications for the industry.
- The Chairman, Chief Executive and Board sponsors of strategic committees briefed managing directors in Sydney and Melbourne on the outputs of strategic committees and the priorities for the coming year.
- Ian Chalmers resigned as Chief Executive of Medicines Australia.
- Medicines Australia held its annual meeting with the PBAC. Discussion included: the interchangeability of medicines; a framework for conducting PBAC-initiated reviews; devising a Medicines Australia/Department of Health and Ageing/PBAC strategic plan to help the development of workforce capability in Health Technology Assessment; and updating the Medicines Australia Code of Practice for Face-to-Face Hearings before the PBAC.
- Medicines Australia was represented at the first PBAC/PBPA meeting in several years. The meeting was convened to discuss issues of common concern with a view to improving communication between the committees.

OCTOBER

- Seventy-one representatives attended Access member briefings held in Sydney and Melbourne.
- The Centre for Strategic Economic Studies (CSES) report *The Impact of PBS Reforms on PBS Expenditure and Savings: Actual and projected from 2008–09 to 2017–18* commissioned by Medicines Australia was released along with Medicines Australia's first occasional paper, *PBS Reforms: Are they*

Working? Briefings on the report took place with relevant ministerial advisers and senior departmental advisers from the Departments of Treasury, Finance and Administration, Health and Ageing, and Innovation, Industry, Science and Research.

- Medicines Australia's Annual General Meeting was held on 27 October. The election of the Medicines Australia Board for 2010–2011 was announced.
- Will Delaat was presented with the 2009 Pat Clear Award for his services to the pharmaceuticals industry.
- Will Delaat delivered his National Press Club address titled *More than just pills; Australia's pharmaceuticals industry and why we should value it* to a live audience of over 200 and television audience of 300,000.
- The Excellence in Health Journalism Awards, sponsored by Medicines Australia, were presented by Minister Roxon.

NOVEMBER

- The Federal Government released the *Mid-Year Economic and Fiscal Outlook* (MYEFO) which included $48.2 million in PBS savings resulting from the creation of three new therapeutic groups.
- The Medicines Australia Board Budget team and the Government Working Group championed the CSES findings on PBS reform in an extensive number of meetings with Members of Parliament and outlined the industry's opposition to the new therapeutic groups.
- The Federal Opposition moved for the establishment of a Senate Inquiry into the creation of the new therapeutic groups.
- Medicines Australia released a new publication, *Facts Book: Edition 1*, which provides a statistical snapshot of the Australian and global pharmaceuticals industry and provides current data on Australian health expenditure.

DECEMBER

- The Australian Competition and Consumer Commission (ACCC) authorised the 16th Edition of the Medicines Australia Code of Conduct for a period of five years.
- The first Australian Public Assessment Reports (AusPARs) were published on the TGA website as part of the TGA reform.
- The Board endorsed market research outcomes and recommendations towards a brand plan for the industry and gave in-principle support for the next phase of the project.

JANUARY

- Medicines Australia's Board for 2010–2011 began its two-year term.
- Dr Brendan Shaw was appointed Chief Executive of Medicines Australia.
- Medicines Australia continued discussions with Minister Roxon's office and the DoHA on the Government's approach to the PBS in the 2010 Federal Budget.

FEBRUARY

- The Government released the Third Intergenerational Report, which contained more moderate projections of pharmaceutical expenditure growth than its predecessor, although pharmaceuticals still remain a significant proportion of growing healthcare expenditure.
- Minister Roxon tabled in Parliament a PricewaterhouseCoopers review of PBS reform. The review confirmed that savings from PBS reform will be more than originally expected (in line with the CSES report commissioned by Medicines Australia). However, the projections of PBS growth were considerably higher than either the CSES report or the Government's Third Intergenerational Report.
- Medicines Australia attended the annual Therapeutic Goods Administration/Medicines Australia bilateral meeting for prescription medicines to discuss fees and charges for 2010–11.
- Medicines Australia made a submission to the Government's Clinical Trials Action Group. The submission called on the group to help reverse Australia's declining competitiveness as a destination for global investment in clinical trials.

MARCH

- The Opposition sought and won a disallowance in the Senate of the instruments which would give effect to the three new therapeutic groups announced in the Government's Mid-Year Economic and Fiscal Outlook.
- Over 200 guests from industry, the Government, the health sector and the indigenous community attended Medicines Australia's parliamentary dinner.
- Medicines Australia presented $1 million from the special purpose fund to the Jimmy Little Foundation to help fund a healthy eating campaign and the establishment of a mobile renal dialysis unit for indigenous communities in the Western Desert.

APRIL

- Treasury released a second exposure draft of the new R&D Tax Credit legislation which incorporated Medicines Australia's suggestions for improvement.
- Medicines Australia made a submission to the Australian Competition and Consumer Commission (ACCC) as part of the consultation process on the Generic Medicines industry of Australia (GMiA) Code of Conduct. The submission was critical of the inadequacies of the GMiA provisions measured against Medicines Australia's own Code of Conduct.
- Medicines Australia's Health Economics Working Group (HEWG), in conjunction with the Association of Regulatory and Clinical Scientists (ARCS), hosted a PBAC Guidelines workshop.

MAY

- Medicines Australia appeared before the Senate Economics Committee's Inquiry into legislation on the proposed R&D tax credit. Medicines Australia argued in favour of the tax incentives.
- Medicines Australia appeared before the Senate Inquiry into Consumer Access to Pharmaceutical Benefits, which included an examination of the establishment of new therapeutic groups.

- The Memorandum of Understanding covering the four-year agreement between Medicines Australia and the Commonwealth in relation to the PBS was signed on 6 May. The Prime Minister, the Minister for Health and Ageing, the Parliamentary Secretary for Health, the Secretary of DoHA and their officers met with the Medicines Australia Board on 11 May. The Government thanked Medicines Australia for the constructive role it played with respect to the future of the PBS and delivery of health reform.
- The MoU formed part of the Government's Budget announcements on 11 May. The Budget papers also contained references to new measures for funding chemotherapy medicines, the listing of four new medicines, and the provision of $10m over five years for a generics awareness campaign. The terms of the Fifth Community Pharmacy Agreement were also announced in the Budget.

