

# MEDICINES AUSTRALIA

ANNUAL REPORT 2012-13

MEDICINES  
*Australia*



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## 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

1. To be an industry role model and build unity and strength
2. To achieve a predictable and positive environment for the registration and reimbursement of medicines in Australia
3. The Australian Government to actively create a favourable environment for investment by the Pharmaceutical industry
4. Uphold and strengthen the reputation of the industry

## Chairman's Report

There is no doubt that 2012-13 was one of the more difficult years for Australia's medicines industry. The industry itself is facing major reductions in sales from unprecedented patent expiries, reductions in staff, ongoing rationalisation and continuing issues in developing new therapies and having them brought to market.

The industry also faced a range of unwelcome challenges from Federal Government policy through the year, including a more difficult reimbursement environment, changed and more challenging requirements from the Pharmaceutical Benefits Advisory Committee, the ramping up of Government PBS post-market reviews as a cost saving exercise rather than one based on health outcomes, and a range of mooted changes to patent law, including a major review of pharmaceutical patents sprung on the industry with no prior consultation or rationale provided. The industry also had to face growing calls for it to be more transparent about its relations with health care professionals and respond to a proposal from the Australian Greens to impose significant additional regulations on the industry to achieve this.

I took over the role as interim Chair of Medicines Australia in February 2013 after former Chair, Mark Masterson, stepped down from the role to pursue new business opportunities. Mark represented the industry at the political level by engaging substantially with the Government, Opposition and the Greens, engaged with Government departments on key issues and gave an important televised address to the National Press Club in December 2012. Mark also played an important role in chairing the Medicines Australia Board and helped provide some continuity through what was a period of significant turnover in Board personnel. I'd like to take this opportunity to acknowledge Mark's contribution through a significant portion of 2012-13 as Chair and wish him well in his future endeavours.

Since taking on the role as Chair until a permanent Chair could be identified and appointed, I have worked closely with the Medicines Australia Board to set a direction for the association that focusses on the key priorities for the industry. Together the Board has worked to adopt a more flexible and dynamic approach to issues by restructuring the strategic plan, the organisation and the committee structure to ensure the organisation is better placed for the future.

In terms of policy issues the Board has made numerous vigorous representations to the Government on industry's increasing frustration with the PBS listing process and changes in Government policy, developed strategy on a possible future agreement with government on expiry of the Medicines Australia-Government Memorandum of Understanding next year, publicly advocated the value of innovation and the industry, and led the debate on transparency between companies and health care professionals.

The Board has also been heavily engaged with representing the industry to all political parties in the lead up to the Federal Election in September 2013 and campaigned vigorously for the industry in these discussions. The industry was successful in gaining a number of commitments from the Coalition during the course of the campaign. These include restoring the PBS process to a stable, apolitical, evidence based approach, returning the independence of the PBAC and recognising its recommendations, increasing the threshold for new medicines requiring Cabinet approval to \$20m in any one year, and accelerating clinical trials reform. Their health policy document quotes extensively from the Medicines Australia election document, being long term issues that Medicines Australia has been steadily progressing over the years, so to see the incoming Government commit to these is particularly encouraging. In addition, the Coalition Government has committed to several measures to boost manufacturing industries, including the announcement of Strategic Growth Action Agendas. The Board will continue to impress upon the Government the importance of implementing the commitments they have made.

Towards the end of the financial year the Board announced that it will appoint Dr Martin Cross as the new Chair of Medicines Australia from November 2013. Martin will bring a lot of passion, enthusiasm, experience and knowledge to the role and I am sure he will use his numerous talents to passionately advocate on behalf of Medicines Australia's member companies going forward.

It has been an honour to be appointed as Chair of Medicines Australia during this period and I have enjoyed the privilege of working closely with my fellow Board members who have been very supportive. The Board has worked very well together as a team to help drive the industry's agenda forward and for that I thank them.

I also acknowledge the work of the Medicines Australia Secretariat staff who put in a lot of time, effort and hard work on behalf of all the members of Medicines Australia. Working as the secretariat of an industry association is never easy, particularly at a time such as this where the industry is undergoing such change, and I thank them for their endeavours through 2012-13.



**Mark Fladrich**  
INTERIM CHAIR



## Chief Executive's Report

This year has been challenging for Medicines Australia and its member companies.

The industry faced a difficult operating environment through 2012-13. Increasing stringency in the process for listing new medicines on the Pharmaceutical Benefits Scheme, the ramping up of retrospective post-market reviews of medicines on the PBS, and ongoing price reductions brought about by price disclosure policies all imposed severe operating conditions on the industry. While the Memorandum of Understanding with the Government on the management of the PBS continued, a number of issues grew around the MoU to make the operating environment more difficult for industry. Increasing frustration with, and falling confidence in, the PBS listing process characterised industry attitudes during 2012-13. There were many issues around the PBS the industry engaged in through the year and the industry sought to work with Government, politicians, stakeholders and the general public to resolve some of these issues.

There was much debate and dialogue about the PBS on issues like sustainability, the MoU, generic pricing reform, medicine prices and the like. Some of it was informed, much of it was not. To bring some clarity to the debate, in May Medicines Australia released a report by the Centre for Strategic Economic Studies at Victoria University, *The Impact of Further PBS Reforms*. This report modelled the impact of the original 2007 reforms to the PBS and the subsequent MoU and found that these reforms are projected to save in the order of \$18 billion to government and consumers in the period to 2017-18.

Intellectual property was another issue that emerged in 2012-13. The Government announced, without any consultation, a Pharmaceutical Patents Review to examine a range of issues involved in the patent system as it relates to medicines. Medicines Australia engaged in this process extensively, taking the opportunity to highlight the importance of patents and IP to the development of new medicines and vaccines. The Board, the Secretariat and members of the industry identified the key issues and demonstrated the importance of IP to the broader community and government.

The transparency of what the industry does has been an ongoing theme for the industry, and this year was no exception. Medicines Australia successfully introduced Edition 17 of its Code of Conduct and this was well received. This new edition of the Code improved the transparency of how medicines companies interact with health care professionals. In addition, during 2012-13 Medicines Australia initiated the Transparency Working Group, which was charged with looking at how transparency could be increased beyond even what had just been introduced in Edition 17 of the Code. The Transparency Working Group had representatives from a wide range of health stakeholder groups including innovative medicines companies, the generics industry, the medical devices industry, consumer groups, pharmacy, doctors' groups, medical colleges and academics. The Transparency Working Group released its report towards the end of 2012-13, identifying a model whereby financial payments made by medicines companies to individual healthcare professionals could be reported on a public website. This report will be considered by the upcoming Code Review in 2013-14.

Medicines Australia also continued to roll out the Australian Medicines Industry awareness campaign with the general public with several reports launched including *Medicines Milestones* in August. This report looked at the medicines that have been brought to the Australian public over the last decade. The report showed that 795 new medicines were brought to Australians over the last 10 years. Launched in March was a major report, *Facing the Health of Australians*, which reported the results of a survey of 5,000 Australians on what they thought about health, their health concerns and how they used medicines. Both reports generated significant media attention on the Australian medicines industry and showcased some of the achievements of the industry to the broader community.

Our engagement with the political process continued to develop with engagement through the Parliamentary Dinner in March, where the Minister for Health spoke along with John Young, senior global Pfizer executive and former Medicines Australia Chairman. Medicines Australia co-hosted a number of events for the Parliamentary Friends of Medicine network with member companies on topics such as rare cancer therapies, biologic medicines and the process of bringing medicines to market. Medicines Australia also participated in various Parliamentary inquiries and had many meetings with Parliamentarians on all sides of politics through the year.

Of course, the 2012-13 year finished with a tumultuous time in Australian politics with a change of Prime Minister and a federal election expected to be called soon after. Medicines Australia was already prepared, having released our 2013 election document, *Medicines Now*, which detailed a range of policy areas that the industry was seeking commitments on from all sides of politics.

This year also saw some changes in Medicines Australia itself, with the review of the Medicines Australia strategic priorities and organisation. This included streamlining the objectives and priorities and a corresponding reduction in the number of staff and a restructuring of the organisation which has set up the organisation for the future.

Medicines Australia also saw a change in Chair. Former Chair, Mark Masterson, resigned in February 2013 to take up new business opportunities. Mark Fladrich, Managing Director for AstraZeneca and Board Member, stepped in as interim Chair after Mr Masterson's departure and has helped lead the organisation during its process of finding a new permanent Chair. I thank both Mark Masterson and Mark Fladrich for their leadership, guidance and counsel over the course of 2012-13.

I want to thank the Board of Medicines Australia for their engagement, direction and leadership through what has been a difficult year for the industry, as well as the broader membership for their ongoing support for the association. Working together across the industry has again shown the value of industry unity going forward.

Finally, I again want to acknowledge the work and contribution of the Medicines Australia Secretariat staff. Their tenacity, skill, good humour, and dedication to the Australian medicines industry is something I am sure the membership value, as I do. The industry is fortunate to have such talented people working on its behalf.



