

MEDICINES AUSTRALIA /
ANNUAL REPORT 2010-11



MEDICINES
Australia

CONTENTS

3	Medicines Australia Vision + Mission Statement
3	Chairman's Report
5	Chief Executive's Report
7	Medicines Australia Board Members 2010-11
9	Medicines Australia Secretariat 2010-11
11	Medicines Australia Members 2010-11

KEY ISSUES

12	Improving timely access to medicines for Australians
14	Improving the investment environment
17	Celebrating 50 years of the Code of Conduct
19	Code of Conduct performance in 2010-11: a snapshot
20	Introducing The Australian Medicines Industry brand
22	Key Events Diary
26	Conferences and Events
28	Awards
30	Industry Representation on Government Bodies and for Other Organisations
34	Working with our Members
40	Working with the Community
42	Inside Medicines Australia
44	Medicines Australia Publications
45	Index of Acronyms and Abbreviations

MEDICINES
Australia

© Copyright Medicines Australia 2011. All rights reserved.

This Annual Report provides a summary of Medicines Australia's activities, initiatives and achievements for the financial year ending 30 June 2011.

CONTACT Julie Johnson, Medicines Australia, Level 1, 16 Napier Close, Deakin ACT 2600

TELEPHONE 02 6122 8503 • Facsimile 02 6282 6299 • EMAIL Julie.johnson@medicinesaustralia.com.au • WEBSITE www.medicinesaustralia.com.au

Design: Designers Wakefield Bevanda



Medicines Australia Vision + Mission Statement

VISION

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

MISSION

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

STRATEGIC DIRECTIONS

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

Chairman's Report

The focus for Medicines Australia in 2010-11 has been finalising and implementing the Memorandum of Understanding with the Commonwealth, to secure a more predictable and stable policy environment.

This has been a difficult task, in part because of the Federal Cabinet's decision in February 2011 to defer the listing of some new medicines on the Pharmaceutical Benefits Scheme (PBS). While by and large the MoU is delivering on its objectives to deliver savings and improve PBS listing processes, the Government's decision to defer the listing of some new medicines on the PBS is not consistent with the spirit of the MoU.

Medicines Australia has pursued a varied but focussed agenda over the past 12 months, and by working in partnership with government and other stakeholders, we have achieved some significant outcomes in important policy areas.

Indeed, Medicines Australia's parliamentary engagement has been constructive and solutions-oriented, and in the past year I have met personally with key politicians including the Prime Minister, the Treasurer, the Minister for Health and Ageing and the Opposition Health Spokesman.

In December 2010, some seven months after the MoU was first signed with the Commonwealth, the Federal Parliament passed the legislation required to deliver the PBS savings set out in the MoU. The process improvements to the PBS that were negotiated as part of this agreement were implemented in the latter half of the year. The result is that Australian patients should enjoy faster access to innovative new medicines.

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 AMWG has made good progress in driving the implementation of the MoU.

We also co-convened the Joint Medicines Policy Conference in Canberra in late August, the third in a series of successful forums to discuss and debate medicines policy in Australia.

The substantial PBS savings promised under the MoU and earlier PBS reforms have also started to flow. Statutory price cuts and price disclosure of up to 70 per cent in some cases, have put a brake on PBS growth. In fact, at one point towards the end of the year PBS expenditure was growing at less than the rate of inflation.

The fact that the 2011 Federal Budget contained no PBS price-related savings measures, as per the Memorandum of Understanding, was welcome and further evidence of the benefit to industry of the agreement.

However, Federal Cabinet's decision in February to defer the PBS listing of some new medicines, and to effectively remove the \$10 million Cabinet threshold, was extremely disappointing and was opposed universally across the health sector.

The decision breached the intent of the MoU. Medicines Australia will continue to advocate for the return of the well-established, independent, non-political process for bringing new medicines onto the PBS that has served Australian patients well for decades.

The Pharmaceuticals Industry Council, which I have continued to chair this year, has made progress against its priorities, which are to enhance the operating environment for clinical trials in Australia, to achieve a predictable and stable reimbursement pathway for biosimilars and to raise awareness of industry issues among all political stakeholders.

At the Pharmaceuticals Industry Working Group meeting in May, the Minister for Health and Ageing, Nicola Roxon and the Minister for Innovation, Industry, Science and Research, Kim Carr reaffirmed their commitment to work with the industry to tackle these issues.

In November 2010 I gave an address to 300 guests at the National Press Club of Australia titled *The medicines industry and a healthier Australia*. The address, which set out Medicines Australia's policy agenda, was also broadcast nationally on ABC television. A transcript of the address is available [here](#).

Medicines Australia has continued to support the community in a number of areas where assistance is most needed. In January Medicines Australia donated \$100,000 to the Queensland flood disaster relief appeal, while industry's aggregate contribution to the appeal exceeded \$1.7 million.

In partnership with the Jimmy Little Foundation we have continued to roll out a healthy eating awareness program for indigenous children in northern Australia and made considerable progress towards the construction of a mobile dialysis unit to treat indigenous patients in the Western Desert region.

There have been three additions to our membership this year. I am pleased to welcome to the association as new members—Fresenius Kabi, FIT BioCeuticals and Leo Pharma.

Medicines Australia has benefited enormously from the excellent leadership of our chief executive Brendan Shaw, who has earned the respect of the Board and the membership, and who has been a consistently passionate and energetic advocate for the industry.

I would also like to place on record my sincere thanks to my fellow Board members for their staunch support and assiduous work on behalf of member companies over the past year.



WILL DELAAT



Chief Executive's Report

Medicines Australia has recorded some significant achievements in 2010-11, despite the Federal Cabinet's troubling decision to defer the listing of some new medicines on the Pharmaceutical Benefits Scheme.

The election outcome in August 2010 has presented a much more complex political environment. This makes the job of representing industry's interests that much more challenging. We have responded to these challenges over the past 12 months by increasing industry engagement with Parliament and by directing dedicated resources to parliamentary liaison.

These efforts were exemplified by the successful Medicines Australia parliamentary dinner in March, an event which put the industry on show and drew an attendance of over 30 Members of Parliament. The evening was particularly memorable for two excellent speeches by the Minister for Innovation Senator Kim Carr and the Director General of the World Intellectual Property Organization, Dr Francis Gurry. Video of both speeches can be viewed [here](#).

Through the second half of 2010 Medicines Australia finally secured the Memorandum of Understanding with the Commonwealth on the management of the PBS. This historic agreement followed a long and difficult process of negotiation. It is intended to help secure savings for the Government, provide policy predictability for industry and deliver a range of process improvements that will allow Australians to get access to new medicines more quickly.

Following the completion of the agreement, Medicines Australia and the Government have been working together to implement the provisions of the MoU. Indeed, the fact that the 2011 Federal Budget contained no price-related savings measures was testament to the benefit of the MoU for industry.

Nevertheless, in February 2011 the Government dropped a bombshell by announcing that it was tightening Cabinet control of all PBS listings, indefinitely deferring the listing of seven new medicines and one vaccine.

This announcement was made with no prior consultation and clearly breached the intent of the MoU. It is disappointing for a whole range of reasons, not least of which is that it came less than three months after the MoU legislation was passed by the Parliament with industry's support. It is poor policy and will adversely impact Australian patients, industry and ultimately Government itself.

Accordingly, Medicines Australia and its member companies have joined patient groups, the generics industry, doctor groups, independent economic commentators, the Australian community, the Coalition and the Australian Greens, and the media in a campaign to have this flawed policy overturned.

Among the many disappointments of the Government's decision is that it flies in the face of the intent of the MoU to provide policy predictability. Medicines Australia will continue to campaign vigorously for the Government to overturn its decision.

In spite of the setback of Cabinet's deferral decision, however, the Government has introduced a number of reforms to which industry has contributed and fully supports.

The Therapeutic Goods Administration's business process reforms are an important step towards making Australia's medicines regulatory environment more efficient, effective and transparent. They will improve the regulatory approval time and position Australia as one of the world's premium regulatory jurisdictions.

Whilst welcoming the Australian and New Zealand governments' announcement that they will revive the trans-Tasman regulatory agency, it will be important to ensure this reform does not dilute the efforts to improve the TGA's operations.

In the first half of 2011 the Government announced it was implementing all recommendations of its Clinical Trials Action Group to ensure a more competitive regulatory environment for clinical trials in Australia. Medicines Australia advocated strongly for these reforms and we look forward to their implementation.

Medicines Australia also warmly welcomes the Government's announcement that its long-awaited reforms to R&D tax incentives would be passed by the Parliament in early 2011-12. The Australian medicines industry has been supporting the Government's R&D tax reforms for some years. The new tax credit will effectively reduce the cost of eligible R&D by up to 10 per cent.

A raft of changes to intellectual property laws was proposed in the Parliament over the past year. They included a private members Bill to ban the patenting of all biological materials. This Bill threatens the future development of new medicines, industry's commercial viability in Australia, our long and proud tradition of medical research, patient access to new therapies and Australia's international trade obligations.

Medicines Australia and its member companies have partnered with a range of stakeholders in business, the medical research sector and the broader community to advocate for the defeat of the Bill. At year's end, the outcome of this proposed legislation was unclear. However, I am hopeful that the Bill will be rejected.

Other changes to intellectual property law included removing copyright for Product Information, which industry did not oppose, and the *Raising the Bar Bill*, tabled in Parliament and supported by Medicines Australia. This latter reform to Australia's patent regime will bring us into line with international standards, while ensuring scientific freedom.

The Government also proposed a new system of compulsory licensing to allow companies to manufacture other companies' medicines while under patent, for supply to medical emergencies in the least developed countries. This legislation is consistent with Paragraph 6 of the TRIPS provisions of the World Trade Organisation. Medicines Australia will continue work with the Government to implement these provisions.

Throughout 2010-11 Medicines Australia has been preparing for a major public awareness initiative for The Australian Medicines Industry. The initiative has received significant support from Medicines Australia member companies and has been enthusiastically embraced.

An enormous amount of hard work has been invested in the preparation of this project and we look forward to seeing the rewards of that work in the second half of 2011.

The industry continued to uphold the high standards of ethical engagement with the health sector and the community set out in the Medicines Australia Code of Conduct. Conduct by member companies remains well regarded here and internationally.

Medicines Australia was also an active contributor to the Government-initiated cross-sector working group on the promotion of therapeutic products, chaired by Anne Trimmer, chief executive of the Medical Technology Association of Australia (MTAA).

The working group's report was due to be released in early 2011-12 and I am confident it will provide a good framework for a more level playing field across the health sector.

In closing, while the past year has been challenging for Medicines Australia and the industry, I am confident that we are performing well as an organisation that represents its members to the broader community.

The strategic committees and working groups play an integral part in Medicines Australia's operations and continue to make an enormous contribution. I thank the individuals who have taken time to contribute and help foster a strategic direction for the industry, particularly the industry co-chairs of the three strategic committees, Michelle Burke (Access), Tim Murphy (Innovation) and Libby Keohane (Image).

The Board has provided strong leadership and direction for the Australian medicines industry throughout the year, and they have been astutely led by the chairman Will Delaat. It has been a pleasure working with all of them.

Finally, none of our achievements would have been possible without the good humour, capability and extraordinary dedication of the Medicines Australia secretariat staff. Their contribution to the Australian medicines industry is truly inspiring and it is a genuine privilege to work with this fine team. They are a credit to the industry they serve.