JUNE

- The *National Health Amendment (PBS) Bill 2010*, which gives effect to the savings for the Government embodied in the MoU between Medicines Australia and the Commonwealth was tabled in the House of Representatives on 2 June.
- Medicines Australia held a members conference to discuss key priorities for Medicines Australia on 3 June.
- The report of the Medicines Australia 2009 economic survey of members, *Winds of Change* and the first edition of *MA Quarterly* were released.
- The Senate Selection of Bills Committee resolved to send the provisions of the *National Health Amendment (PBS) Bill 2010* directly to the Senate Community Affairs Legislation Committee for an inquiry.
- The Bill for the new R&D tax credit was delayed for Senate consideration at least until the spring sitting of Parliament. However, the Minister for Innovation, Industry, Science and Research, Senator Carr, confirmed the Government's intentions to apply the credit retrospectively from 1 July 2010.
- Medicines Australia announced a donation of $150,000 to the Shalom Gamarada Ngiyani Yana Scholarship Program to provide a residential scholarship for two indigenous medical students at the University of New South Wales.

Conferences and events

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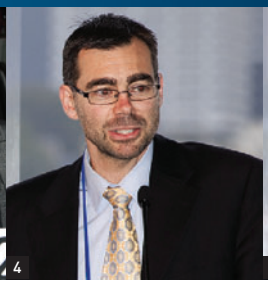
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1 *Medicines Australia Chairman Will Delaat delivering his National Press Club address.*

2 *Will Delaat and Health and Ageing Minister Nicola Roxon at the Medicines Australia parliamentary dinner.*

3 *Medicines Australia Chief Executive Dr Brendan Shaw and Dr Angela Pratt, Chief of Staff to Minister Roxon, at the Medicines Australia parliamentary dinner.*

4 *Chief Executive Dr Brendan Shaw seeks members' views on key priorities for Medicines Australia.*

5 *Will Delaat, Medicines Australia Chairman, addresses participants at the members conference.*

The Chairman's National Press Club Address

On 28 October 2009, the Chairman delivered his annual National Press Club address entitled *More than just pills: Australia's pharmaceuticals industry and why we should value it* to a live audience of over 200 and an estimated television audience of 300,000. Will explored the role and contribution of the pharmaceutical industry in Australia within the context of the four pillars of the National Medicines Policy and raised the challenge of a national debate on how much the community values extending life and the cost of life-extending medicines.

Medicines Australia Parliamentary Dinner

On 16 March 2010, over 200 guests from industry, the Federal Parliament, the health sector and the indigenous community attended Medicines Australia's parliamentary dinner in Canberra. Speakers included Chairman Will Delaat, Minister for Health and Ageing Nicola Roxon, and Dr Jimmy Little, who was presented with $1 million to support his Foundation's healthy eating campaign and to establish a mobile renal dialysis unit for indigenous communities in the Western Desert. The Minister addressed several issues of interest to the industry including: the contribution of medicines to the health system; the need to reform the PBS in order to 'fund new and innovative medicines'; the reduction of regulatory barriers as an important component of effective health technology assessment; and the close link between PBS sustainability and industry certainty. She committed to ensure 'that there is certainty and stability for a vibrant pharmaceutical industry'.

6 Workshopping the issues at the members conference.

7 Michael Roche, Chairman of the Pharmaceutical Benefits Pricing Authority, addresses managing directors at a dinner on 25 August 2009.

8 Guest speaker Dr Michael Wooldridge and Medicines Australia Chief Executive Dr Brendan Shaw, at a managing directors dinner on 2 June 2010.

9 Managing directors Peter Mayrick (iNova), Jeremy Morgan (Eli Lilly) and Donna Edman, Executive Director, Public Affairs for Medicines Australia, in lively discussion at the managing directors dinner on 2 June 2010.

Medicines Australia Members Conference

Over 120 highly engaged and energetic member company participants attended the members conference on 3 June 2010. The one-day event provided members with the opportunity to discuss the future of the industry in Australia and contribute to Medicines Australia's priorities. Outgoing Chair of the Pharmaceutical Benefits Advisory Committee, Professor Lloyd Sansom, and Professor Ken Wiltshire from Queensland University were guest speakers. Professor Wiltshire provided an analysis of elements of the political environment in the year ahead. Professor Sansom reminded industry that medicines have not been a major political issue in Australia because there is relative policy consistency and stability and a high degree of transparency.

Managing Directors Dinners

Michael Roche, Chairman of the Pharmaceutical Benefits Pricing Authority (PBPA), was the guest speaker at a managing directors dinner on 25 August 2009. Michael presented his views and responded to questions from the floor on the current PBS reimbursement environment, with particular reference to the existing and potential future roles of the PBPA.

On 2 June 2010 former Federal Health Minister Dr Michael Wooldridge shared his insights into the history, dynamics and leadership within the Australian political landscape. He noted that the Memorandum of Understanding between Medicines Australia and the Commonwealth was an extraordinary outcome for the industry.

Awards

2009 Pat Clear Award

The Pat Clear Award was established in 2002 to recognise the contribution Pat made to the pharmaceutical industry in Australia. Pat's association with Medicines Australia was marked by his determination, commitment and dedication, particularly in the areas of industry relations, marketing, relations with external stakeholders, the development of people within the pharmaceutical industry and the economic development of the industry in Australia. The award is intended to recognise similar levels of commitment by individuals or groups to the Australian pharmaceutical industry.

In 2009 the award went to Medicines Australia Chairman Will Delaat. Will has made an extraordinary contribution to the Australian medicines industry over the 12 years that he has served as chair, vice-chair and Board member of Medicines Australia. During his time as chair and vice-chair, Will has been influential in securing some groundbreaking policy changes or initiatives which have advanced the industry's agenda. In addition, he has been responsible for significant relationship building activities to extend the industry's circle of influence and constructive approaches to working with government. As Managing Director of Merck Sharp & Dohme, Will also played a key role in fostering a range of successful coalitions including the Pharmaceutical Alliance, the Coalition for Healthcare Reform in Papua New Guinea and the Rural Health Education Foundation. Board member Dr Graeme Blackman presented Will with the Award at the 2009 Annual General Meeting.