**Dr Brendan Shaw**

CHIEF EXECUTIVE

## Medicines Australia Board Members 2012-2013



### DIRECTORS 2012-13

			APPOINTED TO BOARD
1	Mr Mark Fladrich	Managing Director, AstraZeneca Pty Ltd	1 January 2012
2	Mr Shaju Backer	Managing Director, Merck Serono Australia Pty Ltd	20 March 2013
3	Dr Dominic Barnes	Vice President & General Manager, Shire Australia Pty Ltd	1 January 2012
4	Dr Graeme Blackman	Chairman, Institute of Drug Technology Australia Ltd	June 1995
5	Mr Wesley Cook	Managing Director, Boehringer Ingelheim Pty Ltd	11 September 2012
6	Dr Susanne Fiedler	Vice President & Managing Director Australia & New Zealand, MSD Pty Ltd	1 July 2012
7	Mr Chris Hourigan	Managing Director, Janssen Pty Ltd	5 December 2012
8	Mr James Jones	Managing Director, Takeda Pharmaceuticals Australia Pty Ltd	11 September 2012
9	Mr Geoff McDonald	Vice President/General Manager, GlaxoSmithKline	15 June 2012
10	Ms Kirsten O'Doherty	General Manager, Abbvie Pty Ltd	24 May 2012
11	Mr Jason Smith	Managing Director, Novartis Pharmaceuticals	11 September 2012
			APPOINTED
			RESIGNED
12	Mr Mark Masterson	Chairman (joined Board May 2012)	1 May 2012
13	Mr James Cain	Bristol-Myers Squibb Australia Pty Ltd	7 September 2010
14	Mr Bruce Goodwin	Janssen Pty Ltd	12 May 2009
15	Mr Rene Klemm	Bayer Australia Limited	24 May 2012
16	Mr John Latham	Pfizer Australia Pty Ltd	6 March 2007
17	Mr Chris Miskel	Eli Lilly Australia Pty Ltd	1 January 2012
18	Mr Ian Thompson	Amgen Australia Pty Ltd	1 May 2009

## Medicines Australia Secretariat 2012-2013



### CORPORATE

1	Brendan Shaw	Chief Executive	3	Katie Whitehead	Director Corporate Services
2	Clair Petrie	Executive Assistant to the Chief Executive & Chairman	4	Caroline Wood	Finance Manager
			5	David Newman	IT Manager
			6	Rochelle Pelaez	Executive Officer
			7	Amna Khanzada	Office Administrator



### POLICY & ADVOCACY

1	Elizabeth de Somer	Director, Policy & Advocacy	4	Andrew Simpson	Government Relations Manager
	Vacant	Regulatory Affairs Manager	5	Samuel Develin	Access to Medicines Policy Officer
	Vacant	Reimbursement Strategies Manager		Vacant	Public Affairs Officer
2	Kristin Trace	Policy Manager		Vacant	Policy & Research Officer
3	Omar Ali Khan	Industry Manager			





## COMPLIANCE

1	Deborah Monk	Director Compliance	3	Karen Patten	Code of Conduct Officer
2	Sophie Hibburd	Code of Conduct Manager			



## STAFF WHO DEPARTED IN 2012-2013

1	Andrew Bruce	Director Health Policy and Research	8	Zoe Morton	Code of Conduct Administration Officer
2	Kayla Calladine (No photo)	Regulatory Manager	9	Mathew Munro (No photo)	Reimbursement Strategies Manager
3	Amish Chaturvedi	Research Manager	10	Jamie Nicholson	Media Communications Manager
4	Louise Collett	Executive Assistant to the Chief Executive	11	Di Phillips	Finance Manager
5	Jim Crompton	Reimbursement Strategies Manager	12	Prya Sonah	Finance Assistant
6	Donna Edman	Executive Director Public Affairs	13	Diana Terry	Stakeholder Relations Manager
7	Julie Johnson	Public Affairs Officer	14	James Turnley	Access to Medicines Policy Officer



## Medicines Australia Members 2012-2013

### CLASS ONE

Abbvie Pty Ltd	Bristol-Myers Squibb Australia Pty Ltd	MSD Australia Pty Ltd
Abbott Australasia Pty Ltd	Celgene Pty Ltd	Mundipharma Pty Ltd
Actelion Pharmaceuticals Australia Pty Ltd	CSL Limited	Novartis Pharmaceuticals Australia Pty Ltd
Alcon Laboratories (Australia) Pty Ltd	Eli Lilly Australia Pty Ltd	Novo Nordisk Pharmaceuticals Pty Ltd
Allergan Australia Pty Ltd	Genzyme Australasia Pty Ltd	Nycomed Pty Ltd
Amgen Australia Pty Ltd	Gilead Sciences Pty Ltd	Pfizer Australia Pty Ltd
AstraZeneca Pty Ltd	GlaxoSmithKline Australia Pty Ltd	Roche Products Pty Ltd
Baxter Healthcare Pty Ltd	Ipsen Pty Ltd	Sanofi Australia Pty Ltd
Bayer Australia Pty Ltd	Janssen Pty Ltd	Servier Laboratories (Aust) Pty Ltd
Biogen Idec Australia Pty Ltd	Lundbeck Australia Pty Ltd	Shire Australia Pty Limited
Boehringer Ingelheim Pty Ltd	Merck Serono Australia Pty Ltd	UCB Pharma

### CLASS TWO

Fresenius Kabi Australia Pty Ltd	Invida Australia Pty Ltd	
iNova Pharmaceuticals Pty Ltd	Norgine Pty Limited	

### CLASS THREE

Astellas Pharma Inc	IDT Australia Ltd	Vifor Pharma Pty Ltd
FIT-BioCeuticals Ltd	Leo Pharma Pty Ltd	

### CLASS FOUR

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

### HONORARY LIFE MEMBERS

There are six Honorary Life Members of Medicines Australia who are remembered for their meritorious service to the industry.

Mr P Bell	Mr A Ferguson	Mr J Robertson
Mr R Davies	Mr JA Purches	Mr Al Stahel

## Key Issues

### IMPROVING TIMELY ACCESS TO MEDICINES FOR AUSTRALIANS

#### The industry has delivered a sustainable PBS

During 2012-2013 the access to medicines environment remained a contentious and uneven terrain to navigate. Despite clear evidence demonstrating that PBS expenditure is constrained by effective pricing policy, and growth is forecast to be moderate, the industry is still seeking policy predictability and a stable business environment. Additionally, it is important to note that the Government will continue to operate under economic and fiscal pressure and this will compel the need to continue to seek measures to enable accurate prediction and management of PBS expenditure and growth into the future.

#### MOU: 2012-2013 (YEAR 3)

The provisions within the MOU managed to contain unrestrained policy action through the specific terms of the agreement. This is confirmed by the absence of new Therapeutic Groups and the fourth consecutive Budget containing no sweeping announcements to the pricing and policy structure of the PBS.

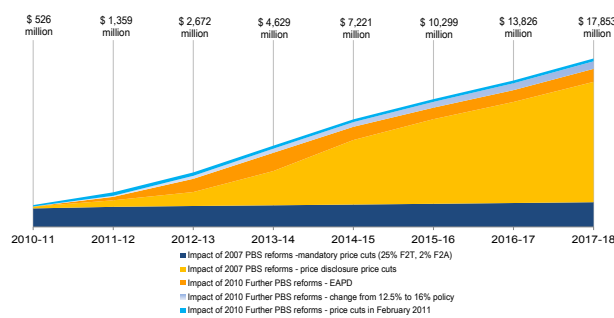
Monitoring of the MOU reaffirmed that members continued to make use of the parallel TGA/PBAC processing provision; with a number of major submissions in the 2012-2013 year selecting this route. However, the formal reporting from the Department of Health and Aging diminished, as reduced resources left them ill-equipped to provide the key activity reports. It is therefore difficult to ascertain the percentage of major submissions benefitting from the provisions within the agreement.

Other available data supports the Department's claims that Cabinet decisions on medicines recommended for listing by the PBAC have been consistently achieved within the 6 month timeframe agreed in the MOU, and there have been no further deferrals. In the meantime, short term horizon scanning and assessment of PBAC anticipated workflow has continued to assist in planning for both the companies and the PBAC.

Medicines Australia's finalised report by Victoria University's, Centre for Strategic Economic Studies (CSES) on the Impact of Further PBS Reforms released in May 2013 made some significant assertions regarding the access environment. The report and subsequent commentary heightened a divergence between industry's contributions to a sustainable system and the ongoing Government search for policy flexibility and new savings.