BRENDAN SHAW

Medicines Australia Board Members 2010-11



- | | | |
|-------------------|-------------------------------|-----------------------|
| 1 Will Delaat | 7 Frederic Guerard | 13 Deborah Waterhouse |
| 2 Klaus Abel | 8 John Latham | 14 Tim McCormick |
| 3 Graeme Blackman | 9 Jane Orr | 15 Jez Moulding |
| 4 James Cain | 10 Dean Phizacklea | 16 Jeremy Morgan |
| 5 Mark Glover | 11 Ian Thompson | 17 Dieter Torheiden |
| 6 Bruce Goodwin | 12 José Antonio Toledo Vieira | |

Medicines Australia Board Members 2010–11

DIRECTORS 2010–11

Mr Will Delaat	Appointed Chairman	August 1998
Mr Klaus Abel	Managing Director, Lundbeck Australia Pty Ltd	1 January 2010
Dr Graeme Blackman	Chairman, Institute of Drug Technology Australia Ltd	June 1995
Mr James Cain	Managing Director, Bristol-Myers Squibb Australia Pty Ltd	7 September 2010
Mr Mark Glover	Allergan Australia Pty Ltd	30 May 2011
Mr Bruce Goodwin	Managing Director, Janssen Pty Ltd	12 May 2009
Mr Fredric Guerard	Managing Director, Novartis Pharmaceuticals Australia Pty Ltd	23 June 2009
Mr John Latham	Regional Director (Australia & New Zealand), Pfizer Australia Pty Ltd	6 March 2007
Ms Jane Orr	Managing Director, Merck Sharp & Dohme (Australia) Pty Ltd	18 December 2008
Mr Dean Phizacklea	Managing Director, Abbott Australasia Pty Ltd	7 September 2010
Mr Ian Thompson	Managing Director, AMGEN Australia Pty Ltd	1 May 2009
Mr José Antonio Toledo Vieira	Managing Director, AstraZeneca Pty Ltd	1 January 2008
Ms Deborah Waterhouse	General Manager, GlaxoSmithKline Australia Pty Ltd	9 December 2008

APPOINTED TO BOARD

		APPOINTED	RESIGNED
Mr Tim McCormick	Managing Director, Biogen Idec Australia Pty Ltd	7 September 2010	30 April 2011
Mr Jez Moulding	Managing Director, sanofi-aventis Australia Pty Ltd	1 January 2008	9 August 2010
Mr Jeremy Morgan	Managing Director, Eli Lilly Australia Pty Ltd	6 March 2007	13 August 2010
Mr Dieter Torheiden	General Manager, Solvay (now Abbott Products Ltd)	3 April 2007	31 August 2010

Medicines Australia Secretariat 2010-11

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 | Amna Khanzada | Office Administrator |
| 7 | Prya Sonah | Finance Assistant |

ACCESS



- | | | |
|----|--------------------|-------------------------------------|
| 8 | Andrew Bruce | Director Health Policy and Research |
| 9 | Jim Crompton | Reimbursement Strategies Manager |
| 10 | Elizabeth de Somer | Regulatory Affairs Manager |

- | | | |
|----|------------------|-----------------------------|
| 11 | Larissa Karpish | Policy Manager |
| 12 | Amish Chaturvedi | Research Manager |
| 13 | Kristin Trace | Policy and Research Officer |

Medicines Australia Secretariat 2010–11

INNOVATION AND ETHICAL CONDUCT



14 Deborah Monk Director Innovation and Industry Policy
15 Sophie Hibburd Code of Conduct Manager

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

IMAGE



18 Donna Edman Executive Director Public Affairs
19 Jamie Nicholson Media Communications Manager
20 Andrew Simpson Government Relations Manager
21 Diana Terry Stakeholder Relations Manager

22 Julie Johnson Public Affairs Officer
23 Juanita Wall Personal Assistant to the Innovation and Industry Policy and Public Affairs Directors



STAFF WHO DEPARTED IN 2010–11

24 Michael Fitzsimons Policy Manager
25 Sue Elderton Public Affairs Officer
26 Helen Cox Policy Coordination Officer
27 Joanne Toogood Office Manager

28 Janelle Andre Morgan Executive Officer
29 Sam Shirley Policy and Research Officer
30 Ivan Trofimov Access to Medicines Policy Officer

Medicines Australia Members 2010-11

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 Pty Ltd
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 Pty Ltd
Lundbeck Australia Pty Ltd
Merck Serono Australia Pty Ltd
Merck Sharp & Dohme (Australia) 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
Servier Laboratories (Aust) Pty Ltd
Shire Australia Pty Limited
UCB Pharma

CLASS TWO

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

CLASS THREE

FIT-BioCeuticals Ltd
IDT Australia Ltd
Leo Pharma Pty 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
Pretium Pty Ltd
PricewaterhouseCoopers
Princeton Publishing Pty Ltd
Quintiles Pty Ltd

KEY ISSUES

It's a bad policy, and frankly Australia shouldn't be a country where we can't afford to provide medicines to sick people.

BRENDAN SHAW • The Alan Jones Show, 2GB. 9 June 2011.



Industry, patient groups and the AMA met with Minister Roxon in April to discuss the Government's decision to defer the listing of a number of PBAC-recommended medicines on the PBS.

Improving timely access to medicines for Australians

2010-11 was a mixed bag for access to medicines in Australia. On the positive side, the Memorandum of Understanding with the Commonwealth formally took effect in November, with Budget night in 2011 providing industry with some predictability by having no new price-related savings measures. The MoU also delivered important policy changes which have been designed to speed up time to listing. Most notably both parallel TGA/PBAC processing and Phase 1 of the Managed Entry Scheme have put Australia on the international policy map, and these policy innovations are being watched with some interest in other jurisdictions.

It is pleasing that parallel TGA/PBAC processing, in particular, has been wholeheartedly embraced by industry. Since the introduction of this option on 1 January 2011, 43 per cent of all major PBS submissions have been submitted in parallel to TGA consideration. This trend is only likely to increase as the business process reforms at the TGA are bedded down. Designed to provide industry

with both faster and more predictable registration timelines, it is in industry's interests to work closely and cooperatively with the TGA to introduce what are complex process reforms in a tight fiscal and workforce environment. Combined with parallel processing, the business process reforms promise to deliver significant reductions in time to access for many medicines. Medicines Australia will be devoting considerable resources during 2011-12 to help ensure the smooth introduction and interaction of the policies.

Counterbalancing these improvements in the access environment during 2010-11 was the disappointing decision by the Federal Government in February to defer the listing of a number of PBAC-recommended medicines on the PBS. At the same time, the Government also announced that it would require all PBAC-recommended medicines to be considered and approved by the Federal Cabinet prior to listing, effectively doing away with the long-standing \$10 million threshold, introducing an additional layer of uncertainty into the business environment, and politicising the PBS listing process.

Medicines Australia argued strongly that this was poor public policy, and a breach of the intent, if not strictly the letter, of the MoU. In the first half of 2011, Medicines Australia campaigned to have this decision overturned, a process that included a heightened engagement with central economic departments in Government.

Medicines Australia was particularly disappointed with the deferrals decision because it occurred at a time when PBS expenditure growth was at a historical low. Medicare data showed that for 2010-11, the PBS grew only at 2 per cent in real terms. Medicines Australia has been at pains to communicate that the price disclosure policy from the original 2007 PBS reforms and augmented by the 2010 MoU will generate PBS savings through market-based competition in F2 well in excess of that which the Federal Government has conservatively estimated. This needs to be acknowledged and made visible to the key fiscal decision makers in the Government so that headroom for new listings can continue to be provided. Ultimately, this argument will be won only by the data, and we will have to wait until April 2012 and beyond before we know for certain what we now believe. In the meantime, we can confidently assert that industry has done its part towards maintaining a sustainable PBS, by delivering the Government a minimum estimated \$1.9 billion in savings by the MoU. Medicines Australia will continue to work to ensure that the Government honours fully its part of the bargain.

The Access Strategic Committee, along with its working groups, has played a central and steadying role for the industry association during what can best be described as a turbulent period for medicines policy in Australia. In a little over 12 months, the Committee has overseen the industry's participation in two Senate inquiries, finalised negotiations and overseen the timely implementation of some complex MoU provisions (eg parallel TGA/PBAC processing and expanded and accelerated price-disclosure), worked closely with the TGA to introduce the business process reforms, and commenced work to make the listing process for vaccines more predictable and transparent. The Access Committee has also been engaged with Government to find suitable solutions to outstanding policy problems in the area of biosimilar reimbursement and co-dependent technologies.

All of this would not have been possible without the committed and tireless work of volunteers from Medicines Australia member companies who sit on the Committee and/or its working groups. The latter comprise the Regulatory Affairs Working Group (RAWG), the Health Economics Working Group (HEWG), the International Policy Scanning Working Group (IPSWG), the Medicines Australia Vaccines Industry Group (MAVIG) and the PBS Reform Advisory Group (PRAG). Special mention must be given to the industry co-chairs of these groups, namely Michelle Burke (Access Committee), Sue Alexander (RAWG), Greg Cook (HEWG), Alissa Brown (IPSWG), Lauren Conyer (MAVIG), and Mendel Grobler (PRAG).

Special mention must also be given to the industry members of the Access to Medicines Working Group, co-chaired by Will Delaat (Medicines Australia) and David Learmonth (DoHA). This group finalised negotiations around the MoU policy provisions and ensured their timely implementation.

KEY ISSUES

Our whole approach to industry policy hinges on attracting investment in Australian capabilities and skilled Australian workers. All Australians are the beneficiaries if we get that right.

MINISTER FOR INNOVATION, INDUSTRY, SCIENCE AND RESEARCH
KIM CARR • announcing the Government's acceptance of the recommendations of the Clinical Trials Action Group at the Medicines Australia Parliamentary Dinner on 2 March, 2011.



Improving the investment environment

Clinical Trials Action Group

The Clinical Trials Action Group was set up in October 2009 to help “cement Australia’s position as a good place to conduct clinical trials”. It was co-chaired by the then Parliamentary Secretaries for Health (Mark Butler MP) and Innovation (Richard Marles MP). Other members included Dr Tim Dyke of the National Health & Medical Research Council (NMHRC), Mitch Kirkman of Novartis, and Professor Jim Bishop, then the Chief Medical Officer.

In its report, which was released in March 2011, the Action Group made over 20 recommendations, mostly aimed at improving patient recruitment and making the process of initiating new clinical trials in Australia significantly more efficient.

In remarks at the Medicines Australia Parliamentary dinner in March, the Minister for Innovation, Industry, Science and Research, Senator Kim Carr, announced that the Australian Government had accepted the Action Group’s recommendations. He added that these reforms “will lead to improved productivity and have benefits for

Australian patients, industry, researchers and governments”. In addition, the Minister for Health & Ageing, Nicola Roxon, said that implementing the Action Group’s recommendations will help “keep Australian clinicians at the cutting edge of medical science”.

Medicines Australia strongly supports the Action Group’s recommendations and has been working closely with the relevant government departments, including the departments of Health & Ageing and Innovation & Industry and the NHMRC, to ensure their rapid implementation.

The NHMRC is responsible for implementing the majority of the Action Group’s recommendations and it provides regular progress reports which are available on its website.

The Department of Innovation, Industry, Science and Research is also responsible for the implementation of some of the Action Group’s recommendations, most importantly the development of a consumer-friendly clinical trials website. The Department has been working with the Consumers Health Forum (CHF) to develop materials to improve public awareness in Australia about the benefits of conducting and participating in clinical trials.

Finally, a CTAG Coordination Group was established within Government to oversee the implementation of the Action Group’s recommendations. The group consists of representatives from industry, state and federal governments and the CHF.

R&D Tax Credit

In May 2010, the Australian Government introduced a Bill in Parliament to replace the existing R&D Tax Concession system with a new R&D Tax Credit system. This followed a 12-month consultation process, during which Medicines Australia worked closely with various government departments to ensure the new system delivers tangible benefits for our member companies. Despite being passed twice by the House of Representatives, the Bill failed to pass the Senate in time to allow the new tax incentive to commence on 1 July 2010. Then on 15 June 2011, the Government announced that it had secured enough cross-party support in the Senate to finally pass the Bill into law. The start date for the new tax incentive will be 1 July 2011.

Medicines Australia has, from the start, strongly supported the implementation of the R&D Tax Credit system. It will replace a program which failed to help Australian companies attract a larger share of the global bio-pharmaceutical industry's R&D investment budget, which is worth more than \$70 billion annually. The R&D Tax Concession program was outdated, unpredictable and too complicated, and it did not provide a globally competitive incentive for companies to conduct R&D in Australia.