Health Journalism Awards

Medicines Australia is the principal sponsor of the National Press Club's Excellence in Health Journalism Awards. These awards seek to create awareness of health, medicine and innovation issues and contributions to health science and innovation in Australia. The awards honour journalists who have contributed the best work on health and health science each year. In 2009 *Australian Doctor*'s Paul Smith was named Health Journalist of the Year for the second year running for his vivid, incisive and disturbing report on patients living with severe dementia, *Why aren't they screaming?* Among other issues, the report dealt with the vexed question of indefinitely sustaining the life of people enduring a frightening, confused and demeaning existence without any real hope of respite. Other Award winners were:

- Best News Feature, Article or Presentation; Health, Health Sciences or Innovation: Tory Shepherd (*Adelaide Advertiser*) for *My Mary thought she would be cured: Tough questions for alternative medicine*.
- Best Documentary or Documentary Series; Health, Health Science or Innovation: Mark Horstman and Dr Holly Trueman for the ABC TV *Catalyst* program *Monkey Malaria*.
- Best Feature, Article or Presentation; Health Policy, Health Economics and Health Business: Maryanne Demasi for the ABC TV *Catalyst* program *Clearing the Fog*.
- Best News Feature, Article or Presentation: Health, Health Science or Innovation directed to Medical Professionals: Paul Smith (*Australian Doctor*) for *Why aren't they screaming?*

1 Health and Ageing Minister Nicola Roxon, award winner Paul Smith and Medicines Australia Chairman Will Delaat, at the National Press Club Health Journalism Awards.

2 Recipients of the 2009 Continuing Education Program Awards.

3 Dr Graeme Blackman presents Will Delaat with the 2009 Pat Clear Award.

Continuing Education Program Awards

The Medicines Australia Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. The CEP Awards for 2009 (students enrolled between January and December 2009) were presented at the CEP Awards dinner on 20 April 2010. Medicines Australia Chairman Will Delaat highlighted the importance of a highly trained and ethical workforce interacting with healthcare professionals. Medical representatives are the ambassadors for the industry and provide reliable and accurate information on medicines to healthcare professionals.

In her presentation of the University of Queensland Active Learning Prizes, Associate Professor Michele Groves from UQ referred to the role of continuing education in the healthcare sector and the high level and quality of engagement of pharmaceutical staff when participating in the CEP online tutorials.

UQ Health Insitu Active Learning Prize

Based on the level and quality of participation in group discussions and personal reflections in the online tutorials, the winner is selected by a panel from the University of Queensland.

UQ Health Insitu Active Learning Awards were presented to:

- David Yew Choong Kam (MSD) for Semester 1, 2009
- Allanah Campton (Novo Nordisk) for Semester 2, 2009

Code of Conduct Award

To be eligible for this award a student must achieve a final mark of 100 per cent for the Code of Conduct Program. The Code of Conduct Award was presented to:

- Colin Clarke (AstraZeneca)

CEP Achievement Awards

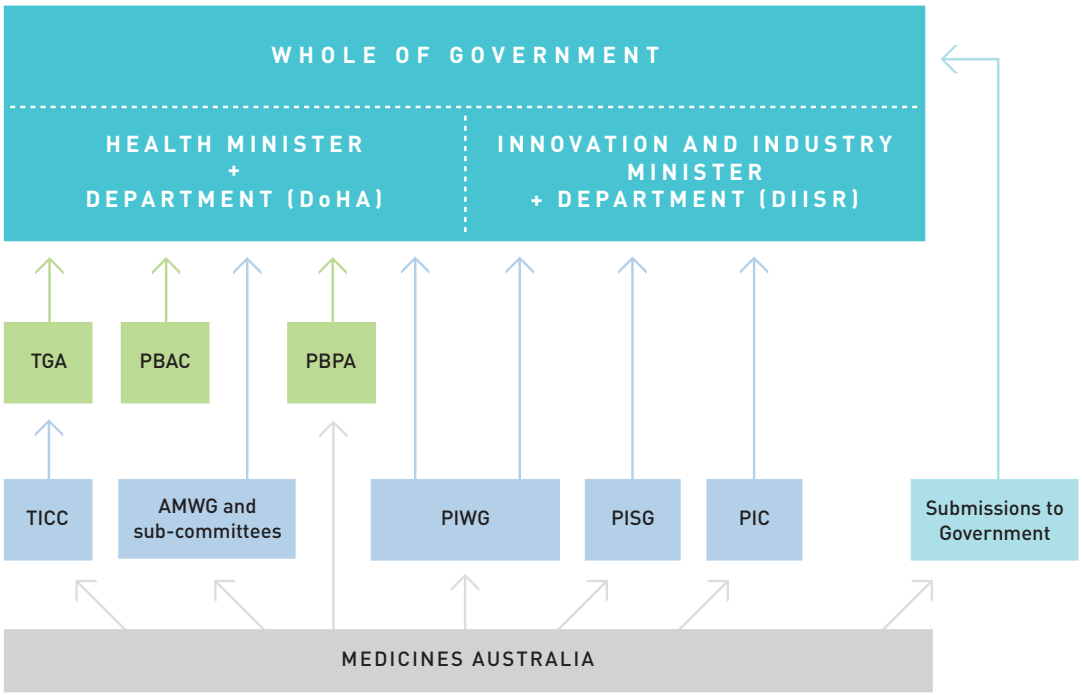
The winners of these awards are the students who achieve the 10 highest aggregate marks for the five core programs (out of a possible total aggregate of 500).