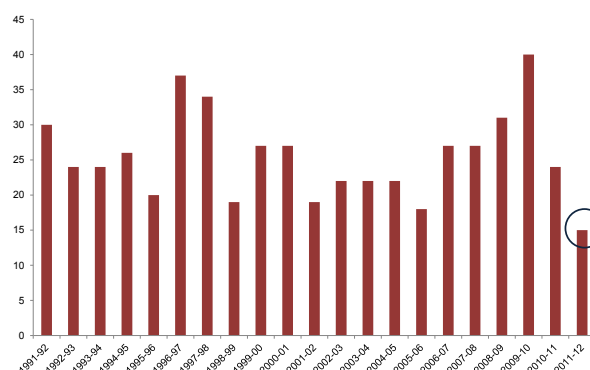
The report clearly demonstrates that the enduring savings measures achieved through Initial Price Disclosure in 2007 and built upon with Expanded Accelerated Price Disclosure (EAPD) in 2010 is delivering and will continue to deliver savings, several orders of magnitude greater than anticipated, with an estimated \$18 Billion to be derived in savings out to 2018. The report provides further assurances of the successful measures introduced to deliver savings in the multi-brand market, whilst simultaneously creating headroom for listing of new medicines in the value based single brand formulary.

FIGURE 1 Cumulative savings from PBS reforms, \$m<sup>1</sup>



However, the report also highlights a significant decline in the number of new, innovative medicines listed on the PBS since 2009-10; in fact there is an historic low in 2012 with the lowest number of new medicines listed in 20 years. Although this figure does not reflect extensions to existing listings, it is nevertheless of significant concern to industry. The inference is that, although PBS expenditure is being radically constrained through agreed savings measures, there is little fresh investment in new medicines.

FIGURE 2 New PBS medicines listings, number, 1991-92 to 2011-12<sup>2</sup>



<sup>1</sup> Sweeney, K, Impact of Further PBS Reforms, Centre for Strategic Economic Studies, Victoria University, March 2013

<sup>2</sup> Sweeney, K, Impact of Further PBS Reforms, Centre for Strategic Economic Studies, Victoria University, March 2013

In other matters, there has been limited progress in improving flexibility in the co-dependent submission process. Transparency of decision making and listing timeframes from Medical Services Advisory Committee (MSAC) recommendations needs further work. We are continuing to seek opportunity to make this progress and will continue to do so. Difficulties facing Pharmaceutical co-dependent submissions will likely require a separate approach.

There has been minimal progress in the utilisation or refinement of the Managed Entry Scheme. We remain convinced of the potential value of such a scheme and will continue to work towards a system that is acceptable, achievable and useful to both industry and Government.

Notwithstanding the achievements of the MOU between the Industry and the Commonwealth, the Government has continued to expand on a range of existing policies around the MOU which has led to a growing instability within the PBS process. This lack of certainty and growing disquiet has created an oppositional atmosphere between the industry and the Government that has had a negative impact on the business setting for the industry.

### Post market reviews

Confidence in the system has been markedly undermined by the ongoing swathe of post market reviews. Medicines Australia has clearly and repeatedly articulated industry concerns with regards to the procedural and policy deficiencies of the post market review program. There have been repeated proposals to work with the department to correct the failings in the program; the lack of an appropriate framework; the ad hoc conduct and poor management for implementation of the outcomes from post market reviews.

The outcomes of the Alzheimer's review endorsed industry's concerns with the process. Industry has expressed an ongoing commitment to correct the procedural deficiencies, establish an appropriate framework, and examine the policy implications that are equally evident in the subsequent reviews such as the Diabetes review and the Asthma review.

Whilst the Department has been slow to acknowledge industry's concerns, they have agreed to further working together on the issues raised. A series of meetings have been arranged to progress the dialogue.

### Technology improvements delayed by policy interpretation

The reinterpretation of section 99ACB/ACD of the *National Health Act (1953)* has led to inappropriate application of mandatory price cuts to single brand products attempting to bring a technology advance to the market. This interpretation is in apparent conflict with the original intention of the *Act*, which is to disallow inappropriate delays to generic entry. The application of this section of the *Act* to products that are not subject to generic competition has resulted in companies delaying or halting the introduction of new technologies to Australian patients due to untenable price cuts being improperly imposed.

Despite delegations requesting policy work to be conducted in partnership to resolve this matter, again there has been slow acceptance of the issue. The Department has agreed to work with the industry to review the matter.

### Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) has provided data on the timeframes for registration decisions, showing reasonable achievement in predictable timeframes, but still a lack of certainty in the process. Planning the timing of parallel submissions with sufficient interval to receive the relevant TGA documentation has, therefore, remained challenging.

The TGA are continuing to work with the industry to resolve the difficulties in meeting predictable regulatory timelines to further assist companies in planning for early submission to the Pharmaceutical Benefits Advisory Committee (PBAC). The heavy program of regulatory reform since 2011 and scheduled for implementation over the next few years will continue to exert pressure on their resource capacity. The industry will continue working with the Commonwealth agencies to resolve the issues that persist.

### Engaging with stakeholders

The Medicines Australia policy and advocacy team continued to meet regularly with the central agencies and will seek to further this relationship in the coming year to improve their understanding of the broader value of medicines within the health system and a balanced and informed dialogue.

Furthermore, there has been unexpected public commentary during the year from prominent academic think-tanks, with Commonwealth funding, recommending radical funding reforms. The use of selective or incomplete data created a false impression of both the cost and the sustainability of the PBS in Australia. This generates an added element of uncertainty that will require concerted effort to re-establish a balanced and informed debate in the coming year.

### The future

The policy and advocacy team will continue to work with the Commonwealth and stakeholders to determine the most favourable environment for access to medicines. The current restrictions in resources across Government departments as well as internal and external pressures for certainty will require the policy and advocacy team to re-establish where the focus for access to medicines should be concentrated.

It is clear that the industry will face a number of challenges in the coming year with continued pressure from the government for fiscal security. The PBAC listing process and overcoming the hurdles faced at the PBAC will continue to create uncertainty for the industry. The Government desire for policy flexibility and the need to constrain expenditure will also feature. There will be continued and increased scrutiny from the PBAC and Government over the prices of existing medicines, with the primary purpose of re-evaluating cost effectiveness. Additional pressures will be placed on monitoring post market efficacy in this context. This will continue to challenge business certainty and transform the role of other stakeholders when negotiating with Government.



## IMPROVING THE INVESTMENT ENVIRONMENT

This year was unprecedented in terms of the number and scope of proposed reforms of intellectual property rights in Australia. Medicines Australia actively contributed to several reviews of intellectual property rights in 2012-13.

### Pharmaceutical Patents Review

The most concerning and challenging was the Pharmaceutical Patents Review in which the Government tasked a three-person panel to analyse Australia's patent system as it relates to pharmaceutical products. Medicines Australia's submissions to the Review emphasised that Australia must maintain a strong, stable and predictable intellectual property environment if we are to continue to attract global investment in R&D and high-tech manufacturing.

The Review's Draft Report attracted significant local and international attention, with most stakeholders noting that the Panel's recommendations, if implemented, would significantly erode IP protection in Australia. Medicines Australia's opposition to the Draft Report's recommendations was supported by submissions from many member companies as well as other Australian and international organisations.

The Pharmaceutical Patents Review Final Report was submitted to Government in May 2013, but the Government had not responded to it before the federal election was called. Consideration of the Review Report will now be a matter for the incoming Government.

### Review of innovation patents

In September 2012, IP Australia commenced consultation on its proposal to 'Raise the Step' for innovation patents. The proposal was to raise the patentability threshold for innovation patents to the same level of inventiveness as required for standard patents. Medicines Australia supported the principle of raising the standard for innovation patents in Australia, but challenged the assertion that there had been an unusual increase in applications for this form of IP for pharmaceuticals. Since 2006, "pharmaceuticals and cosmetics" accounted for about 15% of the total number of innovation patent filings in Australia on average. Medicines Australia noted that the pharmaceutical industry in Australia relies primarily on standard patents to protect their inventions.

A proposed amendment to implement this change was not introduced to Parliament before the federal election.

### Review of compulsory licensing

In August 2012, the Productivity Commission commenced a review of compulsory licensing in Australia. This review resulted from recommendations from previous reviews by the Australian Law Reform Commission, the Advisory Council on Intellectual Property and the Senate Community Affairs Committee, which found that Australian law may make it too difficult to apply for a compulsory licence.

Medicines Australia told the Commission that there was no reason to change the current arrangements. We said that weakening the Australian patent system by making it easier to obtain a compulsory license would seriously harm Australia's ability to attract global investment in R&D and jeopardise Australians' access to innovative medicines.

The Commission's Final Report was released on 27 May 2013, finding (in part) that "there are no clear alternatives to the Federal Court that would make compulsory licence applications significantly less costly and time consuming, without also raising concerns about the quality of outcomes and scope for appeals." The Report also recommended reforms to rationalise overlap and potential inconsistency between the *Competition and Consumer Act* and the *Patents Act* and replace the current "reasonable requirements of the public" criteria with a "public interest test" for granting a compulsory licence. Medicines Australia accepted these recommendations, which are yet to be implemented by Government.