The implementation of the new R&D Tax Credit system will make access to tax benefits more predictable, and will help reduce the cost of conducting eligible R&D in Australia by up to 10 per cent. Together, these factors will enable our members to better demonstrate to global headquarters the advantages of sending R&D investment to Australia.

Gene Patents

In November 2010 a private members Bill was introduced in Parliament containing a proposal to ban patents on "biological materials including components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature". The Bill was immediately referred to the Senate Legal and Constitutional Affairs Committee for review. Public hearings, at which Medicines Australia testified, were held at Parliament House in April. The Committee was initially expected to issue its final report in June, but the reporting date was postponed.

The "problem" of gene patents has been on the minds of policy makers for many years. In 2004, for example, the Government asked the Australian Law Reform Commission to investigate whether, as some critics claim, patents restrict patient access to new treatments and diagnostic tests or make it difficult for scientists to conduct medical research. The Commission did not discover a widespread problem. It recommended a number of changes to the Australian patent system, but not to laws

governing patentable subject matter. In November 2010, the Senate Community Affairs Committee (to which Medicines Australia made multiple [submissions](#)) released its final report after a two-year inquiry into gene patents. The Committee also recommended changes to the Patents Act, but stopped well short of recommending a ban on patents on genetic and biological materials.

However, recent developments, especially an unexpected decision in 2010 by a US district court related to patenting of gene sequences, influenced the debate on amendments to Australia's patent law.

Medicines Australia has urged the Senate Legal and Constitutional Affairs Committee, in [submissions](#) as well as in public testimony and media statements, to recommend that the private members Bill be rejected and that Parliament investigate other, more meaningful ways to achieve the Bill's goals, which we support. These are:

- to improve Australian patients' access to new health technologies; and
- to ensure Australian scientists are free to conduct research on patented inventions (so long as it is for the purpose of investigating a patented invention, and not their intention to infringe valid patents by selling these inventions without the inventors' permission).

Medicines Australia submitted that excluding all biological materials from patentable subject matter would, contrary to the Bill's intention, harm Australian patients, destroy jobs and stall medical research in Australia. It would also be in breach of Australia's international obligations under Article 27(1) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.

The Senate Legal and Constitutional Affairs Committee has received over 110 submissions, more than two thirds of which contain statements strongly opposing the implementation of the Bill.

Medicines Australia has worked closely with AusBiotech to argue against the Bill.

Patent Reform

On 22 June 2011, the Australian Government introduced legislation in Parliament to overhaul Australia's patent system. *The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* includes the introduction of an explicit research-use exemption. Other elements of the legislation include changes to harmonise Australian patent law with American and European patents laws.

Between 2008 and 2010, Medicines Australia made a number of submissions in response to invitations from Government for comments on proposed changes to Australia's patent system. *Raising the Bar* is the result of this long public consultation process.

On balance, Medicines Australia supports the implementation of *Raising the Bar*, and we have publicly encouraged Parliament to pass this legislation as soon as possible.

We especially support the implementation of the research-use exemption, which will directly address concerns among certain stakeholders that patents on biological materials (or even patents generally) have the potential to stifle scientific research. An explicit research-use exemption will make it absolutely clear that scientists are free to conduct research on patented inventions, so long as it is for the purpose of investigating the patented invention and not their intention to infringe valid patents by selling or inappropriately using these inventions without the inventors' permission.

Medicines Australia is also pleased that the Government has accepted our recommendation that existing patent applications will be judged against existing, not new, criteria. Medicines Australia had recommended that the new provisions should apply only to applications filed on or after the date of the commencement of the new legislation to give applicants the opportunity to have their existing applications judged against a known set of standards rather than against a new set of standards, which, by definition, raise the bar of patentability.

Data Exclusivity

The current term of data exclusivity in Australia is five years, beginning from the date of a new active ingredient's first inclusion on the Australian Register of Therapeutic Goods. This makes Australia's data exclusivity system among the weakest in the OECD.

In December 2010, Medicines Australia sent a survey to our member companies, requesting specific examples of medicines which have not been (or are not likely to be) marketed in Australia primarily due to a shorter than average term of data exclusivity. This was done to help establish a specific link between data exclusivity and access to new medicines, and, therefore, between data exclusivity and better health outcomes for Australian patients. Eight companies identified 13 medicines which they chose not to sell in Australia (or whose sale was delayed or otherwise affected in Australia) over the last 10 years due to what they perceived as an insufficient period of data exclusivity. The 13 medicines covered several therapeutic areas, including those on the Australian Government's Health Priority List such as mental health, neurology, oncology and infectious diseases.

Medicines Australia's Data Exclusivity Taskforce has worked to develop Medicines Australia's position on data exclusivity and identify the reasons for extending it.

Extending data exclusivity in Australia will:

- bring the Australian intellectual property system in line with leading OECD nations;
- improve Australia's attractiveness as a destination for foreign investment by global biopharmaceutical companies;
- support the local biotechnology sector, which has only recently begun entering the international market;
- encourage companies to bring new medicines to Australia, and in doing so ensure that Australian patients continue to have access to as many treatment options as possible; and
- reduce reliance on patent protection, which involves expensive litigation and which, in any event, will become increasingly unreliable in preventing the premature market entry of generic biological medicines.

TRIPS Protocol

In March 2011, the Federal Government announced its intention to implement measures consistent with the principles of the Doha Declaration on the TRIPS Agreement and Public Health (TRIPS Protocol). Under the proposed system, the Federal Government will be able to issue compulsory licenses for the manufacture and export of generic copies of patented medicines to the world's least developed countries should they face specific and prolonged health emergencies. This internationally accepted system is being progressively implemented around the world. It has already been implemented in Canada and the European Union.

Medicines Australia supports the implementation in Australia of the TRIPS Protocol. In a submission to IP Australia in July 2010, we said we would welcome the introduction of laws that would make it easier for Australian companies to play a major role in addressing sudden and prolonged health crises in the world's least developed countries. Medicines Australia's principal recommendation to IP Australia was that the authority to issue and amend compulsory licenses under the new system should be vested in the Federal Court of Australia rather than the Commissioner of Patents as originally proposed. We also recommended strict safeguards such as distinctive packaging and labelling requirements to prevent redirection of exported medicines to other markets. Both these recommendations were reflected in the Government's announcement in March as well as in the drafting instructions given to IP Australia.

To date, specific legislation to implement the TRIPS Protocol has not been introduced in Parliament.

KEY ISSUES



Chairman Will Delaat cuts a ceremonial cake at the celebratory dinner to mark the 50th anniversary of the Code of Conduct. Left to right: Brian Stafford (CHF), Tricia Greenway (CHF), Russell Edwards (Code Monitoring Committee), Mike Wyer (Code Monitoring Committee), Robyn Napier (AMA), Bernard O'Shea (Code and Appeals Committees), Sophie Hibburd (Medicines Australia), John Kelly (Code and Appeals Committees), Mike Daniel (Code and Appeals Committees), Will Delaat and Deborah Monk (Medicines Australia).

Celebrating 50 years of the Code of Conduct

The Medicines Australia Code of Conduct 16th edition was implemented in January 2010. During 2010-11 our members have continued to demonstrate a strong commitment to maintaining high standards of ethical conduct in all their interactions with health professionals, consumers and other stakeholders.

Principles of Ethical Conduct

In late June 2010 the then Parliamentary Secretary for Health, Mark Butler issued the Government's Position Paper on the Promotion of Therapeutic Goods. This paper challenged the therapeutic goods industry to strengthen and standardise its self-regulation by developing consistent industry Codes incorporating high-level principles for promotion, both to health professionals and consumers where this is permitted under the therapeutic goods legislation.

A Working Group was established by the Parliamentary Secretary to develop those principles and consider mechanisms to ensure a level playing field across all companies that supply therapeutic goods in Australia, and particularly between members and non-members of industry associations.

Medicines Australia chief executive Dr Brendan Shaw represented Medicines Australia on the Working Group, which was chaired by Anne Trimmer, chief executive of the Medical Technology Association of Australia. The Working Group included representatives for consumers, pharmacists, doctors, specialist physicians, nurses, and all sectors of the therapeutic products industry (OTC and complementary medicines, medical devices and diagnostics).

The Working Group's Report was submitted to the new Parliamentary Secretary for Health, Catherine King on 18 March 2011. The Government is expected to respond to the report in the second half of 2011 along with its response to a separate consultation on regulation of therapeutic goods advertising. This latter consultation was primarily concerned with products that may be advertised directly to consumers, and therefore was not directly relevant to prescription medicines.

It is Medicines Australia's intention to incorporate the Working Group's recommendations into the Medicines Australia Code of Conduct in the next edition of the Code. Medicines Australia anticipates that only minor changes will be required to its Code of Conduct.

Fifty Years of Self-Regulation

In October 1960 the first edition of the Code of Conduct was adopted by the then Australian Association of the Ethical Pharmaceutical Industry. On 26 October 2010 more than 200 guests gathered for a celebratory dinner in Sydney to mark the 50th anniversary of the Medicines Australia Code of Conduct.

Medicines Australia chairman Will Delaat noted that the one constant in a fast-changing industry over the last 50 years has been its collective commitment to upholding a high standard of ethical conduct in engaging with health professionals, consumers and other stakeholders.

"Fifty years ago the association recognised that if we were going to be successful as an industry and earn the trust of the people that we were communicating and negotiating with in government, we had to behave as an ethical and responsible industry that upheld high standards for the promotion of our products," Mr Delaat said.

PricewaterhouseCoopers partner Mike Daniel, one of the Code of Conduct Committee chairs, recalled some of the more quixotic provisions of the first Code of Conduct that now stands rather at odds with the current approach to transparency and independence of the complaint handling processes. Mr Daniel encouraged continued 'glasnost' by Medicines Australia and challenged the generic medicines sector to require equal standards of its members.

Other highlights of the celebration were a live performance by indigenous health champion and musician Jimmy Little and a ceremonial cutting of a 50th birthday cake.

The cycle of review and revision of the Code doesn't stand still and at the end of June 2011 plans were well advanced to begin the next review of the Code, leading to a new edition planned for January 2013.

Educational Event Reports

Member companies continued to report all educational meetings and symposia that they organise or sponsor. These reports are published every six months on the Medicines Australia [website](#). Companies have consistently demonstrated a high level of compliance with the Code and ongoing commitment to improved transparency of these interactions with healthcare professionals, which deliver and support valuable education about the treatments available to Australians.

In December 2010 and June 2011 Medicines Australia published educational event reports for the periods April - September 2010 and October 2010 - March 2011 respectively. There were almost 17,000 events reported for April - September 2010 and almost 14,000 events reported for October 2010 - March 2011. The lower number of

events in this period most likely reflects the fact that it covers the December-January holiday period.

In June, the Monitoring Committee was completing its review of three randomly selected months from the last 12 months of reports. Outcomes of this review will be published in the next Code of Conduct Quarterly Report.

Reporting educational events is now standard good business practice for Medicines Australia member companies. We are pleased to see that during the last year Generic Medicines Industry Association members also started reporting the events that they organise or sponsor for health professionals, as required under the GMiA's Code of Practice.

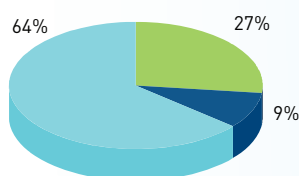
How we performed

In 2010-11 member companies have maintained a high level of compliance with the Code.

During the year 14 new complaints were received, which is a decrease from 2009-10 when 39 complaints were submitted to Medicines Australia. Six of the new complaints received this year were from pharmaceutical companies, with the balance from healthcare professionals (four complaints), members of the public (two complaints) and the Monitoring Committee (two complaints). Of the new complaints received, 11 were finalised by 30 June 2011. Of the finalised complaints, seven were found not in breach of the Code and four were found to be in breach in relation to some or all of the alleged breaches. Details of the complaints considered and finalised in 2010-11 and the outcomes are reported in the [Code of Conduct Annual Report](#), which is published on the Medicines Australia website.