CEP Achievement Awards were presented to*:

- Kieran Kellett (AstraZeneca)
- Trudie Renowden (AstraZeneca)
- Katie Card (Bayer Healthcare)
- Claudia Tassone (Boehringer Ingelheim)
- Travis Mai (Eli Lilly)
- Soenke Tremper (Gilead Sciences)
- Alison Evans (Mundipharma)
- Kresimir Valinger (Novartis)
- Robert Crumpler (Pfizer)
- Russell Mathisen (Servier)

** Award recipients' companies were current at the time of completion of CEP. Some award recipients may have since moved to other companies or roles outside industry.*

Industry representation on government bodies and for other organisations



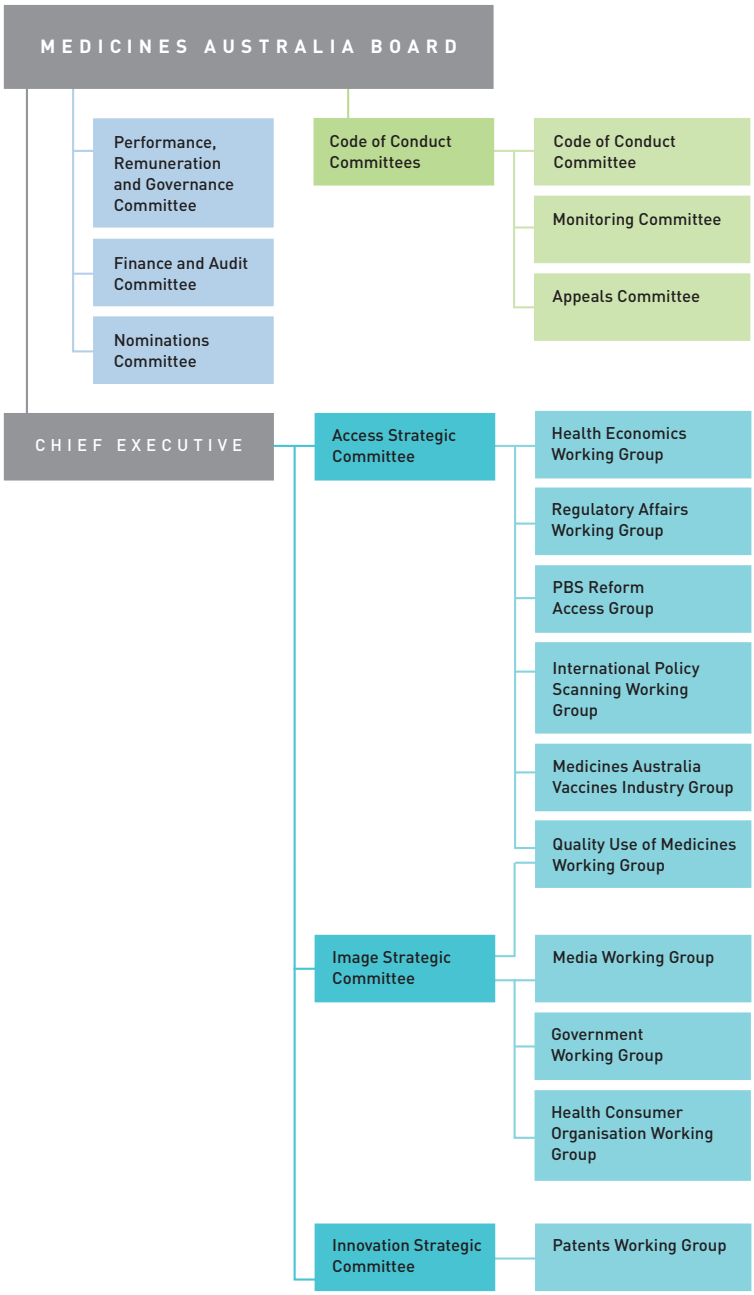
This chart summarises Medicines Australia's engagement with the Federal Government on regulation, reimbursement and industry issues, through formal committees and working groups.

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Access to Medicines Working Group (AMWG) and sub-groups	Provides strategic oversight of joint activities by Medicines Australia and DoHA to enhance PBS processes.	Will Delaat (Co-chair), Brendan Shaw, Mendel Grobler (Pfizer), David Grainger (Eli Lilly), Ian Noble (Amgen), Andrew Bruce, Jim Crompton
TGA Industry Consultative Committee (TICC)	High-level forum to discuss TGA broad policy, resource allocation and program performance issues.	Brendan Shaw, Elizabeth de Somer
Pharmaceutical Benefits Pricing Authority (PBPA)	Makes recommendations to the Minister for Health and Ageing on prices of PBS and NIP programs.	Brendan Shaw (member), Andrew Bruce (observer)
Economic Sub-Committee of the PBAC (ESC)	Reviews, interprets and advises the Pharmaceutical Benefits Advisory Committee on economic analyses of medicines submitted for listing on the PBS.	Andrew Bruce
Drug Utilisation Sub-Committee of the PBAC (DUSC)	Collects and analyses information on drug utilisation patterns in Australia. It also contrasts such information with observations internationally.	Andrew Bruce
Paediatric Medicines Advisory Group	Advises the PBAC and DoHA on paediatric medicines issues. Identifies and prioritises medicines which may be useful in a paediatric setting.	Andrew Bruce
Clinical Advisory Group on PBS Access for Refugees and Humanitarian Entrants	Provides information to the PBAC about disease trends and medicines specific to the refugee and humanitarian entrant population.	Andrew Bruce
Palliative Care Medicines Working Group	Provides clinical and technical support and advice to DoHA on how to improve access to and quality use of palliative care medicines in the community.	Jim Crompton