### Implementation of the TRIPS Protocol

In May 2013, the Government introduced the *Intellectual Property Laws Amendment Bill 2013* in Parliament. The Bill would implement the "TRIPS Protocol" in Australia, which provides a mechanism for generic companies to manufacture and supply patented medicines to least-developed and developing countries in response to public health emergencies. Medicines Australia worked closely with IP Australia to design a system that is consistent with the principles of the *Doha Declaration on the TRIPS Agreement and Public Health* and would protect the rights of Australian patent holders. We supported these reforms which will give Australian companies the ability to respond to health crises in less developed countries. The *Amendment Bill 2013* passed the lower House on 25 June 2013 but is yet to be considered by the Senate.

The Coalition did not support the Bill on the grounds of poor drafting and "unintended consequences". It is unclear what the Bill's future will be.

### Gene patents

We are pleased to report that in 2012-13 there were no legislative efforts to ban the patenting of genetic and biological materials in Australia. However, this remains an ongoing issue, particularly in light of the June 2013 US Supreme Court decision concerning patents on the BRCA1 and BRCA2 genes. The US Supreme Court held that a naturally occurring DNA segment is a product of nature and not patentable merely because it has been isolated. On the other hand, genetic material which has been transformed through human intervention (e.g. cDNA) is patent eligible because it is not naturally occurring. The Supreme Court decision differed from the Australian Federal Court's decision in February 2013 on the same subject matter. The Federal Court held that isolated genetic materials such as DNA and RNA are patentable subject matter. This Australian decision is under appeal.

## Trans Pacific Partnership Agreement (TPPA)

A delegation from the US Biotechnology Industry Organisation (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) visited Australia in July 2012 to discuss US proposals on the 'intellectual property' and 'transparency and procedural fairness for health technologies' chapters of the TPPA with key Australian politicians and bureaucrats. Medicines Australia joined the delegation's meeting with the departments of Foreign Affairs and Trade, Innovation and Industry, Health and Ageing, AusAID and IP Australia. The delegation also met with advisers to the (then) Ministers for Industry, Trade and Health and with the Director of Policy for the Opposition Leader Tony Abbott.

These chapters of the TPPA made slow progress at the six formal negotiation rounds between July 2012 and July 2013. Medicines Australia has continued to advocate for an outcome that will not impose any more onerous regulatory burden on the industry or erode Australian IP rights. The TPPA does provide an opportunity to bring Australia's data protection provisions up to the standard offered by many developed countries.

## R&D tax credit

Once again in 2012-13, there was an attempt to wind back the R&D tax incentive. In August 2012, the Government asked the newly constituted Business Tax Working Group (BTWG) to make recommendations on potential changes to the R&D tax incentive (among other areas of tax law) in order to achieve a revenue neutral reduction in the corporate income tax rate. Medicines Australia opposed most of the BTWG's proposed reforms including the abolition of the non-refundable component of the R&D tax credit, a reduction of the rate of the non-refundable tax benefit from the existing 40% to 37.5%, or the exclusion of companies with a group aggregated annual turnover of greater than \$10 or \$20 billion from being eligible to claim tax benefits. We said that we may be able to support the imposition of a \$100 million cap on the amount of eligible R&D that can be claimed annually, but cautioned that imposing a cap would be a disincentive to growing R&D investment.

Following broad consultation, the BTWG was unable to recommend any changes that would deliver a corporate tax rate cut without negatively impacting on business investment.

## Bio-Pharmaceutical Innovation Partnership

Medicines Australia joined members GlaxoSmithKline, AstraZeneca, bioCSL and IDT, along with Aspen, AusBiotech, BioMelbourne Network, Catalent, Hospira, Monash University and Stiefel R&D, to apply for Government funding to establish the Bio-Pharmaceutical Innovation Partnership. (Then) Ministers Combet and Plibersek had announced the establishment of 10 Industry Innovation Precincts (later renamed 'Partnerships') as part of the Innovation Statement released on 18 February 2013. The Ministers stated that these Precincts (or Partnerships) "will be industry-led networks focusing on industries in areas of Australian competitive advantage and emerging opportunity. They will focus nationally to better coordinate existing services, leverage Australian research capacity as well as provide new tools and services to enable Australian businesses to invest, create export opportunities, innovate and grow." The Government had allocated up to \$4 m per annum to 'established industry' and \$1.4 m per annum for 'emerging industry' partnerships.

The Bio-Pharmaceutical Innovation Partnership application was successful, as announced during the election campaign, with the then Government announcing the creation of the Partnership.

## McKeon Review of Health and Medical Research

On 5 April 2013, following two years of public consultation, including two submissions from Medicines Australia, the Strategic Review of Health and Medical Research in Australia released its final report. Among other reforms, the Review Panel emphasised the importance of a strong, stable and globally harmonised IP system. It called on the Government to ensure the strength and stability of Australia's IP system by, for example, rejecting calls to ban biological materials from patentable subject matter and extending the term of data exclusivity to harmonise and important element of the Australian IP system with global best practice, which are consistent with Medicines Australia's recommendations. Importantly, the Review Panel also recommended that Government should implement the recommendations of the Clinical Trials Action Group as a matter of "urgent national priority".

## Clinical Trials Action Group (CTAG)

There was slow progress in implementing the Clinical Trials Action Group's (CTAG) recommendations during the year.

On 10 August 2012, the Standing Committee on Health, which consists of all Federal, State and Territory health ministers, set July 2013 as the deadline for the implementation of a nationally harmonised system of single ethics review for multi-centre clinical trials. However, the deadline was not met. The Committee also agreed to ask the Independent Hospital Pricing Authority to prioritise the development of a standard table of costs associated with conducting clinical trials in Australia.

On 11 October 2012, Ministers Plibersek and Combet launched the new Australianclinicaltrials.gov.au website at Parliament House, which partly addressed the implementation CTAG recommendation E. The new website was designed to help boost patient recruitment into clinical trials.

Progress towards full implementation of the CTAG recommendations received a stimulus in early 2013. In February, Ministers Combet and Plibersek announced \$9.9m funding over five years to implement the CTAG recommendations as part of the Government's Industry and Innovation Statement, *A Plan for Australian Jobs*. However, this funding will be subject to review by the incoming Government.

## Clinical Trial Costing Study

In August 2012 the Minister for Health instructed the Independent Hospital Pricing Authority (IHPA) to determine the 'national efficient price' for a list of standard items associated with conducting clinical trials in Australia. This project involved consultation with a number of Medicines Australia member companies, public and private hospitals and State and Territory governments. Member representatives also participated on the expert Steering Committee that directed the project.

Medicines Australia strongly supported this initiative, which will help companies to reliably predict the cost of conducting clinical trials in Australia and significantly reduce the time it takes them to negotiate contracts with individual research sites.

## E-health

On 22 October 2012, the Pharmaceuticals Industry Council organised a full-day workshop in Sydney to examine how the needs of the Australian clinical research community can be incorporated into the design of the national e-health system. Over 40 delegates representing academia, Federal and state governments, research institutes, teaching hospitals, clinical trial networks, health consumer groups, ICT service providers and industry attended the workshop. The event was sponsored by the Department of Industry, Innovation, Science, Research and Tertiary Education, the Department of Health and Ageing and the National E-Health Transition Authority.

A report on the outcomes of the workshop was prepared and continues to form the basis for further discussions among stakeholders on how to ensure the e-health system can be used to promote research in Australia.

## Pharmaceuticals Industry Working Group

Medicines Australia joined other industry leaders in two meetings of the Pharmaceuticals Industry Working Group during the year – in November 2012 and May 2013. Ministers Combet and Plibersek chaired both meetings and engaged in robust discussion with industry on topics ranging from the sustainability of the PBS and the Pharmaceutical Patents Review to the Government's Industry Statement and implementation of the CTAG recommendations.

## THE AUSTRALIAN MEDICINES INDUSTRY CAMPAIGN



This year, the Australian Medicines Industry public awareness campaign included ongoing advertisements in print and electronic media about the

industry, featuring key facts and figures about the industry and highlighting the benefits the industry brings to the community. The advertisements continued to use the stories of real people employed in member companies to demonstrate the industry's contribution to Australia.

The campaign also featured several key reports released during 2012-13. The *Medicines Milestones* report, released in August 2012, highlighted the contribution the industry made by the medicines it has brought to the Australian community. The report found that the Australian medicines industry brought 795 medicines to Australians over the decade to 2011 in areas such as cancer, cardiovascular disease and vaccines. The report generated significant positive media coverage and resulting discussion on the value of the industry to Australians.

Similarly, the *Facing the Health of Australians* report was released in March 2013, with preliminary findings released in November 2012. This report contained survey results from 5,000 Australians surveyed about their attitudes to their health, their health concerns, use of medicines and how they value medicines. The releases, in

November and March, generated significant media coverage of the industry and the medicines they develop. The November release focussed on Australians' concerns around Alzheimer's Disease and the treatments being developed by the industry, which generated two full days of media coverage. The March release focussed on diabetes medicines and the concerns in the community about diabetes and, again, generated significant media coverage of the industry and the medicines it produces.

## MEDICINES NOW

Medicines Australia also released its policy document for the upcoming 2013 federal election, *Medicines Now*. The document contained six key policy issues that it called on all political parties to support. These were:

- Reaffirm its commitment to the National Medicines Policy
- List on the PBS all medicines currently recommended by the PBAC
- Work with industry to ensure a predictable and stable business environment
- Improve PBS processes
- Uphold and strengthen Australia's intellectual property system; and
- Commit to Industry policies that keep the medicines industry investing in Australia.