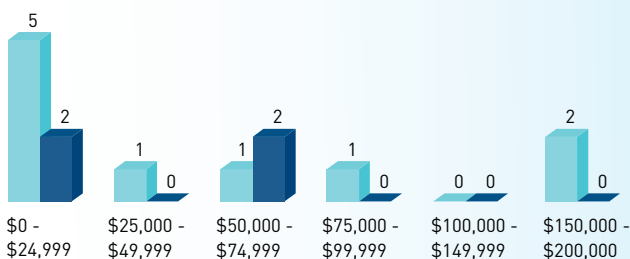
The Monitoring Committee undertook a substantial number of reviews of company promotional materials and other activities during the year. In 2010-11 the Monitoring Committee undertook seven reviews of materials associated with particular therapeutic areas as well as reviews of company controlled websites, prescribing software communications and market research with health professionals. The review of market research was particularly extensive, taking three meetings of the Committee to complete its examination of materials and responses from companies to questions raised by the Committee.

Code of Conduct Performance in 2010-11: a snapshot



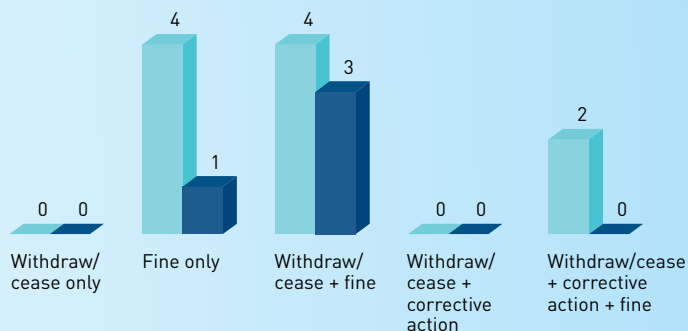
Outcomes of complaints received and finalised in 2010-2011

- Where no aspects of a complaint were found to be in breach N = 7
- Where all aspects of a complaint were found to be in breach N = 1
- Where some aspects of a complaint were found to be in breach N = 3



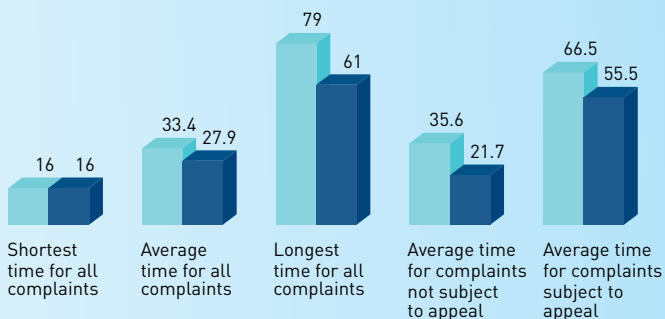
Fines imposed by the Code and Appeals Committee on companies

- Complaints received in 2009-2010 and finalised in 2010-2011
- Complaints received and finalised in 2010-2011



Sanctions imposed by the Code and Appeals Committees on companies

- Complaints received in 2009-2010 and finalised in 2010-2011
- Complaints received and finalised in 2010-2011



Length of time (in days) to resolve all finalised complaints

- Complaints received in 2009-2010 and finalised in 2010-2011
- Complaints received and finalised in 2010-2011

KEY ISSUES

Introducing The Australian Medicines Industry brand



- *Driven by discovery*
- *Supporting Australian science*
- *Delivering Australian clinical trials*
- *Acting with integrity*
- *Committed to Australia*

This year Medicines Australia finalised the development of a new industry brand to help better inform the Australian public about our industry and what we contribute to the health and wealth of the nation.

The name [The Australian Medicines Industry](#) was chosen. Our brand promise is:

- We deliver and support innovative medicines and vaccines that all Australians need to live healthier, longer and more fulfilling lives.

A network of industry brand champions collaborated with the Image Strategic Committee and the Medicines Australia secretariat to successfully launch the new brand within our industry from 20 May 2010. Medicines Australia member companies were provided with copies of an introductory DVD, an eight-page brochure about The Australian Medicines Industry and a lapel pin that employees can wear with pride as industry ambassadors. An electronic brand resource intranet was developed to

house artwork, guidance on brand use and briefing materials. Many member companies enthusiastically briefed their employees over town hall and cycle meetings, 'munch & learns' and other gatherings. Other sectoral stakeholders were also briefed on the brand.

The Australian Medicines Industry brand will be the collective face of the industry for the general public. Real life people from industry have stepped forward to share their stories and help start our public conversation from 30 July 2011.

All member company employees are encouraged to play a proactive role in improving the understanding of The Australian Medicines Industry among the general public.

A range of initiatives have been put in place to measure progress and success of the industry brand endeavour. However, we are confident that when the rest of Australia gets to know and understand us, they too will be proud of the work we do.



sanofi-aventis managing director Jean Monin and brand champion Claire Russell launch the industry brand to their company colleagues. Many companies held similar launches from May to July.



THE
australian
medicines
INDUSTRY
Supporting Australia's health

Some of the Faces of The Australian Medicines Industry.

Key Events Diary

JULY 2010

- Medicines Australia made a submission to IP Australia on the implementation in Australia of measures consistent with the principles of the Doha Declaration on the Trade-Related Aspects of IP Rights (TRIPS) Agreement and Public Health.

AUGUST

- The Medicines Australia Board determined strategic priorities for 2010-11, and a five-year outlook, at its annual strategic retreat.
- Medicines Australia made a [submission](#) to the Senate Community Affairs Legislation Committee's inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*.
- Medicines Australia launched the Australian medicines industry's election priorities document titled [Medicines and the 2010 Federal election: Supporting Australia's health](#).
- Newspoll chief executive Martin O'Shannessy spoke at a Medicines Australia managing directors dinner.
- The Medicines Australia Vaccines Industry Group sponsored a plenary session titled *New vaccines – review of the latest developments* at the National Immunisation Conference.
- The Senate Community Affairs Committee concluded its inquiry into gene patents without issuing a report or making recommendations.
- Medicines Australia made a [submission](#) to the Australian Competition and Consumer Commission responding to the draft determination on the authorisation of the Generic Medicines Industry Association Code of Practice.

SEPTEMBER

- A briefing was held for managing directors on Medicines Australia's key strategic priorities.
- Medicines Australia held member briefings on the Federal Election result and implications for industry.
- Medicines Australia's chairman Will Delaat addressed the ARCS Scientific Congress on biosimilars medicines, TGA/PBAC parallel processing and the managed entry scheme.
- The Medicines Australia-Pharmaceutical Benefits Advisory Committee held its annual meeting to discuss PBAC processes.
- Medicines Australia chief executive Brendan Shaw attended the TGA Industry Consultative Committee meeting. Discussion included: improved management of product recalls, the business outlook for industry and consumers, and TGA business process reforms.
- Brendan Shaw was guest speaker at the PRIME awards where he spoke about the value of industry to health and the economy.
- The 43rd Parliament sat for the first time.
- The *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, which gave effect to the savings for the Government embodied in the MoU between Medicines Australia and the Commonwealth, and the *Tax Laws Amendment (Research and Development) Bill 2010*, which enables the new R&D tax credit system, were both reintroduced to Parliament.
- Medicines Australia and AusBiotech wrote to the Minister for Foreign Affairs and other ministers encouraging the Government to maintain their opposition to any proposals that would undermine the balance of rights and obligations under the Trade-Related Aspects of IP Rights (TRIPS) amendment.

OCTOBER

- The *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, implementing legislative aspects of the MoU, was passed in the House of Representatives.
- The Pharmaceuticals Industry Council finalised its priorities for the next five years.
- Brand champions were identified from Medicines Australia member companies to drive the introduction of a new industry brand within their organisations.
- The Medicines Australia Annual General Meeting took place in Sydney.
- Approximately 200 delegates attended Medicines Australia's industry conference, *Stepping Out – Stepping Up*, in Sydney. Highlights included lively discussions on consumer engagement, R&D and manufacturing, and a hypothetical panel discussion on the Code of Conduct. The Code of Conduct celebrated 50 years of self-regulation at the conference dinner.
- Will Delaat presented the 2010 Pat Clear Award to Janssen executive Dell Kingsford Smith for her contribution to industry in the areas of health technology assessment and PBAC consumer engagement.

NOVEMBER

- Medicines Australia and several member companies appeared before the Senate Community Affairs Legislation Committee inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* to give evidence on savings measures in the MoU.
- The second edition of the [Medicines Australia Facts Book](#) was released. It included chapters on industry and the Australian economy, industry and Australia's health, the PBS, and a snapshot of global industry.
- Brendan Shaw gave a speech titled [Sustaining the PBS for the Future](#) at the Future of Medicare conference.
- Medicines Australia promoted the Code of Conduct and industry's commitment to ethical relationships at the GP Conference and Exhibition in Melbourne.
- The Health Consumer Organisation Working Group held a workshop for members on successfully partnering with patient groups and health charities.

- The *National Health Amendment (Pharmaceutical Benefit Scheme) Bill 2010* was passed by Parliament with some separate provisions requested by the Senate relating to reporting and transparency.
- The *Tax Laws Amendment (Research and Development) Bill 2010*, which enables the new R&D tax credit system, passed the House of Representatives.
- Will Delaat delivered a National Press Club address titled [The medicines industry and a healthier Australia](#) to a live audience of over 300 and television audience of 300,000.

DECEMBER

- Medicines Australia hosted member briefings on the industry brand project.
- The Senate Community Affairs References Committee reported on its inquiry into gene patents and did not recommend amendment of the Act to prohibit patenting of genes. A private members Bill was simultaneously introduced, calling for an amendment to the Patents Act to prohibit patenting of biological materials. The Bill was referred to the Legal and Constitutional Affairs Committee.
- The first National Press Club Health Forum was broadcast live on ABC television. Four panellists, including Brendan Shaw, debated the question *Healthy Ageing: At What Cost?*
- Brendan Shaw presented freelance writer Emma Young with the [Health Journalist of the Year Award](#) at the National Press Club for her article in *Cosmos* magazine titled *Learning to Forget*.
- Medicines Australia attended the National Immunisation Strategy Stakeholders Forum which considered initiatives in immunisation and vaccine preventable disease surveillance at the national level.
- Medicines Australia attended a meeting of the Government's newly reconvened Price Disclosure Working Group to progress implementation of the provisions of the MoU related to price disclosure.

JANUARY

- Medicines Australia contributed \$100,000 to the Queensland Flood Relief Appeal. Over the next few months, member companies would contribute over \$1.7 million to the Queensland and Victoria flood appeals.
- Medicines Australia presented at the PhRMA Asia Managers Annual Conference in Singapore. The Australian industry received an award from its overseas counterparts for the MoU as an example of constructive engagement with government.

FEBRUARY

- Medicines Australia conducted industry information sessions in Sydney and Melbourne on the risks and benefits associated with the implementation of the PBS managed entry scheme and TGA/PBAC parallel processing arrangements contained in the MoU.
- Medicines Australia managing directors were briefed on progress in implementing Medicines Australia's key priorities.
- Medicines Australia met with the Therapeutic Goods Administration for the annual bilateral meeting to discuss fees and charges for 2011-12.
- Brendan Shaw addressed the Research Australia NSW Policy Forum on key issues affecting medical research in Australia.
- The *Patent Amendment (Human Genes and Biological Materials) Bill* was introduced into the House of Representatives.
- Medicines Australia made a [submission](#) to the Senate Legal and Constitutional Affairs Committee on the *Patent Amendment (Human Genes and Biological Materials) Bill*.
- The Minister for Health and Ageing announced that Federal Cabinet had deferred listing of eight new medicines and vaccines on the PBS and that all future listings would require Cabinet approval, effectively removing the \$10 million threshold for Cabinet consideration of listings.