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Palliative Care Clinical Collaboration Management Advisory Board	Manages a group of palliative care units and conducts scientific research into the safety and efficacy of use of certain medicines in a palliative setting.	Jim Crompton
PBAC Guidelines Working Group	Monitors and implements any changes necessary to the PBAC Guidelines.	Dell Kingsford Smith (Janssen-Cilag), Ian Noble (Amgen), Andrew Bruce
Annual Medical Oncology Group of Australia Drugs Roundtable Meeting	The annual roundtable held by the PBAC with the oncology specialist society.	Mendel Grobler (Pfizer), Andrew Bruce
Australian Commission on Safety and Quality in Healthcare—Medication Reference Group	Provides advice to ACSQH on national strategies and priorities for medication safety and quality.	Elizabeth de Somer
TGA-Industry Working Group	Assists TGA in the development of a streamlined submission and effective business process reform package and provides subsequent implementation and transition advice and support.	Sue Alexander (Roche), Tony Whittaker (Commercial Eyes), Mark Rowland (Amgen), Kirpal Kaur (BMS), Duncan Purvis (Janssen-Cilag), Helen Critchley (Abbott), Warren Back (MSD), Elizabeth de Somer
TGA Best Practice Labelling Guideline Working Group	Reviews the existing TGA best practice labelling advice.	Sue Alexander (Roche), Elizabeth de Somer
CMI Effectiveness Advisory Panel (University of Sydney & Pharmacy Guild)	Provides advice to the Investigating Consumer Medicine Information Project conducted by University of Sydney under the 4th Community Pharmacy Agreement.	Elizabeth de Somer
Australian Pharmaceutical Formulary Advisory Panel	Assists in editing the Australian Pharmaceutical Formulary.	Elizabeth de Somer
Health Infrastructure Assurance Advisory Group	Provides advice to its members and to the Federal Government in the areas of critical infrastructure protection with respect to privately owned and operated critical infrastructure in the health sector and its interface with the public sector.	Elizabeth de Somer (Chair)
Critical Infrastructure Assurance Advisory Council	Consists of representatives of each critical infrastructure sector, a representative of each of the States and Territories, and representatives of relevant Federal Government agencies. The Chair of the HIAAG is a member of the CIAC. The CIAC will advise the Attorney-General on matters of nationally significant critical infrastructure protection.	Elizabeth de Somer

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
AgriFood Skills Australia Standing Committee	Provides advice on pharmaceutical training requirements offered as part of the AgriFood Skills training programs.	Elizabeth de Somer
National Prescribing Service New Medicines Working Group	Produces information for healthcare professionals about new medicines listed on the PBS.	Deborah Monk
National Prescribing Service Consumer New Medicines Editorial Group	Produces Medicines Update, which is information for consumers for new medicines on the PBS.	Deborah Monk
Pharmaceuticals Industry Working Group	High-level forum, co-chaired by the Federal Ministers for Health & Ageing and Innovation & Industry, for wide-ranging discussions between industry leaders and Government.	Will Delaat, Two Board representatives (on rotation), Brendan Shaw
Clinical Trials Action Group	Led by the Parliamentary Secretaries for Health and Innovation & Industry, this group was asked by Government to develop policies to improve the value and efficiency of conducting clinical research in Australia.	Mitch Kirkman (Novartis)
Pharmaceuticals Industry Council (PIC)	Brings together representatives from the biotech, generic and innovative medicines sectors to advise Government on issues affecting the Australian pharmaceuticals industry.	Will Delaat (Chair), Brendan Shaw, Sara Panzer (Amgen), Deborah Monk
Research & Development Taskforce	Develops strategies to improve the business environment for clinical research in Australia. (A working group of the Pharmaceuticals Industry Council.)	Melissa Grady (AstraZeneca, Co-chair), Linda Nielsen (sanofi-aventis), Mitch Kirkman (Novartis), Kaylene O'Shea (Celgene), Annette Jones (Boehringer Ingelheim), Stephan Krug (Amgen), Carlo Maccarrone (GlaxoSmithKline), Jane Frost (Pfizer), Deborah Monk, Omar Ali Khan
Industry Development Taskforce	Develops strategies to improve the business environment for pharmaceutical manufacturing and R&D activities in Australia, particularly in relation to tax-based and other government incentives for investment. (A working group of the Pharmaceuticals Industry Council.)	Sara Pantzer (Amgen), Deborah Monk, Omar Ali Khan
CMI Quality Assurance Reference Group	Promotes the provision of high-quality Consumer Medicine Information documents. Regularly reviews CMIs submitted by companies and makes recommendations on the standards for the content and quality of CMIs. It also promotes consistency of CMIs for medicines in the same therapeutic area.	Deborah Monk (Chair), Deborah Veitch (Pfizer), Duncan Terrett (Roche), Julie Khu (Pfizer)

Working with our members



This chart summarises Medicines Australia's engagement with our members through strategic committees and working groups.

Strategic Committees and Working Groups

Access Strategic Committee

KEY CAPABILITIES

- Provides high-level PBS policy, pricing, registration reimbursement, health economics, access and regulatory positions and advice, undertakes discrete research projects and provides other assistance.
- Has Working Groups on: Health Economics, International Policy Scanning, PBS Reform Access, Regulatory Affairs and Vaccines.

MEMBERS

Michelle Burke	Bristol-Myers Squibb, Co-Chair
Andrew Bruce	Medicines Australia, Co-Chair
Brendan Shaw	Medicines Australia, Co-Chair
Jez Moulding	sanofi-aventis, Board sponsor
Ian Thompson	Amgen, Board sponsor
Deborah Waterhouse	GlaxoSmithKline, Board sponsor
Sue Alexander	Roche
Andrew Carter	Commercial Eyes
Louise Carter	GlaxoSmithKline
Fabian Dwyer	IMS Health
David Garmon-Jones	Merck Serono
Rory Graham	CSL
David Grainger	Eli Lilly
Mendel Grobler	Pfizer
Nic Kurstjens	Novartis
Paul Lindsay	sanofi-aventis
Michael Nobes	Wyeth
Sara Pantzer	Amgen
Christian Sellars	MSD
Dell Kingsford Smith	Janssen-Cilag
Peter Vermeer	Eli Lilly
Charles Waterfield	AstraZeneca
Cammy Yuen	Abbott

Health Economics Working Group (HEWG)

KEY CAPABILITIES

- → Health economics expertise on improving the registration and reimbursement requirements for pharmaceutical products.
- → Generates information and resources to inform and advocate with stakeholders.