The document formed the basis of substantial engagement with politicians and media commentary in the months leading up to the federal election later in the year.

Medicines Australia's parliamentary engagement was well supported by active participation by the Medicines Australia Board and Government Working Group.

## CODE OF CONDUCT PERFORMANCE: A SNAPSHOT

### Code of Conduct Review

The primary purpose for each Code review is to ensure that the provisions of the Code and its administration remain appropriate and relevant to the Australian and international environments, taking into consideration the interests of consumers, government, healthcare professionals and the industry. Through regular consultation with all interested stakeholders it is intended that the Code will keep pace with changing community standards and expectations.

Following a comprehensive, 10 month review process, Edition 17 of the Code of Conduct was adopted by Members on 26 June 2012.



Medicines Australia submitted the new Code, in early July 2012, to the Australian Competition and Consumer Commission (ACCC) for authorisation.

Edition 17 of the Code represents a significant advance towards greater transparency. New provisions include additional transparency reporting, in aggregate, of financial relationships between companies and healthcare professionals, such as payments for health professional consulting services and for participation on Advisory Boards. Further measures also include disclosure of the amount of financial support provided by companies to Health Consumer Organisations.

Following its own consultation and review, the ACCC authorised Edition 17 on 20 December 2013. Medicines Australia received authorisation for two years. In its Final Determination, the ACCC urged the industry to consider further transparency measures about how companies interact with doctors, pharmacists and other healthcare professionals. Prior to the ACCC Determination, Medicines Australia had established a broad-based Transparency Working Group to develop measures and policies that will further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. Further details about the membership and Terms of Reference of the Working Group are available on the Medicines Australia website.

The Transparency Working Group identified a model for introducing greater transparency about payments and transfers of value between companies and healthcare professionals. The Working Group also developed Principles for Transparency to guide its development of a transparency model. The Transparency Model Consultation and Discussion Paper was released on 21 June 2013, which signalled the commencement on the next Code Review, to produce Edition 18 of the Code.

### Transparency Reporting under Edition 17

Member companies continued to report all educational meetings and symposia that they organise or sponsor. Medicines Australia publishes these reports every six months on its website. Companies have consistently demonstrated a high level of compliance with the Code during 2012-13 and their ongoing commitment to improved transparency of interactions with healthcare professionals, which deliver and support valuable education about the treatments available to Australians.

In December 2012 and June 2013 Medicines Australia published educational event reports for the periods April to September 2012 and October 2012 to March 2013 respectively. There were over 18,000 events reported for April to September 2012 and over 13,000 events reported for October 2012 to March 2013. The lower number of events in this period most likely reflects the fact that it includes the December-January holiday period.

In June 2013, Medicines Australia published the first of the new reports required under Edition 17, the Advisory Boards report. These reports covered the period 11 January to 30 March 2013 which represents the first three months following implementation of Edition 17. There were 49 Advisory Board meetings held by 22 Member Companies during that period.

### Continuing Education Program (CEP)

The Medicines Australia Continuing Education Program (CEP) is designed to educate medical representatives to a recognised industry standard. It also educates other company personnel about the Medicines Australia Code of Conduct.

We wish to acknowledge the hard work and diligence of the University of Tasmania team who delivered the CEP in 2012-13 for our Members. Led by Professor Greg Peterson, Professor of Pharmacy and ably managed by Ms Nelle Pittman, Research and Business Development Manager, the CEP has continued to improve and develop. During the last twelve months Program 1, the Code of Conduct Module was fully revised and updated, as were Program 2, The Pharmaceutical Industry; Program 4, Introduction to Pharmacology; Program 5, Understanding Product Information; and Program 6, Understanding Clinical Trials and Scientific Literature.

In the interest of extending the value of CEP to our Member employees, UTAS now offers CEP students concurrent enrolment in a UTAS undergraduate degree, counting the full 6 CEP Programs towards 3 UTAS units (equivalent to one eighth of a Bachelor degree).

### Promoting Industry Wide Ethical Conduct

In May 2012, in response to the recommendations of the Working Group on the Promotion of Therapeutic Goods, the Labor Government allocated \$1.4 million over four years "to assist the therapeutic goods industry to develop strong, consistent and enforceable codes of conduct based on a common framework of high level principles, better communication mechanisms and shared systems for complaints reporting."

In March 2013 Dr Brendan Shaw joined representatives from across the sector to form the Codes of Conduct Advisory Group, chaired by Emeritus Professor Lloyd Sansom. The Advisory Group has been tasked with implementing those Working Group recommendations that the Government had accepted.

Ms Deborah Monk and Mrs Sophie Hibburd contributed to the Advisory Group's work through two subgroups that are considering establishing a common complaints portal that will be easily accessible by consumers and evaluating progress towards implementation of the Working Group on Promotion's recommendations.

The Codes of Conduct Advisory Group's work is very important to "leveling the field" across the sector, particularly in light of the new transparency measures included in Edition 17 of the Code and further transparency measures under consideration for Edition 18.

### How we performed

In 2012-2013 Member Companies continued to demonstrate their commitment to ethical conduct in their interactions with healthcare professionals and consumers.

In 2012-2013, Medicines Australia received 18 new complaints. This is an increase over each of the previous two years, where 12 and 14 complaints were received. The majority of complaints were submitted by Member Companies (12 complaints) with the balance submitted by healthcare professionals (three complaints) and the Monitoring Committee (three complaints).

Of the new complaints received in 2012-2013, 10 complaints were considered and finalised by the end of the financial year. One complaint was against a non-member company. The Subject Company declined to have the complaint heard by the Code of Conduct Committee; therefore, the Secretariat referred the complaint to the TGA. Of the finalised complaints, four were found not in breach of the Code and six complaints were found to be in breach of some or all aspects of the alleged breaches.

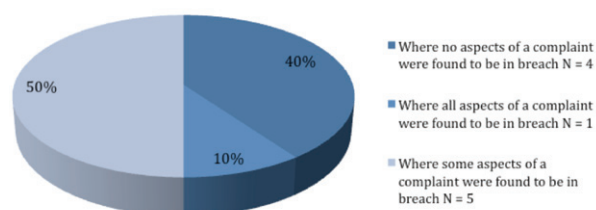
There were only two appeals against the Code of Conduct Committee's decisions during the year. One appeal was upheld and the other not upheld. Details of the complaints considered and finalised in 2012-2013 and the outcomes are reported in the [Code of Conduct Annual Report](#), published on the Medicines Australia website.

The seven complaints received but not finalised or considered by the Code and/or Appeals Committees in 2012-2013 will appear in the Quarterly Report for July–September 2013 and the 2013-2014 Annual Report.

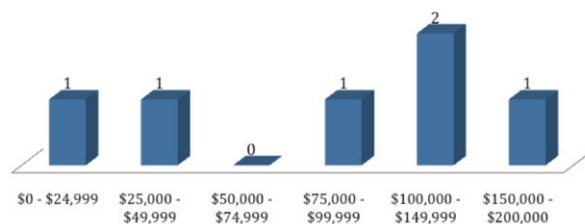
The Monitoring Committee undertook a substantial body of work during 2012-2013. The Committee undertook two reviews of materials associated with particular therapeutic areas (Product Familiarisation Programs in the Central Nervous System area and printed promotional material in the infectious diseases area). It also undertook five reviews across all therapeutic classes covering corporate websites, market research, media releases to the health professional media, company CEP policies and procedures and starter pack policies and procedures. The review of company CEP policies and procedures was particularly extensive, taking two meetings of the Committee to complete its examination of materials and companies' responses to questions raised by the Committee. These reviews are in addition to the regular annual review of one quarter of all educational event reports submitted by Member Companies, for events held between 1 April 2012 and 31 March 2013. This review covered just over 10,000 events from 36 companies.

## CODE OF CONDUCT PERFORMANCE IN 2012-2013: A SNAPSHOT

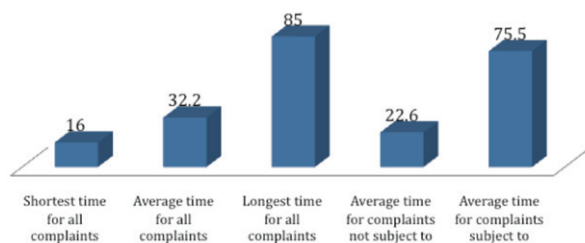
**FIGURE 1** Outcomes of the 10 complaints received and finalised in 2012-2013



**FIGURE 2** Fines imposed by the Code and Appeals Committee on companies found in breach of the Code



**FIGURE 3** Length of time to resolve all finalised complaints (in working days)



## Key Events Diary

### July 2012

- Medicines Australia submitted the revised [Code of Conduct](#) Edition 17 to the Australian Competition and Consumer Commission for authorisation. The ACCC called for submissions on the revised Code by 30 July.
- The Government released its [response](#) to the recommendations of the Finance and Public Administration References Committee Report on the Government's Administration of the PBS.
- Medicines Australia chairman Mark Masterson and chief executive Brendan Shaw attended a meeting of the Access to Medicines Working Group (AMWG). The AMWG is a collaboration between the Department of Health and Ageing and Medicines Australia which provides strategic oversight on activities undertaken to enhance PBS processes.