MARCH

- Brendan Shaw and several Board members met with the Minister for Health and Ageing to argue against the Federal Government's decision to defer listing of a number of medicines on the PBS.
- Eighty member company representatives attended a Medicines Australia member briefing session on the political outlook for 2011, patenting of human genes and biological materials and Medicine Australia's key strategic priorities for 2011.
- Over 200 guests from industry, Parliament, and the wider health sector attended Medicines Australia's parliamentary dinner. The Minister for Innovation Kim Carr gave the [opening address](#). The [keynote address](#) was given by the Director-General of the United Nations World Intellectual Property Organization, Dr Francis Gurry.
- An open letter signed by Medicines Australia, Research Australia, AusBiotech and others was sent to the Australian Parliament arguing the need for Federal Government to maintain current levels of funding for medical research in the May Budget.
- Fifteen member company sales representatives received awards for high achievement at the Medicines Australia Continuing Education Program Awards dinner.
- Will Delaat gave an annual State of the Industry Symposium address at the Pharmacy Guild APP Conference.
- Brendan Shaw represented industry at the biannual TGA Industry Consultative Committee meeting. Items discussed included transparency, TGA budget forecasts, and fees and charges.

APRIL

- Brendan Shaw represented the International Federation of Pharmaceutical Manufacturers and Associations at the World Medical Association Council meeting in Sydney.
- Medicines Australia made a [submission](#) to IP Australia on the *Patent Laws Amendment (Raising the Bar) Bill* 2011.
- Medicines Australia appeared before the Senate Legal and Constitutional Affairs Committee to speak about the *Patent Amendment (Human Genes and Biological Materials) Bill* 2010. The industry representatives argued against banning patents on biological materials, stating that such a ban would have greater consequences than the Bill's supporters anticipated.
- Brendan Shaw represented industry at a Roundtable Discussion with the Minister for Health and Ageing to discuss the Cabinet deferrals issue. Other groups represented at the Roundtable included the Consumers Health Forum, the Australian Medical Association, the Generic Medicines Industry Association and a number of patient organisations.
- Rollout to industry of [The Australian Medicines Industry](#) brand began. Medicines Australia provided a briefing on the brand launch to member company managing directors and brand champions. Member companies undertook a variety of internal brand launch activities.
- Liberal Senator Guy Barnett put forward a motion in the Senate deploring the Government's policy of Cabinet consideration of medicines for PBS listing and arguing that evaluation of medicines should be "transparent, evidence-based and not subject to capricious political interference". A mirror of Senator Barnett's motion was put forward in the House of Representatives by Liberal MP Judi Moylan.
- Will Delaat and Brendan Shaw met with a number of health sector industry associations to brief them on The Australian Medicines Industry brand launch.

JUNE 2011

MAY

- Will Delaat, Brendan Shaw and several member company managing directors represented the medicines industry at the Pharmaceutical Industry Working Group meeting, chaired by the Ministers for Health and Innovation. Discussion included the state of the industry, Cabinet deferrals, Clinical Trials Action Group reforms, the R&D tax credit, MoU initiatives and TGA regulatory reforms.
- Brendan Shaw [addressed](#) the Future of the PBS conference and discussed the lack of evidence-based decision-making by the Government in relation to PBS costs and listings.
- The 2011-12 Federal Budget contained no price-related savings to the PBS, as per the MoU. Industry also received important support from the Opposition on the Cabinet deferrals issue with the Leader of the Opposition stating in his Budget reply that the PBS should not be turned from a "demand-driven to a budget-limited scheme".
- Medicines Australia attended the first meeting of the Biologics Working Group, established by the Government to advance policy discussions on regulatory and reimbursement issues related to biologics and biosimilars.
- The Treasurer and the Minister for Innovation announced that the Government had the support of the Greens to pass the R&D tax credit. The Senate was expected to pass the Bill in August 2011.
- Parliament passed a motion that the listing of new medicines on the PBS should not be "subject to capricious political interference".
- The Senate passed an Opposition motion directing the Finance and Public Administration References Committee to inquire into the administration of the PBS with particular reference to the Cabinet deferrals.

Conferences and Events



- 1 Chief executive Brendan Shaw kicks off the industry conference.
- 2 Chairman Will Delaat chats with PhRMA vice-president Chris Singer.
- 3 Journalist Peter Roberts, Warwick Anderson from NHMRC and CSL executive vice-president Jeff Davies in discussion.

- 4 Delegates unwind after the first day of the industry conference.
- 5 Chairman Will Delaat addresses the National Press Club.
- 6 Chief executive Brendan Shaw makes a point during the first National Press Club Health Forum.

Medicines Australia Industry Conference

The Medicines Australia Industry Conference held in Sydney in October was voted by member companies as 'the best yet'. Over 250 representatives from member companies attended the conference, as well as delegates from health consumer organisations, the public sector, PR agencies and other organisations.

The theme of the conference was *Stepping Out – Stepping Up! Embrace the challenges and opportunities for the future*. In his keynote speech, PhRMA vice-president Chris Singer spoke about healthcare reform in the United States, the global dynamics of the pharmaceutical industry and their implications for Australia. Another highlight of the conference was the degree of community involvement with many consumers asking questions and representatives of consumer organisations participating in panel discussions. The next biennial conference is scheduled for 2012.

The Chairman's National Press Club Address

Medicines Australia chairman Will Delaat [addressed](#) the National Press Club on 17 November, using the occasion to articulate the benefits of the Memorandum of Understanding for the PBS.

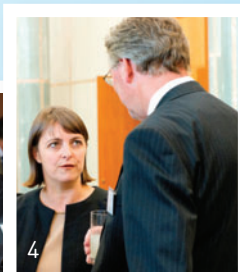
Mr Delaat's address, titled *The medicines industry and a healthier Australia*, also set out a four-point plan for the industry. The plan included implementing the R&D tax credit system, ensuring a more efficient regulatory regime for clinical trials, bringing data exclusivity provisions into line with world standards and contributing to the debate about healthcare reform and an ageing population.

The address was watched by a live audience of over 300 and television audience of 300,000.

National Press Club Health Forum

Chief executive Brendan Shaw was one of four panellists who took part in the first National Press Club Health Forum on 8 December. The Forum, broadcast live on ABC television, debated the question *Healthy ageing – at what cost?*

Other panellists were the renowned demographer Bernard Salt, AMA President Dr Andrew Pesce, and Chair of the Sydney University School of Health Economics, Professor Deborah Schofield. The stimulating discussion highlighted the rapidly growing number of retirees in Australia and high consumer expectations about their health and lifestyle. Implications for government budgets and the health system were discussed, along with the role innovative medicines and other health technologies will play in ensuring Australia's ageing population remains healthy and productive.



- 1 Chairman Will Delaat welcomes guests to the Medicines Australia parliamentary dinner.
- 2 Director-General of the World Intellectual Property Organization, Francis Gurry, gives the keynote address.
- 3 Will Delaat, Minister for Innovation Kim Carr and chief executive Brendan Shaw listen to Francis Gurry's speech.

- 4 Will Delaat chats with Health Minister Nicola Roxon at pre-dinner drinks.
- 5 Guests fill the Great Hall at Parliament House for the Medicines Australia parliamentary dinner.

Medicines Australia Parliamentary Dinner

More than 240 guests from industry, Parliament, Government and the broader healthcare sector gathered in the Great Hall at Parliament House in March for the 2011 Medicines Australia parliamentary dinner.

The theme of the evening was *Innovation for the Health of the Nation*, celebrating the achievements and highlighting the challenges of positioning Australia at the forefront of global pharmaceutical industry innovation and investment. Almost 30 Members of Parliament attended.

In his [introductory address](#), Minister for Innovation, Industry, Science and Research, Senator Kim Carr said the significant number of Members of Parliament at the dinner was "a measure of how importantly this Parliament regards this industry and its importance to the economy". Dr Francis Gurry, Director General of the United Nations World Intellectual Property Organization, provided the evening's [keynote address](#). Dr Gurry discussed the IP challenges facing the health sector, acknowledging both commercial realities and society's right to health. He said that finding the right balance between the two was particularly challenging.

The evening provided members and other guests with an opportunity to meet and discuss issues of importance to the industry.

Managing Directors Dinners

- Martin O'Shannessy, Newspoll chief executive, addressed managing directors on 18 August 2010 – just days before the 2010 Federal election. Mr O'Shannessy shared his views on political trends and the political environment in the lead up to election (as well as correctly predicting the result!). Newspoll is regularly published in *The Australian* newspaper and is one of Australia's leading political polling agencies.
- On 30 November and 1 December dinners were held in Sydney and Melbourne to update managing directors on The Australian Medicines Industry brand. These dinners also gave managing directors an opportunity to discuss other industry issues.

Awards



1 Medicines Australia chief executive Dr Brendan Shaw and Health Journalist of the Year Emma Young, at the National Press Club Health Journalism Awards.

2 Recipients of the 2010 Continuing Education Program Awards.

3 Pat Clear Award winner Dell Kingsford Smith, from Janssen.

2010 Pat Clear Award

The Pat Clear Award was established in 2002 to recognise the contribution Pat made to the medicines 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 medicines industry and the economic development of the industry in Australia. The award recognises similar levels of commitment by individuals, groups or teams to The Australian Medicines Industry.

In 2010 the award went to Janssen executive Dell Kingsford Smith. Dell received the award for her ongoing leadership of the industry's engagement with the Government on health technology assessment. She has been at the forefront of the industry's negotiations with the Department of Health and Ageing over the past five years that have led to improved transparency of the PBS listing process. Dell has been a tireless advocate for better assessment processes that enable Government to make more informed choices about the value of the medicines they subsidise. Medicines Australia Chairman Will Delaat presented Dell with the award at a celebratory dinner held in October to mark 50 years of the Code of Conduct.

Excellence in Health Journalism Awards

Medicines Australia is the principal sponsor of the National Press Club Excellence in [Health Journalism Awards](#). These awards 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. The prize for category winners is \$1000 in cash. The prize for the Health Journalist of the Year is \$1000 in cash and an international study tour.

In 2010 freelance writer Emma Young was named Health Journalist of the Year for her insightful report in *Cosmos* magazine titled *Learning to forget*. The report investigated the possibilities of altering specific memories to treat post-traumatic stress disorder. Other Award winners were:

- Best News Feature, Article or Presentation: Health, Health Sciences or Innovation; Emma Young (*Cosmos* magazine) for *Learning to Forget*.
- Best Documentary or Documentary Series: Health, Health Science or Innovation; Rebecca Le Tourneau and Rahni Sadler for the Sunday Night Seven Network program *The Vanishing*.
- Best Feature, Article or Presentation: Health Policy, Health Economics and Health Business; Mary Gearing for the ABC TV 7:30 Report program *e-health*.

- Best News Feature, Article or Presentation: Health, Health Science or Innovation directed to Medical Professionals; Stephen Pincock (*Australian Doctor*) for *Jumping through Hoops*.

Special Commendations went to:

- Frances Pratt (*Kalgoorlie Miner*) for *Lareia Needs Help*
- Roy Eccleston (*sawekend* magazine – *The Advertiser*) for *Inside Bob's Brain*
- Ben Jhoty (*Men's Health*) for *The Enemy Within*
- Paul Smith (*Australian Doctor*) for *V is for Vioxx*

Continuing Education Program Awards

Fifteen sales representatives from Medicines Australia member companies received the industry's top accolade for ethical sales and marketing at the Continuing Education Program Awards ceremony in Sydney on 7 March.

The CEP awards are presented annually to sales representatives who achieve maximum marks in their compulsory ethics education program.

The awards were presented by Australian Medical Association president Dr Andrew Pesce, Dr Harry Parekh from the University of Queensland's School of Pharmacy, and Janssen managing director Bruce Goodwin.

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:

- Colin Clarke (AstraZeneca)
- Deborah Motta-Marques (Allergan)

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:

- Paul Wilson (Janssen)

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).