MEMBERS

Dell Kingsford Smith	Janssen-Cilag, Co-Chair
Andrew Bruce	Medicines Australia, Co-Chair
Jim Crompton	Medicines Australia, Co-Chair
Alissa Brown	Pfizer
Greg Cook	Bristol-Myers Squibb
Sheryl Dunlop	Schering-Plough
Diana Edwards	Abbott
Peter Germanos	Boehringer Ingelheim
Gary Hamann	Servier
Richard Lourenco	Covance
Grace Malanos	Roche
Andrew Manton	GlaxoSmithKline
Ian Noble	Amgen
Michael Ortiz	Solvay
Beth O'Leary	Covance
Martin O'Rourke	Eli Lilly
Margaret Rumpf	GlaxoSmithKline
Delia Schaffer	Nycomed
Sam Shirley	Medicines Australia
Jodie Thomas	Bayer
Alison Wright	AstraZeneca
Cammy Yuen	Abbott

Regulatory Affairs Working Group (RAWG)

KEY CAPABILITIES

- → Shapes and maintains a sustainable and competitive registration environment to result in timely access to innovative prescription medicines for all Australians.

MEMBERS

Sue Alexander	Roche, Co-Chair
Elizabeth de Somer	Medicines Australia, Co-Chair
Helen Critchley	Abbott, Deputy Chair
Stuart Armstrong	sanofi-aventis
Warren Back	MSD
Mandy Cooke	GlaxoSmithKline
Rory Graham	CSL
Brian Hewitt	Pfizer
Mary Flannery	Eli Lilly
Kirpal Kaur	Bristol-Myers Squibb
Sarah Lam	AstraZeneca
George Lillis	Novartis
Andrew Notley	Gilead Sciences
Duncan Purvis	Janssen-Cilag
Mark Rowland	Amgen
Tony Whittaker	Commercial Eyes

PBS Reform Access Group (PRAG)

KEY CAPABILITIES

→ Provides policy advice and support to Medicines Australia members of the Access to Medicines Working Group (AMWG).

MEMBERS

Mendel Grobler	Pfizer, Co-Chair
Andrew Bruce	Medicines Australia, Co-Chair
Sue Alexander	Roche
Karen Barfoot	Bristol-Myers Squibb
Greg Cook	Bristol-Myers Squibb
Jim Crompton	Medicines Australia
David Grainger	Eli Lilly
David Herd	GlaxoSmithKline
Dell Kingsford Smith	Janssen-Cilag
Paul Lindsay	sanofi-aventis
Michael Nobes	Wyeth
Ian Noble	Amgen
Sara Pantzer	Amgen
Christian Sellars	MSD
Mike Smith	AstraZeneca
Michael Wonder	Novartis

International Policy Scanning Working Group (IPSWG)

KEY CAPABILITIES

→ IPSWG provides a general overview of the international policy landscape pertaining to the provision of medicines. The international evidence and advice relevant to the priority areas of Medicines Australia strategic committees is a core responsibility of IPSWG. IPSWG consolidates this information to provide context for discussions around current healthcare related policy in Australia and guidance for the identification of potential future policy trends in Australia.

MEMBERS

Alissa Brown	Pfizer, Co-Chair
Amish Chaturvedi	Medicines Australia, Co-Chair
Elizabeth Arnold	Bristol-Myers Squibb
Georgie Broadbent	Bristol-Myers Squibb
Lesley Chim	AstraZeneca
Geoffrey Chin	Novartis
Sheryl Dunlop	Schering-Plough
Michelle Frost	MSD
Fernando Gonzalo	sanofi-aventis
Paul Lindsay	sanofi-aventis
Angelika Maerz	Wyeth
Beth O'Leary	Covance
Natalia Price	Abbott
Sam Shirley	Medicines Australia
Andrew Wheatley	Janssen-Cilag
Carolyn Winkler	Mundipharma
Rob Wiseman	Pfizer

Medicines Australia Vaccines Industry Group (MAVIG)

KEY CAPABILITIES

→ Provides advice to the Access Strategic Committee and Medicines Australia relating to the provision of vaccines under the National Immunisation Program (NIP) and advice on policy regarding other vaccine issues.

MEMBERS

Lauren Conyer	Wyeth, Co-Chair
Sam Shirley	Medicines Australia, Co-Chair
John Anderson	CSL
Christine Apostopoulos	Novartis
Louise Carter	GlaxoSmithKline
Helen Concilia	CSL
Grant Duff	Solvay
Alex Gosman	GlaxoSmithKline
Brent MacGregor	sanofi-aventis
Glen Mason	sanofi-aventis
Sheryl Page	GlaxoSmithKline
Caroline Pilot	Solvay
Tony Shelton	Baxter
Edward Stauber	Novartis
George Weber	Novartis
Scott Williams	Pfizer

Quality Use of Medicines Working Group

This Working Group reports to both the Access and Image Strategic Committees. The term of the Working Group will run to 31 December 2010, at which point its future will be reviewed by the Image and Access Committees.

KEY CAPABILITIES

→ High-level strategic, policy and technical advice on matters pertaining to the quality use of medicines.

MEMBERS

Andrew Carter	Commercial Eyes, Co-Chair
Jude Tasker	Pfizer, Co-Chair
Elizabeth de Somer	Medicines Australia
Stephen Gray	sanofi-aventis
Malcolm Handel	Janssen-Cilag
Kristen King	Baxter
Helen Leonard	MSD
Ross Linsley	Merck Serono
Joyce Lloyd	Pretium
Lee McKerracher	Pfizer
Diana Terry	Medicines Australia
Carolyn Winkler	Mundipharma
Cammy Yuen	Abbott

Image Strategic Committee

KEY CAPABILITIES

- Reputation management, communication strategy, issue and crisis management, message formation and delivery, stakeholder engagement and advocacy advice to achieve credibility with, and obtain the trust of, key stakeholders for industry. Demonstrates the commitment of the industry to healthcare in Australia. Expertise to:
  - build community and stakeholder perceptions about the industry;
  - rebut any unjust attacks on the industry;
  - harness some of the positive images associated with the broader health sector;
  - inform consumers about the benefits the industry provides for individuals, families, the community and the Australian economy.