### August

- Medicines Australia briefings were held in Sydney and Melbourne to update members on Medicines Australia's strategic priorities for 2012-13 and the implementation status of the Memorandum of Understanding.
- Brendan Shaw participated in a roundtable hosted by Minister for Health, Tanya Plibersek MP, and Parliamentary Secretary for Industry and Innovation, Mark Dreyfus QC MP, to discuss issues related to gene patents. The roundtable brought together leaders from across industry, healthcare, research, the law, and consumer groups.
- Medicines Australia established a Transparency Working Group to identify possible measures to further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. The group's Terms of Reference are available on the [Medicines Australia website](#).
- Mark Masterson and Brendan Shaw met with Minister of Health, Tanya Plibersek MP, to discuss Cabinet's deferral of PBS listings.
- Medicines Australia co-sponsored a Parliamentary Friends of Medicines event with Roche and Amgen. The theme of the luncheon was biologic medicines.
- Medicines Australia hosted Managing Directors' Dinners in Melbourne and Sydney to discuss progress on the implementation of the MoU with Government and the evolving policy landscape.
- The *Medicines Milestones* report was released as part of The Australian Medicines Industry project. The report tracks medicines approved for use in Australia over the last decade and shows the industry brought 795 medicines to the Australian community over ten years in areas like cancer, cardiovascular disease and vaccines.

### September

- Consumers Health Forum CEO, Carol Bennett, and Parliamentary Secretary for Industry and Innovation, Mark Dreyfus QC MP, were guests of the Board at its September meeting.
- Brendan Shaw attended a meeting of the [Medicines Partnership of Australia](#) (MPA). Parliamentary Secretary for Health and Ageing Catherine King MP was a guest at the meeting which included discussion of Therapeutic Goods Administration reforms. The MPA consists of Medicines Australia, the Australian Self Medication Industry, the National Pharmaceutical Services Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Generic Medicines Industry Association.
- Brendan Shaw attended a meeting of the Pharmaceutical Industry Discussion Group (PIDG). The PIDG is a Government-initiated group that reviews progress on implementing the MoU with a range of other health stakeholders. The Group is chaired by the Department of Health and Ageing.
- The Pharmaceuticals Industry Council (PIC), which brings together representatives from the research-based and generic medicines and medical biotechnology sectors, held a series of meetings with policy makers in Canberra to discuss the challenges facing the Australian medicines industry.
- Brendan Shaw, Generic Medicines Industry Association chairman, Martin Cross, and Consumers Health Forum CEO, Carol Bennett, met with Health Minister Plibersek's office to discuss the Statement of Principles of Commitment in relation to PBS listings and Cabinet deferrals.

### October

- Mark Masterson, Brendan Shaw and other representatives of the Pharmaceuticals Industry Council met with Shadow Minister for Health and Ageing, Peter Dutton MP, Shadow Minister for Mental Health and Ageing, Senator Concetta Fierravanti-Wells, and Senator Arthur Sinodinos to provide presentations on the industry in Australia and to discuss industry issues.
- Medicines Australia hosted a Managing Directors Briefing via webinar to discuss progress against Medicines Australia key priorities.
- Medicines Australia, Novartis and Pfizer co-hosted a Parliamentary Friends of Medicines event at Parliament House. The theme of the event was "Targeting Rare Cancers".
- The Minister for Health, Tanya Plibersek MP, and the Minister for Industry, Greg Combet MP, launched the [www.AustralianClinicalTrials.gov.au](http://www.AustralianClinicalTrials.gov.au) website at Parliament House. The new website is designed to help boost patient recruitment into clinical trials.
- The inaugural meeting of the Transparency Working Group, chaired by Medicines Australia Board member Shire general manager Dominic Barnes was held.
- Mark Masterson travelled to the Northern Territory to visit Medicines Australia's Special Purpose Fund projects based in Alice Springs, including a Baker IDI project at the Hidden Valley Town Camp Community Centre and dialysis treatment facilities at the Purple House. Mr Masterson also attended the Baker IDI educational symposium *Diabetes Care at the Top End*, part-funded through the Special Purpose Fund.



- The Pharmaceuticals Industry Council hosted a full-day stakeholder workshop in Sydney on 22 October to examine how the needs of the Australian clinical research community can be incorporated into the design of the national eHealth system. The event was sponsored by the Department of Industry, Innovation, Science, Research and Tertiary Education, the Department of Health and Ageing, and the National EHealth Transition Authority.
- Shadow Minister for Health and Ageing, Peter Dutton MP, was the guest of the Board at its October meeting.
- The Medicines Australia Annual General Meeting was held in Sydney at which Mark Masterson presented to members the [2011-2012 Annual Report](#), the audited Financial Statements of Medicines Australia and the [Code of Conduct Annual Report](#). The 2012 [Pat Clear award](#) was presented to Mendel Grobler of Pfizer for his ongoing commitment over several decades to improving access to medicines for Australians and to the development of the industry. The AGM was followed by a member briefing which included presentations from Special Purpose Fund recipients and the Chair of Medicines New Zealand, the Hon Heather Roy.
- Approximately 240 delegates attended the [Medicines Australia Conference](#) in Sydney which included presentations by the Director of the Oxford Centre for Accelerating Medical Innovations, Richard Barker, PBAC chair Sue Hill, and academics and representatives from health consumer organisations and other industry stakeholders. Minister for Health, Tanya Plibersek MP, and President of Alzheimer's Australia, Ita Buttrose, spoke at the Conference Dinner the evening prior. Videos of conference presentations are available on the Medicines Australia website
- The Australian Competition and Consumer Commission issued its draft determination in response to the application for reauthorisation of the Medicines Australia Code of Conduct.

## November

- Medicines Australia lodged a [submission](#) in response to the McKeon Review's consultation paper and draft recommendations.
- Medicines Australia lodged a [submission](#) in response to the Government's review of the innovation patent system in Australia.
- The Medicines Australia Board and the Code Panel of Chairs conducted their annual meeting and discussed transparency, the operations of the Code, trends in industry compliance and administrative costs of the Code.
- Medicines Australia attended the inaugural meeting of the Oncology Industry Task Force. The Task Force was convened to discuss challenges related to access for high cost oncology medicines.
- Medicines Australia Managing Directors dinner was held in Sydney with guest speaker Malcolm Farr, National Political Editor at News.com.au.
- Medicines Australia participated in the Advisory Council on Intellectual Property (ACIP) Forum. The Forum, chaired by Professor Jim Butler of the Australian National University, discussed the Government's review of pharmaceutical patents.
- Brendan Shaw presented on issues facing industry in the area of investment in medical research at the National Health and

Medical Research Council (NHMRC) Innovation Forum.

- Mark Masterson, Brendan Shaw and Medicines Australia Board member Mark Fladrich (AstraZeneca) attended a Pharmaceutical Industry Working Group (PIWG) meeting with Industry Minister Greg Combet MP, Health Minister Tanya Plibersek MP and Industry Parliamentary Secretary Mark Dreyfus QC MP.

## December

- Mark Masterson delivered the Medicines Australia Chairman's Address at the National Press Club. Mr Masterson laid out Medicines Australia's vision for the industry in 2020, in an economy driven by high-tech, high-value manufacturing and innovation. The Address was delivered to an audience of 180 guests and viewed by a live television audience of approximately 100,000. The [transcript](#) of the Address is available on the Medicines Australia website.
- The [Excellence in Health Journalism Awards](#) were presented at the National Press Club.
- Mark Masterson, Mark Fladrich (AstraZeneca, Medicines Australia Board member), Brendan Shaw, and members of the Access Strategic Committee and working groups attended the annual Medicines Australia – Pharmaceutical Benefits Advisory Committee meeting in Sydney.
- The Australian Competition and Consumer Commission granted authorisation for Edition 17 of the [Code of Conduct](#) for two years, taking effect on 11 January 2013. A copy of ACCC's determination and public submissions are available on the Medicines Australia website.

## January

- Edition 17 of the [Code of Conduct](#) came into effect on 11 January.
- Medicines Australia lodged a [submission](#) to the Australian Government's Pharmaceutical Patents review.

## February

- Independent Senator Nick Xenophon and DLP Senator John Madigan moved for a Senate Inquiry into PBS price disclosure and price reductions in chemotherapy drugs, with a reporting date of 22 April 2013.
- Medicines Australia, AbbVie, and Eli Lilly co-hosted a Parliamentary Friends of Medicines event at Parliament House. The theme of the event was "Turning science into caring: Research and development from the laboratory to the patient".
- Brendan Shaw and other representatives of Medicines Australia appeared before the Pharmaceutical Patents Review Panel in Canberra. The hour-long hearing covered issues including data exclusivity, patent linkage, the relationship between incremental innovation and the patent system, and Australia's international obligations under TRIPS and AUSFTA.
- Medicines Australia lodged a [response](#) to the Productivity Commission's interim report on compulsory licensing in Australia.
- Representatives from Medicines Australia and member companies met with Therapeutic Goods Administration National Manager, John Skerritt, and other TGA executives for a twice yearly strategic liaison meeting.