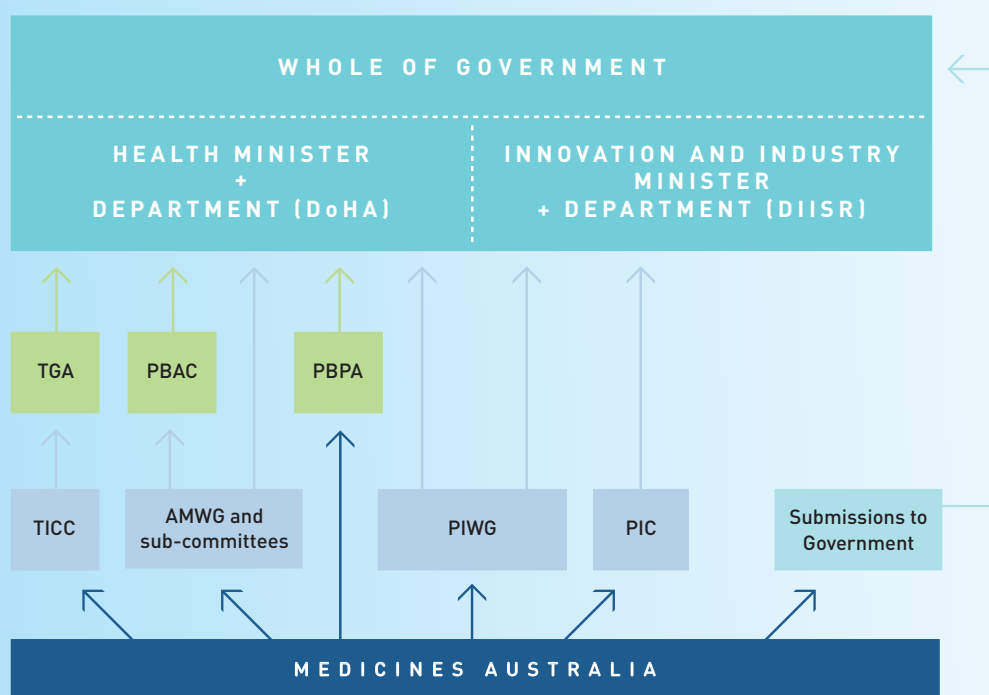
CEP Achievement Awards were presented to*:

- Amy Beamish (AstraZeneca)
- Laura Boyd (Invida)
- Leonie Brown (Boehringer Ingelheim)
- Colin Clarke (AstraZeneca)
- Eritsa Cook (Servier)
- Michelle Dyson (Pfizer)
- Jonathan Koch (AstraZeneca)
- Pearl-Li Chong (MSD)
- Matthew Lisle (Novo Nordisk)
- Timothy Ludlow (GlaxoSmithKline)
- Lindsay Prodea (GlaxoSmithKline)
- Emma Rohrlach (Invida)
- Catherine Spencer (Amgen)

*Award recipients' companies were current at the time of completion of CEP. Some award recipients may have 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.



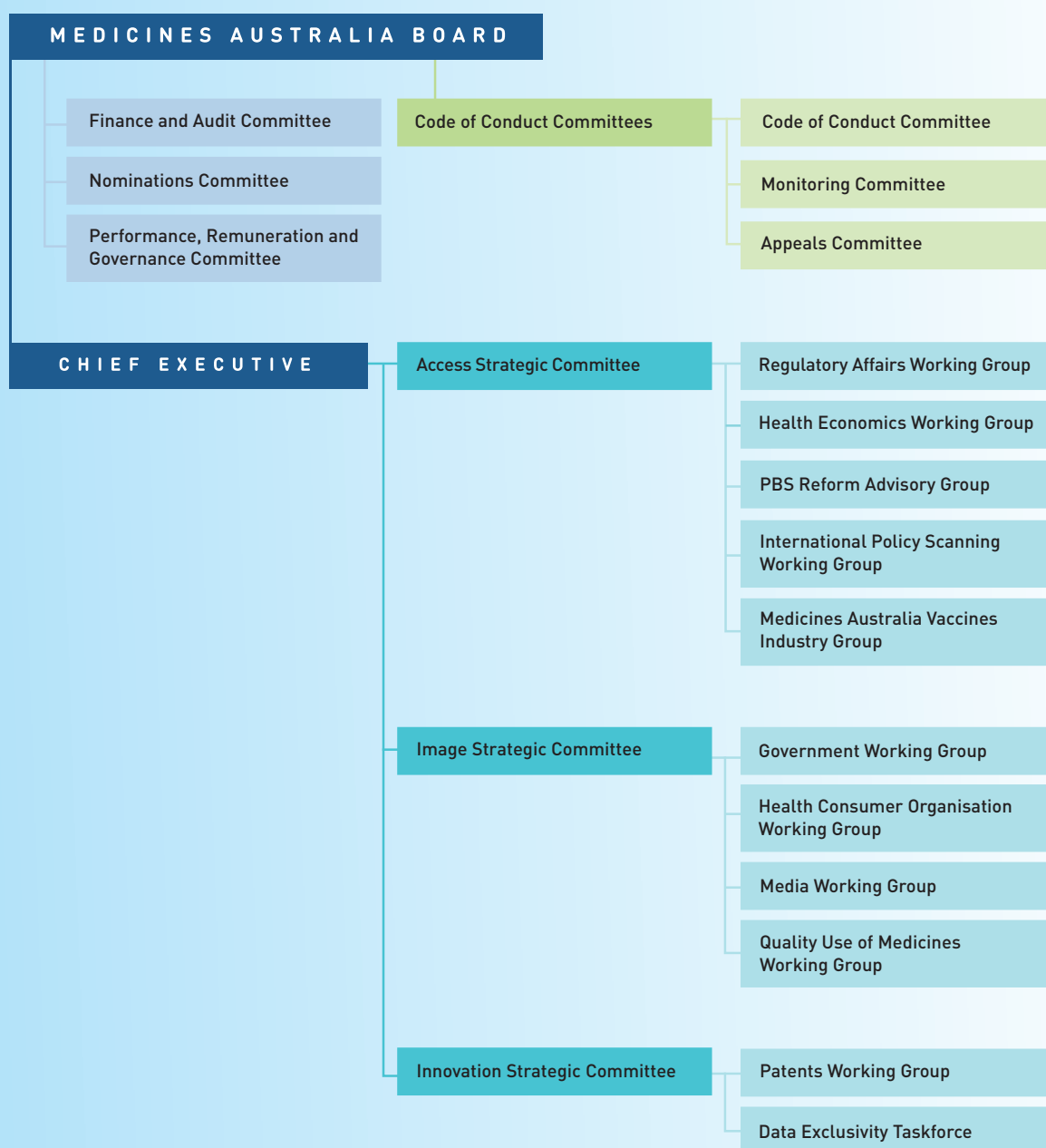
TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Access to Medicines Working Group (AMWG) and sub-groups	Provides strategic oversight of joint activities by Medicines Australia and DoHA to enhance PBS processes.	Will Delaat (Medicines Australia chairman), Brendan Shaw, Mendel Grobler (Pfizer), David Grainger (Eli Lilly), Ian Noble (Amgen), Andrew Bruce, Jim Crompton
Medicines Partnership of Australia (MPA)	A forum for dialogue across the whole medicines supply chain.	Will Delaat, Brendan Shaw Others by invitation (Elizabeth de Somer for labelling and packaging)
TGA Industry Consultative Committee (TICC)	Discusses 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, Jim Crompton (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, Jim Crompton
Drug Utilisation Sub-Committee of the PBAC (DUSC)	Collects and analyses information on drug utilisation patterns in Australia. They also contrast such information with observations internationally.	Jim Crompton
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 medications specific to the refugee and humanitarian entrant population.	Andrew Bruce
Palliative 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
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.	Ian Noble (Amgen), Richard de Abreu Lourenco (Covance), Jim Crompton
Annual Medical Oncology Group of Australia Drugs Roundtable Meeting	The annual roundtable held by the PBAC with the oncology specialist society.	Elizabeth de Somer, Jim Crompton

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Australian Commission on Safety and Quality in Healthcare (ACSQHC) —Medication Reference Group	Provides advice to ACSQHC on national strategies and priorities for medication safety and quality.	Elizabeth de Somer
TGA-Industry Working Group	Assists the 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 (Bristol-Myers Squibb), Duncan Purvis (Janssen), Helen Critchley (Abbott), Warren Back (MSD), Rory Graham (CSL), Elizabeth de Somer
TGA technical working groups (sterile TWG and non-sterile TWG)	Represents industry on manufacturing technical quality and standards groups.	David Peacock (Pfizer), Graham Garside (iNova)
TGA Transparency Review Panel	Reports to the Parliamentary Secretary for Health and Ageing on a review of TGA provision of information to the public.	Elizabeth de Somer
Precursor Chemicals Industry Reference Group	Provides industry advice on regulation of precursor chemicals that may be diverted for illicit use and organised crime.	Elizabeth de Somer
Generic Medicines Advisory Group	Provides industry advice on NPS generic medicines awareness campaigns.	Elizabeth de Somer
GS1 Australia – Healthcare Recall Portal Advisory Council	Provides industry advice on development of electronic medicines recall portal.	Elizabeth de Somer
Health Sector Group	Provides advice to its members and to the Federal Government in the areas of critical infrastructure resilience and interface with the public sector (such as supply chain and essential medicines).	Elizabeth de Somer (Chair)
Critical Infrastructure Advisory Council	Provides advice to the Attorney-General on nationally significant critical infrastructure issues (such as supply chain and essential medicines).	Elizabeth de Somer
National Prescribing Service RADAR Editorial 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 (PIWG)	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

TITLE OF COMMITTEE OR GROUP	PURPOSE	MEDICINES AUSTRALIA REPRESENTATION
Clinical Trials Action Group	Led by 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 Pantzer (AMGEN), Jeff Davies (CSL), Deborah Monk, Omar Ali Khan
Research & Development Taskforce	Develops strategies to improve the business environment for clinical research in Australia (working group of the Pharmaceuticals Industry Council).	Annette Jones (Boehringer Ingelheim), Kaylene O'Shea (Celgene), Carlo Maccarrone (GlaxoSmithKine), Mitch Kirkman (Novartis), Stefan Krug (AMGEN), Michael Daly (Bristol-Myers Squibb), Linda Nielsen (sanofi -aventis), Deborah Monk, Omar Ali Khan
Industry Development Taskforce	Develops strategies to improve the business environment for industry investment in R&D and manufacturing facilities in Australia (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. 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.



→ Committee and working group representative companies are current at 30 June. Some representatives may have since moved to other companies or roles outside industry.

Access Strategic Committee

KEY CAPABILITIES:

Provides high-level PBS policy, pricing, registration reimbursement, health economics, access and regulatory advice, undertakes discrete research projects and provides other assistance.

Has Working Groups on: Health Economics, International Policy Scanning, PBS Reform, Regulatory Affairs and Vaccines.

MEMBERS AT 30 JUNE 2011:

Michelle Burke	Bristol-Myers Squibb, Co-Chair
Andrew Bruce	Medicines Australia, Co-Chair
Ian Thompson	AMGEN, Board sponsor
José Vieira	AstraZeneca, Board sponsor
Deborah Waterhouse	GlaxoSmithKline, Board sponsor
Sue Alexander	Roche
Andrew Carter	Commercial Eyes
Louise Carter	GlaxoSmithKline
Rory Graham	CSL
Mendel Grobler	Pfizer
Nicol Kurstjens	Novartis
Sara Pantzer	AMGEN
Michael Rasmussen	Boehringer Ingelheim
Christian Sellars	MSD
Peter Vermeer	Eli Lilly
Charles Waterfield	AstraZeneca
Cammy Yuen	Abbott
Larissa Karpish	Medicines Australia

The following were also members for part of 2010-11:

Jez Moulding	sanofi-aventis, Board sponsor
David Garmon-Jones	Merck Serono
Dell Kingsford Smith	Janssen

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 AT 30 JUNE 2011:

Sue Alexander	Roche, Co-Chair
Elizabeth de Somer	Medicines Australia, Co-Chair
Mandy Cooke	GlaxoSmithKline
Helen Critchley	sanofi-aventis
Mary Flannery	Eli Lilly
Rory Graham	CSL
Brian Hewitt	Pfizer
Kirpal Kaur	Bristol-Myers Squibb
Sarah Lam	Baxter
George Lillis	Novartis
Anna Pohl	Boehringer Ingelheim
Duncan Purvis	Janssen
Mark Rowland	AMGEN
Elizabeth Thompson	Bayer
Tony Whittaker	Commercial Eyes

The following were also members for part of 2010-11:

Stuart Armsworth	sanofi-aventis
Warren Back	MSD
Andrew Notley	Gilead Sciences
Ivan Trofimov	Medicines Australia

HEALTH ECONOMICS WORKING GROUP (HEWG)

KEY CAPABILITIES:

Provides expertise on improving the registration and reimbursement requirements for pharmaceutical products, and generates information and resources to inform and influence stakeholders.