MEMBERS

Libby Day	Roche, Co-Chair
Donna Edman	Medicines Australia, Co-Chair
John Latham	Pfizer, Board sponsor
Jeremy Morgan	Eli Lilly, Board sponsor
Jane Orr	MSD, Board sponsor
Jose Vieira	AstraZeneca, Board sponsor
Karen Barfoot	Bristol-Myers Squibb
Alan Brindell	sanofi-aventis
Lisa Maguire	GlaxoSmithKline
Glenn Montgomery	Merck Serono
Peter Murphy	Novartis
Adam Roach	Janssen-Cilag
Jude Tasker	Pfizer
Jackie Wilson	Abbott

Media Working Group (MWG)

KEY CAPABILITIES

- Provides strategic media communications advice and tactical planning for all issues across the industry.
- Provides advice on expected media reaction, message development, risk management, media engagement, training, measurement, monitoring and analysis.

MEMBERS

Libby Day	Roche, Co-Chair
Jamie Nicholson	Medicines Australia, Co-Chair
Will Collie	sanofi-aventis
Michelle d'Heureux	Eli Lilly
Paul de Leon	MSD
Adrian Dolahenty	Bayer Schering Pharma
Lisa Julian	Eli Lilly
Peter Poggioli	Wyeth
Simone Prideaux	AstraZeneca
Adam Roach	Janssen-Cilag
Maida Talhami	Pfizer

Government Working Group (GWG)

KEY CAPABILITIES

- → Provides political intelligence and political engagement strategies to manage issues and identify approaches within government that can affect our industry.
- → Acts as a conduit for political advocacy and policy message delivery to increase the value of the relationship of Medicines Australia and its members with elected officials.

MEMBERS

Sara Pantzer	Amgen, Co-Chair
Donna Edman	Medicines Australia, Co-Chair
Karen Barfoot	Bristol-Myers Squibb
Rowena Cowan	sanofi-aventis
Stuart Englund	Eli Lilly
Tim James	Janssen-Cilag
David Miles	Pfizer
Michael Riley	Servier
Kieran Schneemann	AstraZeneca
Todd Stephenson	Roche
Patrick Tung	Merck Serono

Health Consumer Organisation Working Group (HCOWG)

KEY CAPABILITIES

- → Expertise on issues relating to health consumer and patient groups, especially those organisations which demonstrate a willingness to partner with industry and support for issues of shared interest.
- → Providing advice on key principles in establishing successful HCO partnerships between the non-profit and commercial worlds.

MEMBERS

Peter Murphy	Novartis, Co-Chair
Diana Terry	Medicines Australia, Co-Chair
Gillian Adamson	Pfizer
Fiona Bailey	Eli Lilly
Zarli French	MSD
Holly Kania	Roche
Ian McKnight	Wyeth
Monique McLaughlin	Amgen
Jennifer Stevenson	Abbott
Neil Wildman	Pfizer

Innovation Strategic Committee

KEY CAPABILITIES

→ Develops and implements policy and program measures for:

- continuing industry development;
- growth in investment in research and development;
- protection of intellectual property.

MEMBERS

Tim Murphy	GlaxoSmithKline, Co-chair
Deborah Monk	Medicines Australia, Co-chair
Klaus Abel	Lundbeck, Board sponsor
Graeme Blackman	IDT, Board sponsor
Bruce Goodwin	Janssen-Cilag, Board sponsor
Dieter Torheiden	Solvay, Board sponsor
Adrian Bootes	Roche
Candice Braithwaite	Wyeth
Alex Condoleon	sanofi-aventis
Paul Dale	Eli Lilly
Ric Degaris	Kendle
Tim Donald	PricewaterhouseCoopers
Simon Fisher	AstraZeneca
Tim James	Janssen-Cilag
Bill Ketelbey	Pfizer
Omar Ali Khan	Medicines Australia
Joyce Lloyd	Pretium

Patents Working Group

KEY CAPABILITIES

→ Design and implement measures to ensure fair and balanced protection of intellectual property rights in Australia.

→ Ensure Australia maintains equity with the highest international standards and its bilateral Australia Free Trade Agreement (AUSFTA) and Trade Related Intellectual Property Rights (TRIPS) commitments.

MEMBERS

Deborah Monk	Medicines Australia, Chair
Rebecca Allsopp	sanofi-aventis
Shahnaz Irani	Spruson & Ferguson
Omar Ali Khan	Medicines Australia
Sara Pantzer	Amgen
Sana Rasool	Pfizer

Working with the community

Special Purpose Fund

The establishment of the special purpose fund was announced at the Annual General Meeting in October 2008. The funds are derived from the Code of Conduct fine income surplus minus costs of running the Code of Conduct.

The Board endorsed in principle the allocation of funds set aside in the special purpose fund to not-for-profit charitable organisations that focus on indigenous health.

The Medicines Australia Finance and Audit Committee oversees the special purpose fund activities.

Jimmy Little Foundation

In 2009–10 $1 million from the special purpose fund was donated to the Jimmy Little Foundation to fund two projects aimed at improving indigenous health.

The first project, to which Medicines Australia contributed $720,000, is the Jimmy Little *Thumbs Up!* Campaign that will raise awareness of the importance of healthy eating in indigenous communities, especially among children.

The second project is a contribution of $360,000 towards a mobile dialysis unit in central Australia. This will have a positive impact on local communities around Alice Springs that are hundreds of kilometres away from dialysis services. This project is being managed by the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation.

Medicines Australia Chairman Will Delaat presented Jimmy Little with a cheque for $1.08 million for the Foundation at the Medicines Australia parliamentary dinner on 16 March 2010.

Shalom Gamarada Scholarships

Medicines Australia has contributed $150,000 over five years towards the education of two indigenous medical students, Laura Fitzgerald and Brendan Phillips, through the Shalom Gamarada Ngiyana Yana Scholarship Program for indigenous students.