- Prime Minister Julia Gillard released the [Government's Industry and Innovation Statement](#). The Statement explicitly recognised the socio-economic importance of the medicines industry to Australia. Among other measures, Ms Gillard announced that the Government would spend \$10 million over five years to expedite the implementation of reforms to improve Australia's competitiveness as a destination for clinical trial investment, and establish up to ten Industry Precincts to encourage collaboration and facilitate commercialisation.
- The Medicines Australia Board met in Melbourne. Chairman Mark Masterson announced his resignation and was replaced by interim chairman Mark Fladrich, Board member and managing director of AstraZeneca.
- Medicines Australia held members briefings in Sydney and Melbourne to discuss current and future strategic priorities. Feedback from members was provided to the Medicines Australia Board for its strategic planning retreat in April.
- Medicines Australia presented new code reporting requirements for Edition 17 of the [Code of Conduct](#) at member workshops in Melbourne and in Sydney.
- Senator Di Natale tabled the [Therapeutic Goods Amendment \(Pharmaceutical Transparency\) Bill 2013](#) in Parliament.

## March

- Medicines Australia lodged a supplementary [submission](#) to the Pharmaceutical Patents Review.
- The [Medicines Australia 2013 Facts Book](#) was released.
- Medicines Australia attended the first meeting of the Codes of Conduct Advisory Group. The Advisory Group, established by Parliamentary Secretary Catherine King, is tasked with strengthening industry selfregulation of promotion across the therapeutic goods industry.
- Medicines Australia attended the first meeting of a revamped Clinical Trials Action Group (CTAG) Coordination Group. The Coordination Group is overseeing the implementation of the Australian Government's new [\\$9.9 million program](#) to expedite the implementation of the CTAG reforms.
- [Facing the Health of Australians](#), a report that reveals the views, attitudes, perceptions and concerns Australians have about their own current health status and that of their families, was released by the Australian Medicines Industry.
- The annual Medicines Australia Parliamentary Dinner was held at Parliament House on 20 March and was attended by close to 300 guests. Minister for Health, Tanya Plibersek, was guest of honour and John Young, Global President and General Manager of Primary Care at Pfizer Inc, and former Medicines Australia Chair, delivered the keynote speech. Speeches can be viewed on the [Medicines Australia website](#).
- The Senate Finance and Public Administration Committee announced that it would conduct an inquiry into Greens Senator Richard Di Natale's [Therapeutic Goods Amendment \(Pharmaceutical Transparency\) Bill 2013](#). The committee invited submissions from a range of stakeholders.
- The top achievers for 2012 in Medicines Australia's Continuing Education Program were recognised at a reception in Sydney. The [awards](#) were presented by AMA President Steve Hambleton.

- Brendan Shaw attended a meeting of the TGA Industry Consultative Committee (TICC). Agenda items included updates on the Blueprint for TGA Reforms, ANZTPA, compounding regulations, and the labelling and packaging review.

## April

- Medicines Australia lodged a [submission](#) to the Government's Post-Market Review of Pharmaceutical Benefits Scheme Medicines Used to Treat Asthma in Children. The submission reiterated industry's ongoing concerns surrounding the deficient reviews process.
- Medicines Australia held a managing directors' orientation and information session to discuss the Australian market and key priorities for the industry going forward.
- The Medicines Australia Board conducted a Board Retreat to review the industry's key priorities for the future. The Retreat built on input from the member briefings held in February.
- Interim chairman Mark Fladrich and Brendan Shaw met with Deputy Secretary of the Department of Health and Ageing, David Learmonth, for the first meeting for 2013 of the Access to Medicines Working Group (AMWG).
- Medicines Australia lodged a [submission](#) to the Senate Committee inquiring into the Pharmaceutical Transparency Bill 2013.
- Medicines Australia appeared before a public hearing into the Pharmaceutical Transparency Bill 2013. A transcript of the hearing is available on the Parliament [website](#).
- Medicines Australia lodged a submission in response to the Government's Pharmaceutical Patents Review draft report. The submission is available on the review's [website](#).

## May

- Medicines Australia representatives took part in the Charity Pollie Pedal ride hosted by Coalition leader Tony Abbott. The ride covered over 1000k's from Adelaide, through South Australia and Victoria, finishing in Geelong. The 2013 ride raised funds for [Carers Australia](#).
- Medicines Australia held member briefings in both Sydney and Melbourne, over 35 Member companies were represented with discussions concentrating on PBS, transparency, Patent Reviews, Budget, and Medicines Australia's priorities for the 2013 federal election.
- Medicines Australia hosted a Diabetes Roundtable review to discuss the post market reviews on products currently being used in the management of diabetes.
- Medicines Australia met with representative from the Department of Health and the Department of Industry to discuss on how PBS growth trends should be reported. Outcomes were reported to ministers at the PIWG Meeting.
- Medicines Australia and the Department of Health met to progress actions arising from the AMWG (Access to Medicines Working Group). It was agreed a subsequent workshop would be organised for Industry representatives and the Department to discuss the post market reviews process.
- Medicines Australia and the Department for Finance met to discuss price disclosure and its impact on the PBS as well as PBS growth trends.

- Medicines Australia supported submissions made from a number of member companies and also International counterparts in support of Medicines Australia position of the Pharmaceutical Patents review.
- The Pharmaceuticals Industry Council (PIC) made a submission to the Independent Hospital Pricing Authority (IHPA) on the development of a standard table of costs for conducting clinical trials in Australia. The submission is available on the [Medicines Australia website](#).
- Medicines Australia and industry representatives attended the 2013/2014 Federal Budget night where the Treasurer handed down the 2013-14 Federal Government Budget.
- Medicines Australia appeared before the Pharmaceutical Patents Review Panel. The hearing was in relation to the draft review and covered issues such as the importance of patent terms extensions.
- Medicines Australia publicly released its commissioned report from the Centre for Strategic Studies (CSES). The report, *The Impact of Further PBS*, reforms models the effect of further reforms over the next 5 years to 2017-2018 using data from 2010 to present. It also estimates on savings made from the 2007 PBS reforms. The report is made available on the [Medicines Australia website](#).
- Medicines Australia hosted a Managing Directors dinner to discuss the membership's strategic priorities for 2013-2014. Medicines Australia met with the Pharmaceutical Industry Working Group (PIWG). Agenda items included the Patents Review, Clinical trial reforms and PBS sustainability and trends. The findings from the recently released CSES report were also discussed.
- The Transparency Working Group held their final meeting and agreed in principle on a proposed transparency model on payment transfers of value to healthcare professionals in Australia.
- Medicines Australia released its federal election priorities document—*Medicines Now*. The document is available on the [Medicines Australia website](#).
- Medicines Australia attended the National Party Federal Council. Discussions focussed on PBS listing issues and the Medicines Australia election document.
- A Parliamentary Friends of Medicine event was held at Parliament House, co-sponsored by Boehringer Ingelheim and Novartis. It briefed MPs on the CSES report on the impact of PBS reforms and the value of medicines to the Australian community.
- Medicines Australia provided two submissions to the Therapeutic Goods Administration on mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI) and the feasibility of a new-to-market risk communication scheme for therapeutic goods.
- The Senate Finance and Public Administration Committee recommended that the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* not be passed by the Senate. Both Government and Opposition senators opposed the Greens' bill to impose a regulated Sunshine Act-style system of transparency on the industry and ban much company-doctor interaction.
- The House Select Committee on Social Policy and Legal Affairs recommended that Parliament pass the *Intellectual Property Laws Amendment Bill 2013*. Medicines Australia supports the Bill in its current form; among other things, it will implement the TRIPS protocol in Australia and clarify Crown Use provisions in the Patents Act.
- The Transparency Working Group released its transparency model for consultation and discussion with all stakeholders. The model consultation paper and the Principles for Transparency can be found here: [Transparency Working Group Webpage](#).
- Brendan Shaw participated in the Committee for Economic Development in Australia (CEDA) Health Update Forum in Melbourne, delivering a presentation to the forum titled "A long term focus for innovation, R&D and healthcare" a copy of the speech is available on the [Medicines Australia website](#).

## June 2013

- Medicines Australia met with the Parliamentary Friends of Diabetes to discuss the PBAC's post-market review of diabetes medicines.
- Medicines Australia met with various Parliamentarians and political staffers to brief them on the Medicines Australia election priorities.
- Medicines Australia met with senior officials from the Department of Health and Ageing to raise concerns about the conduct of PBAC post-market reviews and proposed a framework that would provide industry with more transparency and clarity when reviews are run.