MEMBERS AT 30 JUNE 2011:

Greg Cook	Bristol-Myers Squibb, Co-Chair
Jim Crompton	Medicines Australia, Co-Chair
Alissa Brown	Pfizer
Mirella Daja	Novo Nordisk
Peter Germanos	Boehringer Ingelheim
Fernando Gonzalo	sanofi-aventis
Louise Graham	AMGEN
Gary Hamann	Servier
Grace Malanos	Roche
Andrew Manton	GlaxoSmithKline
Beth O'Leary	Covance
Delia Schaffer	Nycomed
Jodie Thomas	Eli Lilly
Alison Wright	Janssen
Cammy Yuen	Abbott

The following were also members for part of 2010-11:

Dell Kingsford Smith	Janssen, Co-Chair
Martin O'Rourke	Eli Lilly
Ian Noble	AMGEN
Sam Shirley	Medicines Australia
Ivan Trofimov	Medicines Australia

PBS REFORM ADVISORY GROUP (PRAG)

KEY CAPABILITIES:

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

MEMBERS AT 30 JUNE 2011:

Mendel Grobler	Pfizer, Co-Chair
Andrew Bruce	Medicines Australia, Co-Chair

Michelle Burke	Bristol-Myers Squibb
Greg Cook	Bristol-Myers Squibb
Steve Crowley	Janssen
David Grainger	Eli Lilly
David Herd	GlaxoSmithKline
Ian Noble	AMGEN
Christian Sellars	MSD
Mike Smith	AstraZeneca
Jim Crompton	Medicines Australia

The following were also members for part of 2010-11:

Michael Wonder	Novartis
----------------	----------

INTERNATIONAL POLICY SCANNING WORKING GROUP (IPSWG)

KEY CAPABILITIES:

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

MEMBERS AT 30 JUNE 2011:

Alissa Brown	Pfizer, Co-Chair
Amish Chaturvedi	Medicines Australia, Co-Chair
Lesley Chim	AstraZeneca
Michelle Frost	Allergan
Fernando Gonzalo	sanofi-aventis
Beth O'Leary	Covance
Susan Phillips	GlaxoSmithKline
Natalia Price	Abbott
Peter Dean Sharpe	Eli Lilly
Andrew Wheatley	Janssen
Kristin Trace	Medicines Australia

The following were also members for part of 2010-11:

Georgie Broadbent	Bristol-Myers Squibb
Geoffrey Chin	Novartis
Carolyn Winkler	Mundipharma
Sam Shirley	Medicines Australia

MEDICINES AUSTRALIA VACCINE 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 AT 30 JUNE 2011:

Lauren Conyer	Pfizer, Co-Chair
Elizabeth de Somer	Medicines Australia, Co-Chair
John Anderson	CSL
Christine Apostopoulos	Novartis
Louise Carter	GlaxoSmithKline
Helen Concilia	CSL
Brent MacGregor	sanofi-aventis
Glen Mason	sanofi-aventis
Sheryl Page	GlaxoSmithKline
Tony Shelton	Baxter
Scott Williams	Pfizer
Jodie Wilson	Abbott

The following were also members for part of 2010-11:

Caroline Pilot	Abbott
Edward Stauber	Novartis
Sam Shirley	Medicines Australia

Image Strategic Committee

KEY CAPABILITIES:

Provides reputation management, communication strategy, issues and crisis management, message formation and delivery, stakeholder management 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;
- harness some of the positive images associated with the broader health sector; and
- inform consumers about the benefits the industry provides for individuals, families, the community and the Australian economy.

MEMBERS AT 30 JUNE 2011:

Libby Keohane	Baxter, Co-Chair
Donna Edman	Medicines Australia, Co-Chair

John Latham	Pfizer, Board sponsor
Jane Orr	MSD, Board sponsor
Dean Phizacklea	Abbott, Board sponsor
Helen Craig	MSD
Lisa Maguire	GlaxoSmithKline
Glenn Montgomery	Merck Serono
Adam Roach	Janssen
Jude Tasker	Pfizer
Jackie Wilson	Abbott

The following were also members for part of 2010-11:

Tim McCormick	Biogen IDEC, Board sponsor
Jeremy Morgan	Eli Lilly, Board sponsor
José Vieira	AstraZeneca, Board sponsor
Karen Barfoot	Bristol-Myers Squibb
Alan Brindell	sanofi-aventis
Peter Murphy	Novartis

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 AT 30 JUNE 2011:

Sara Pantzer	AMGEN, Co-Chair
Andrew Simpson	Medicines Australia, Co-Chair
Karen Barfoot	Bristol-Myers Squibb
Rowena Cowan	sanofi-aventis
Helen Craig	MSD
Stuart Englund	Eli Lilly
Cameron Milliner	Abbott
Andrew Plumley	Pfizer
Kieran Schneemann	AstraZeneca
Todd Stephenson	Roche
Patrick Tung	Merck Serono

The following were also members for part of 2010-11:

Donna Edman	Medicines Australia, Co-Chair
David Miles	Pfizer
Tim James	Janssen
Michael Riley	Servier

HEALTH CONSUMER ORGANISATION WORKING GROUP (HCOWG)

KEY CAPABILITIES:

Provides expertise on issues relating to health consumer and patient groups, especially organisations which demonstrate a willingness to partner with industry and support issues of shared interest.

Provides advice on key principles in establishing successful HCO partnerships between the non-profit and commercial sectors.

CURRENT MEMBERS AS AT 30 JUNE 2011:

Neil Wildman	Pfizer, Co-Chair
Diana Terry	Medicines Australia, Co-Chair
Deborah Chan	Janssen
Zarli French	MSD
Holly Kania	Roche
Monique McLaughlin	AMGEN
Arli Miller	Eli Lilly
Peter Murphy	Novartis
Jennifer Stevenson	Abbott
Rebecca Willocks	sanofi-aventis

The following were also members for part of 2010-11:

Fiona Bailey	Eli Lilly
--------------	-----------

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.

CURRENT MEMBERS AS AT 30 JUNE 2011:

Libby Keohane	Baxter, Co-Chair
Jamie Nicholson	Medicines Australia, Co-Chair
Will Collie	sanofi-aventis
Adrian Dolahenty	Bayer
Lisa Julian	Eli Lilly
Lisa Maguire	GlaxoSmithKline
Loucineh Mardirossian	Abbott
Adam Roach	Janssen
Maida Talhami	MSD

The following were also members for part of 2010-11:

Michelle d'Heureux	Eli Lilly
Simone Prideaux	AstraZeneca

QUALITY USE OF MEDICINES WORKING GROUP

Reports to both the Access and Image Strategic Committees. The term of the Working Group runs to 30 September 2011, at which point its future will be reviewed by the Image Committee.

KEY CAPABILITIES:

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

MEMBERS AT 30 JUNE 2011:

Andrew Carter	Commercial Eyes, Co-Chair
Jude Tasker	Pfizer, Co-Chair
Helen Craig	MSD
Stephen Gray	sanofi-aventis
Malcolm Handel	Janssen
Kristin King	Baxter
Joyce Lloyd	Pretium
Lee McKerracher	Pfizer
Diana Terry	Medicines Australia
Cammy Yuen	Abbott
Elizabeth de Somer	Medicines Australia

The following were also members for part of 2010-11:

Ross Linsley	Merck Serono
--------------	--------------

Innovation Strategic Committee

KEY CAPABILITIES:

Develops and implements policy and program measures for continuing industry development, growth in investment in research and development, and protection of intellectual property.

MEMBERS AT 30 JUNE 2011:

Tim Murphy	GlaxoSmithKline, Co-chair
Deborah Monk	Medicines Australia, Co-chair
Graeme Blackman	IDT Australia, Board sponsor
Bruce Goodwin	Janssen, Board sponsor
Alex Condoleon	sanofi-aventis
Luke Cornish	MSD
Tim Donald	PricewaterhouseCoopers
Paul Dale	Eli Lilly
Simon Fisher	AstraZeneca
Bill Ketelbey	Pfizer
Joyce Lloyd	Pretium
Dieter Torheiden	Abbott
Omar Ali Khan	Medicines Australia

The following were also members for part of 2010-11:

Klaus Abel	Lundbeck, Board sponsor
Adrian Bootes	Roche
Candice Braithwaite	Pfizer
Ric Degaris	Kendle
Tim James	Janssen

PATENTS WORKING GROUP

KEY CAPABILITIES:

Designs and implements measures to ensure fair and balanced protection of intellectual property rights in Australia.

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

MEMBERS AT 30 JUNE 2011:

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

DATA EXCLUSIVITY TASKFORCE

KEY CAPABILITY:

Develops detailed arguments to support Medicines Australia's case for extending the term of data exclusivity in Australia.

Taskforce members (assigned task completed; taskforce disbanded May 2011):

Deborah Monk	Medicines Australia
Luke Cornish	MSD
Paul Dale	Eli Lilly
Tim James	Janssen
Omar Ali Khan	Medicines Australia

Working with the Community



- 1 Jimmy Little entertains the audience at the 2010 Medicines Australia Industry conference dinner.
- 2 Children participating in one of Uncle Jimmy's *Thumbs Up!* workshops.

Special Purpose Fund

MEDICINES AUSTRALIA SPECIAL PURPOSE FUND

Medicines Australia is funding a range of indigenous health initiatives through our [Special Purpose Fund](#).

Through our involvement with the Jimmy Little Foundation, the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation (WDNWPT) and the Shalom College at the University of New South Wales, Medicines Australia has been able to contribute a small way towards "closing the gap".

This is in response to the Minister for Health and Ageing, Nicola Roxon, who has indicated on a number of occasions a need to develop indigenous preventative health programs.

UNCLE JIMMY THUMBS UP!

Medicines Australia's support for the Jimmy Little Foundation is in the last six months of its commitment.

In addition to \$730,000 support for Uncle Jimmy *Thumbs Up!* during the past 18 months the secretariat has assisted the Foundation in project management. Medicines Australia member PricewaterhouseCoopers has provided *pro bono* services.

There have been a number of successes in the project, including support by the Northern Territory Department of Education to assist in the development of a school resource, the [Thumbs Up! website](#). In addition, the Federal Department of Health and Ageing has launched its own program, [Get Active! Eat Good Tucker! Live Longer!](#) Healthy Community Days, under the Local Indigenous Community Campaign to Promote Better Health, (the "Local Community Campaign") to support Aboriginal and Torres Strait Islander communities deliver healthy lifestyle messages. This program complements the work of the Jimmy Little Foundation.

A significant success of the *Thumbs Up!* project is its achievement in gaining a \$500,000 grant from the Federal Department of Health and Ageing Local Community Campaign.

A key objective for Medicines Australia was to provide funding to support innovation in indigenous health initiatives and, in the case of the Jimmy Little Foundation *Thumbs Up!* project, to demonstrate its value and effectiveness to attract further funding. That the project has been successful in attracting considerable Federal funding to continue beyond Medicines Australia's commitment is a significant success for Medicines Australia. The Board and our members can be proud of our contribution to advancing improvements in indigenous health.

MOBILE RENAL DIALYSIS UNIT

Medicines Australia has contributed \$360,000 to fund a mobile renal dialysis unit for the Western Desert communities near Alice Springs. Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation (WDNWPT) will be managing the ongoing operations of the mobile unit upon its completion.

Medicines Australia's partnership with WDNWPT is a direct response to the critical and expanding problem of the dislocation of senior Yanangu community members who, after being diagnosed with end-stage renal disease, are taken to Alice Springs for life-long dialysis treatment many hundreds of kilometres from family, community and traditional country. The impacts of this dislocation are devastating at a personal and community level with significant disruption to cultural practices and the passing on of knowledge to the next generation.