Working with Health Consumer Organisations

Medicines Australia supports a range of initiatives through its membership that focus on improving the health outcomes of Australians. These collaborations with health consumer organisations operate in accordance with the *Working Together Guide*, jointly developed by the Consumers Health Forum of Australia and Medicines Australia.

The *Working Together Guide* recognises the rising number of relationships between health consumer organisations and the Australian medicines industry, and the need for both parties to work together in a transparent and accountable way. The Guide is framed by the key principles of respect for independence, achieving and maintaining public trust, fairness, openness and transparency, and accountability.

1 Thumbs up from Medicines Australia Chairman Will Delaat and founder of the Jimmy Little Foundation, Dr Jimmy Little at the Medicines Australia parliamentary dinner in March at which Medicines Australia made a $1 million donation to the Jimmy Little Foundation.

2 Indigenous health champion and musician Dr Jimmy Little entertains guests at the Medicines Australia parliamentary dinner.

3 Dr Jimmy Little and members of the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation; Marlene Spencer, Sarah Brown and Bobby West.

Collaborations are with peak consumer organisations such as **Arthritis Australia**, under the auspices of which, along with member companies, the *Community Chest* supports projects aimed at improving the health outcomes of Australians through evidence-based management of arthritis.

A key achievement of the *Community Chest* has been the successful uptake of an informative booklet on living with arthritis, with supporting web materials that provide a credible source of information for people living with arthritis.

The **Heart Foundation** *Pharmaceutical Roundtable* brings together members of member companies and the Heart Foundation to improve cardiovascular health with supporting research and other relevant projects. Roundtable members support the Heart Foundation Research Program as well as work aimed at improving the quality use of cardiovascular medicines in the Australian community.

A key achievement of the Roundtable has been the commitment by members to work towards the common goal of addressing and improving the cardiovascular health of all Australians. To this end, the Roundtable supports work which promotes the quality use of medicines and seeks to identify opportunities to advocate for change that will lead to improved health outcomes. This commitment was exemplified by the work to improve consumers' adherence to cardiovascular medicines and lifestyle recommendations advocated by the Roundtable.

The *Pharmaceutical Collaboration* between the **Mental Health Council of Australia** and some member companies aims to support consumers, carers and health professionals to improve the quality of mental healthcare and outcomes for people with mental health problems by promoting the development and implementation of effective mental health policy.

A key achievement of the *Pharmaceutical Collaboration* has been the focus on access to information to promote the quality use of medicines to help consumers and carers at each stage of medication management.

Medicines Australia places great value on its relationships with consumer organisations, in particular with the peak body **Consumers Health Forum of Australia**. This relationship was further strengthened in 2009–10 through a mutual agreement to establish a joint advisory group to address topical issues of importance to health consumers and the industry.

Medicines Australia publications

Publications and Reports

- Occasional Paper 1: *PBS Reforms—Are they Working? The Evidence* (October 2009)
- *Medicines Australia Facts Book*: First Edition (December 2009)
- *The Australian Pharmaceuticals Industry: Winds of Change—Report of the 2009 Medicines Australia Member Economic Survey* (June 2010)

Submissions

- July 2009—Medicines Australia Submission to IP Australia on the Review of the *Patents Act 1990*
- August 2009—Medicines Australia Submission to the Senate Community Affairs Committee on Gene Patents
- September 2009—Medicines Australia Submission to the Joint House and Senate Committee on Foreign Affairs, Defence and Trade on Proposed Amendments to the *Patents Act 1990*
- October 2009—Medicines Australia Submission to the Advisory Council on Intellectual Property on Post-Grant Patent Enforcement Strategies
- November 2009—Medicines Australia Submission to Treasury on R&D Tax Credit Consultation Paper
- November 2009—Medicines Australia Submission to the Department of Health and Ageing on the Effects of Reforms to the Pharmaceutical Benefits Scheme
- December 2009—Medicines Australia Submission to the Intergenerational Report
- February 2010—Medicines Australia Submission to Treasury on R&D Tax Credit Draft Legislation
- April 2010—Medicines Australia Submission to the Senate Community Affairs Reference Committee Inquiry into Consumer Access to Pharmaceutical Benefits
- April 2010—Submission to the Australian Competition and Consumer Commission (ACCC) on the authorisation of the Generic Medicines industry Association (GMiA) Code of Practice
- April 2010—Medicines Australia Submission to Treasury on R&D Tax Credit Second Draft Legislation
- May 2010—Medicines Australia Submission to Senate Economics Committee on R&D Tax Credit Legislation
- June 2010—Medicines Australia Submission to IP Australia on the Implementation of the TRIPS Protocol

Index of acronyms and abbreviations

ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
AMWG	Access to Medicines Working Group
AusPAR	Australian Public Assessment Report
CATAG	Council of Australian Therapeutic Advisory Groups
CEP	Continuing Education Program
CHF	Consumers Health Forum of Australia
CIAC	Critical Infrastructure Advisory Council
CMI	Consumer Medicine Information
CSES	Centre for Strategic Economic Studies
CTN	Clinical Trial Notification
DoHA	Department of Health and Ageing
FPI	First Patient In
GMiA	Generic Medicines industry Association
HREC	Human Research Ethics Committee
HEWG	Health Economics Working Group
HIAAG	Health Infrastructure Assurance Advisory Group
HoMER	Harmonisation of Multi-Centre Ethical Review
IPSWG	International Policy Scanning Working Group
MAVIG	Medicines Australia Vaccines Industry Group
MOGA	Medical Oncology Group of Australia
MoU	Memorandum of Understanding
MYEFO	Mid-Year Economic and Fiscal Outlook
NIP	National Immunisation Program
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
QUM	Quality Use of Medicines
RAWG	Regulatory Affairs Working Group
TGA	Therapeutic Goods Administration
TGP	Therapeutic Group Premium
TRIPS	Trade-Related Aspects of Intellectual Property
UQ	University of Queensland