The mobile unit, due for completion in November 2011, has been meticulously designed to ensure its success as a mobile dialysis clinic in what will be a unique and tough environment. The build, being undertaken by contractors in Adelaide, includes several design features to take into account environmental and logistic issues.

SHALOM GAMARADA RESIDENTIAL SCHOLARSHIP

Medicines Australia is providing funding of \$150,000 over five years for two scholarships under [The Shalom College Residential Scholarship program](#) for indigenous students. The scholarship program is the result of collaboration between Shalom College, the Nura Gili Indigenous Programs at the University of New South Wales and the Muru Marri Indigenous Health Unit, School of Public Health and Community Medicines, University of New South Wales.

It began in 2005 for Aboriginal medical students studying at the University of New South Wales in response to poor learning opportunities for indigenous students. In 2006, the program broadened to include additional medical and optometry students and Australia now has its first indigenous optometrist.

Medicines Australia supported two medical students through the scholarship in 2010-11, Brendan Phillips and Laura Fitzgerald. Both Brendan and Laura are in their third year of medicine.

Working with Health Consumer Organisations

Medicines Australia supports a range of initiatives whose key focus is improving the health outcomes of Australians. This is primarily achieved through unique industry partnerships, formed in accordance with the [Working Together Guide](#), jointly developed by the Consumers Health Forum of Australia (CHF) 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.

Collaborative partnerships with health consumer organisations help us better understand issues of concern to patients; together we seek to address these in the best possible way. By building sustainable relationships, we also work towards advancing dialogue around healthcare issues and seek ways to ensure optimal delivery of healthcare.

The **Arthritis Australia Community Chest** is one example of a collaborative partnership between a health consumer organisation, Medicines Australia and a number of our members companies. The Community Chest, which originated in 2004, supports projects aimed at improving



Arthritis Australia chief executive Ainslie Cahill (left) and Consumers Health Forum chief executive Carol Bennett (right) speaking at the Medicines Australia Industry Conference in October 2010.

the health outcomes of Australians through evidence-based management of arthritis. This collaboration can lay claim to many achievements over that time, most recently [The Ignored Majority – The Voice of Arthritis 2011](#), a national survey to discover the impact of arthritis on Australians.

The **Heart Foundation Pharmaceutical Roundtable**, established in 2003, brings together member companies and the Heart Foundation to improve cardiovascular health by supporting research and other quality use of medicine projects.

A recent key achievement of the Roundtable has been the *Improving Cardiovascular Adherence* project to improve patient adherence to cardiovascular medicines and lifestyle interventions through the education of primary healthcare professionals. Ultimately this project seeks to improve the cardiovascular health of all Australians.

The **Mental Health Council of Australia Pharmaceutical Collaboration**, established in 2003, brings together member companies and the Mental Health Council to work on a number of projects directly related to quality use of medicines in the sector. These initiatives include an information portal for the Mental Health Council of Australia website, a tool for mental health professionals, and a consensus advocacy statement to identify the key high-level principles necessary to ensure that treatment reflects best practice and therefore better health outcomes for mental health consumers.

Medicines Australia places great value on its relationships with consumer organisations, in particular with the peak body the **Consumers Health Forum of Australia**.

Inside Medicines Australia



1 Members vote at the 2010 Annual General Meeting.



2–4 Medicines Australia secretariat staff members

Medicines Australia Member meetings

There was one meeting of members in the 2010–11 financial year. The Annual General Meeting was held on 26 October 2010 at Dockside, Cockle Bay Wharf, Sydney.

Medicines Australia Board meetings

27 July 2010, via teleconference
6 August 2010, Canberra (Board Retreat)
2 September 2010, via teleconference
7 September 2010, Deakin
23 September 2010, via teleconference
1 October 2010, via teleconference
26 October 2010, Sydney
7 December 2010, North Ryde
23 February 2011, Botany
25 February 2011, via teleconference
11 March 2011, via teleconference
31 March 2011, via teleconference
5 April 2011, Canberra (Board Retreat)
10 May 2011, Deakin (Federal Budget night)
13 May 2011, via teleconference
30 May 2011, via teleconference
24 June 2011, via teleconference

Committees of the Medicines Australia Board

FINANCE AND AUDIT COMMITTEE

The Finance and Audit Committee reviews the monthly financial statements of Medicines Australia Limited and provides advice and guidance on how finances are reported to the Board. It reviews the draft annual budget as developed by the secretariat and provides advice and guidance on how the annual budget is presented to the Board. It also reviews the audited annual financial statements and provides advice and guidance on how the annual financial statements are to be presented to the members at the Annual General Meeting.

The committee also has the oversight of the Medicines Australia Special Purpose Fund.

The committee is supported by chief executive Brendan Shaw, director of corporate services Katie Whitehead, and finance manager Di Phillips.

MEMBERS:

John Latham, Pfizer, Chair
Frederic Guerard, Novartis
Dean Phizacklea, Abbott (from October 2010)
Jeremy Morgan, Eli Lilly (until August 2010)

MEETINGS:

6 July 2010
31 August 2010
27 September 2010
24 November 2010
4 April 2011
21 April 2011

NOMINATIONS COMMITTEE

The Nominations Committee identifies and makes available for members in good time before elections the skill sets that are needed on the Board, what skill gaps need to be filled and the personal capabilities that are required for directors to make an effective contribution to the Board. The Committee identifies suitable people who might be nominated for the Board or its committees. It also ensures members are aware of the duties and responsibilities that will be taken on by directors, the time required to perform effectively and the range of legal liabilities applying to directors that all need to be borne in mind when nominating people for election to the Board. The nominations committee is supported by director of corporate services, Katie Whitehead.

MEMBERS:

Graeme Blackman, IDT, Chair
Deborah Waterhouse, GlaxoSmithKline

Meetings:

31 August 2010
3 September 2010
26 May 2011
15 June 2011

PERFORMANCE, REMUNERATION AND GOVERNANCE COMMITTEE

The Performance, Remuneration and Governance Committee monitors and evaluates Board performance including duties and responsibilities of directors, the time required to perform effectively and the range of legal liabilities applying to directors. It monitors and evaluates chair performance and where there is an appointed chair, makes recommendations on the appropriate level of remuneration. It is a consultative body for the chief executive on matters in which he seeks advice and guidance. The committee also monitors and evaluates chief executive performance and makes recommendations on the appropriate level of remuneration. It also approves the remuneration of senior managers who are direct reports to the chief executive.

The committee is supported by chief executive Brendan Shaw.

MEMBERS:

Will Delaat, Chair
John Latham, Pfizer (Chair of the Finance and Audit Committee)
Klaus Abel, Lundbeck

MEETINGS: 30 May 2011

Secretariat

A new position in the Image team of government relations manager was created in January 2010.

A policy officer position in the Access team was re-instated and re-named the access to medicines policy officer

(previously known as health economics officer). The position of policy coordination officer was removed.

During 2010-11 there have been a number of secretariat staff movements.

DEPARTING STAFF:

- Michael Fitzsimons
- Sue Elderton
- Helen Cox
- Joanne Toogood
- Janelle Andre-Morgan
- Sam Shirley
- Ivan Trofimov

NEW STAFF:

- Larissa Karpish
- Andrew Simpson
- Kristin Trace
- Julie Johnson
- Amna Khanzada

Communication with our members

Communication with our members is paramount. In response to member feedback, we have reviewed the effectiveness of our systems in communication to allow us to be proactive and responsive to member needs.

Medicines Australia launched a new [website](#) in March 2011. Stage one of the changes to our website focussed on the technical and structural framework and capability of the site. It has also included some modifications to the design to modernise how we present industry information to the general public. The changes to the public site include revising the layout of the page structure to align it with current IT trends and incorporating Web 2.0 technologies.

The new website provides important security and stability measures. This includes greater functionality and use of the members' only website, reducing the amount of information sent to members via email.

We have endeavoured to present a site that is practical, efficient and easy to reference. We are committed to the continued improvement and enhancement of our member communications.



Medicines Australia Publications

Publications and Reports

- **MA Media Report** (distributed to members by 8am each weekday)
- **MA Weekly** (every Friday)
- **MA Quarterly** (September/December 2010; March/June 2011)
- **Memos to members** (155 memos distributed to members during the financial year)
- **Medicines Matter:** (an information service for Health Consumer Organisations – September 2010; March 2011; June 2011)
- **Medicines Advocate** (Newsletter for Members of Parliament. December 2010 and April 2011)
- **Occasional Paper 2: Innovation for the Health of the Nation** (March 2011)
- **Medicines Australia Facts Book: Second Edition** (October 2010)
- **Code of Conduct Annual Report – 2010** (August 2010)
- **Report on the Outcomes of the Code of Conduct Monitoring Committee Review 2010** (August 2010)
- **Reports of Code of Conduct complaints relating to activities directed at the general public** (July 2010; 1 August 2010 – 31 March 2011; 1 April – 30 June 2011)
- **Code of Conduct Quarterly Reports** (July – September 2010; October – December 2010; January – March 2011; April – June 2011)
- **Code of Conduct Educational Event Reports** (1 April – 30 September 2010, published December 2010; 1 October 2010 – 30 March 2011, published June 2011)

Submissions

- June 2011 – Medicines Australia submission in response to the Department of Health and Ageing's Draft Concept of Operations for the introduction of the PCEHR system
- May 2011 – Pharmaceuticals Industry Council submission on PCEHR Draft Concept of Operations
- May 2011 – Question on Notice response to the Senate Legal and Constitutional Affairs Committee on the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*
- April 2011 – Medicines Australia submission to IP Australia on the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*
- February 2011 – Medicines Australia submission to the Senate Legal and Constitutional Affairs Committee on the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*
- August 2010 – Medicines Australia submission to the Senate Community Affairs Legislation Committee inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*
- August 2010 – Medicines Australia's policy priorities document for the 2010 Federal election
- July 2010 – Medicines Australia submission to IP Australia on the implementation of the TRIPS protocol

Index of Acronyms and Abbreviations

ACSQHC	Australian Commission on Safety and Quality in Healthcare	OECD	Organisation for Economic Co-operation and Development
AMA	Australian Medical Association	OTC	Over The Counter (medicines)
AMWG	Access to Medicines Working Group	PBAC	Pharmaceutical Benefits Advisory Committee
APP	Australian Pharmacy Professional	PBPA	Pharmaceutical Benefits Pricing Authority
ARCS	Association of Regulatory and Clinical Scientists	PBS	Pharmaceutical Benefits Scheme
CEP	Continuing Education Program	PCEHR	Personally Controlled Electronic Health Records
CHF	Consumers Health Forum of Australia	PhRMA	Pharmaceutical Research and Manufacturers of America
CMI	Consumer Medicine Information	PIC	Pharmaceuticals Industry Council
CMO	Chief Medical Officer	PIWG	Pharmaceuticals Industry Working Group
CTAG	Clinical Trials Action Group	PRAG	PBS Reform Advisory Group
DoHA	Department of Health and Ageing	QUM	Quality Use of Medicines
DUSC	Drug Utilisation Sub-Committee	QUMWG	Quality Use of Medicines Working Group
ESC	Economic Sub-Committee	RAWG	Regulatory Affairs Working Group
GMiA	Generic Medicines Industry Association	TGA	Therapeutic Goods Administration
GWG	Government Working Group	TICC	TGA Industry Consultative Committee
HCO	Health Consumer Organisation	TRIPS	Trade-Related Aspects of Intellectual Property
HCOWG	Health Consumer Organisation Working Group	UQ	University of Queensland
HEWG	Health Economics Working Group	WIPO	World Intellectual Property Organization
IP	Intellectual Property	WTO	World Trade Organization
IPSWG	International Policy Scanning Working Group		
MAVIG	Medicines Australia Vaccines Industry Group		
MWG	Media Working Group		
MoU	Memorandum of Understanding		
MTAA	Medical Technology Association of Australia		
NIP	National Immunisation Program		
NHMRC	National Health and Medical Research Council		
NPS	National Prescribing Service		