## Conferences and Events



1. Medicines Australia's Chairman Mark Masterson addresses the National Press Club.
2. Guests listen to Minister for Health Tanya Plibersek at the Medicines Australia Conference Dinner.
3. Minister for Mental Health and Ageing Mark Butler MP shares his insights into policies relating to ageing in Australia.
4. Former media editor and current President of Alzheimer's Australia Ita Buttrose speaks at the Conference dinner.
5. Former Federal Minister Barry Cohen sets up a highly amusing debate on the topic *Living to 150—do we want it?*

### MEDICINES AUSTRALIA CONFERENCE

Over 240 delegates attended the Medicines Australia Conference on 23 and 24 October in Sydney. The conference, titled *Living Longer, Living Well: the role of medicines for an ageing Australia*, attracted representatives from industry, government departments and consumer groups, as well as pharmacists, medical practitioners, medical researchers and the media.

The conference was opened by Minister for Mental Health and Ageing Mark Butler MP, who provided a view from the Federal Government on the opportunities and challenges that come with a rapidly ageing population. The program that followed included presentations by keynote speaker Dr Richard Barker from the Oxford Centre for Accelerating Medical Innovations, PBAC chair Dr Suzanne Hill, and a number of speakers from academia and patient groups, and the launch by National Seniors Australia's Productive Ageing Centre of their report [Senior Australians and Prescription Medicines: Usage, Sources of Information, and Affordability](#). The day ended with a highly amusing and entertaining debate on the question *Living to 150—Do we want it?* facilitated by former Federal Minister, author and raconteur Barry Cohen.

The conference was preceded by a conference dinner which included stimulating presentations by President of Alzheimer's Australia Ita Buttrose and Minister for Health Tanya Plibersek MP. The insights they shared with the audience kicked-off the discussion that was continued the next day.

Information on the conference program and videos of speakers are available on the [Medicines Australia website](#).

### THE CHAIRMAN'S NATIONAL PRESS CLUB ADDRESS

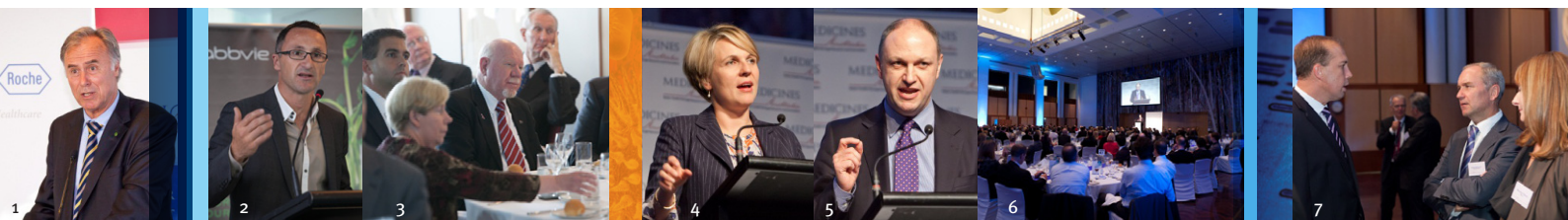
Medicines Australia's Chairman Mark Masterson delivered an address to the National Press Club before a live television audience on 5 December.

His address outlined a new vision for the Australian medicines industry, to double manufacturing output, export and R&D investment over the next decade.

Mr Masterson said that with the right policy settings, the medicines industry in Australia was ideally placed to harness the dramatic rise of Asia.

"We have a genuine, once-in-a-generation opportunity to grow the medicines industry into one of the key Australian high-tech industries that can lay the foundation for a new economy", Mr Masterson said.

The address is available on the [Medicines Australia website](#).



1. John Alexander MP introduces a Parliamentary Friends of Medicines briefing on biologic medicines.
2. Greens health spokesperson, Senator Richard Di Natale, addresses fellow parliamentarians.
3. Mal Washer MP (centre) listens to a Parliamentary Friends briefing on rare cancers.
4. Health Minister Tanya Plibersek assures the industry that she has heard "loud and clear" their need for stability and predictability in PBS policy at the Annual Parliamentary Dinner.
5. General Manager of primary care at Pfizer Inc., Mr John Young, lays out the case for pricing and procurement systems that reward innovation.
6. Dinner guests listen to the keynote speech.
7. Shadow Minister for Health and Ageing Peter Dutton chats with Board members Geoff McDonald (GSK) and Kirsten O'Doherty (AbbVie).

## PARLIAMENTARY FRIENDS OF MEDICINES

The Parliamentary Friends of Medicines Group is a non-partisan forum through which members of the medicines industry can interact with parliamentarians to discuss issues affecting industry and patients. The Group is chaired by John Alexander MP, Mr Shane Neumann MP (until March 2013), Senator Claire Moore (from March 2013) and Senator Richard Di Natale.

In 2012-13, Medicines Australia and individual member companies hosted four luncheon briefings for the Group. Topics covered included:

- Biologic medicines
- Targeting rare cancers
- Turning science into caring: Research and development from laboratory to patient
- Medicines Australia's election priorities.

## MEDICINES AUSTRALIA PARLIAMENTARY DINNER

Close to 300 guests from industry, parliament, Government and the broader healthcare sector gathered in the Great Hall at Parliament House for Medicines Australia's Annual Parliamentary Dinner on 20 March 2013.

Around 35 parliamentarians attended the dinner which explored the theme *Making lives better: From microscope to medicine*. Minister for Health Tanya Plibersek delivered the opening address and was followed by keynote speaker Mr John Young, global president and general manager of primary care at Pfizer Inc. Transcripts of the speeches are available on the [Medicines Australia website](#).

## Awards



1. Medicines Australia's Chairman Mark Masterson (right) and Pat Clear Award recipient Mendel Grobler from Pfizer.
2. Brendan Shaw presents the Health Journalist of the Year Award to Heather Wiseman.
3. Recipients of the Medicines Australia Continuing Education Program Awards.
4. Code of Conduct Award winner, Sharon Wong from Sanofi, receives her award from AMA President Steve Hambleton.

### 2012 PAT CLEAR AWARD

Mendel Grobler, Director of Access and Public Affairs at Pfizer Australia, was the recipient of the Pat Clear Award in 2012 for his ongoing commitment over several decades to improving access to medicines for Australians and to the development of the industry.

Mr Grobler has been a key contributor to the shaping of the policy environment for industry in Australia and an important adviser on major policy issues such as PBS reforms and the Memorandum of Understanding with the Commonwealth.

The Pat Clear Award recognises outstanding levels of commitment by an individual, group or team for the benefit of the Australian medicines industry. The award was established in 2002 to commemorate the substantial contribution Mr Clear made to the medicines industry in Australia during his 40-year career.

For more information on the Pat Clear Awards, visit the [Medicines Australia website](#).

### EXCELLENCE IN HEALTH JOURNALISM AWARDS

The annual Excellence in Health Journalism Awards were presented by Medicines Australia Chief Executive Brendan Shaw at the National Press Club on 4 December 2012.

Medicines Australia is the principal sponsor of the awards which 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.

*Australian Rural Doctor* journalist Heather Wiseman was named Health Journalist of the Year in 2012 for her article 'Mission for life' about one doctor's mission to dramatically lower the suicide rate in his community. Other Award winners were:

- Best News Feature, Article or Presentation; Health, Health Sciences or Innovation: Sarah Colyer (*Australian Doctor*) for 'Dark Corridors'.
- Best Documentary or Documentary Series; Health, Health Science or Innovation: Rahni Sadler and Penelope Cross for network seven program 'M.S.'
- Best Feature, Article or Presentation; Health Policy, Health Economics and Health Business: John Kron (*Australian Doctor*) for 'Where have all the new drugs gone'.
- Best News Feature, Article or Presentation: Health, Health Science or Innovation directed to medical professionals: Heather Wiseman (*Australian Rural Doctor*) for 'Mission for life'

Special Commendations went to:

- Liz Finkel (*Cosmos Magazine*) for 'Your genetic future'
- Amy Corderoy (*Sydney Morning Herald*) for 'Key to cure is evolution and revolution'
- Dr Maryanne Demasi (*ABC*) for 'Orgasm: The trouble with sex'
- Stephen Pincock (*Australian Doctor*) for 'Into the light'

For more information on the Awards, visit the [Medicines Australia website](#).

## CONTINUING EDUCATION PROGRAM AWARDS

Thirteen sales representatives from Medicines Australia member companies were honoured at the Continuing Education Program Awards ceremony in Sydney on 26 March 2013 where they received the industry's top accolades for ethical sales and marketing

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

### UNIVERSITY OF TASMANIA PRIZE FOR EXCELLENCE

CEP Course Facilitators at the University of Tasmania nominate one finalist from their program 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.



UTAS Prize for Excellence was presented to:

Ms Michalina Filipowicz from Lundbeck Australia (pictured receiving the award from Professor Greg Peterson, Professor of Pharmacy, University of Tasmania)

### CODE OF CONDUCT AWARD

Finalists for the Code of Conduct Award include all students who achieve a final mark of 100% for Program 1.

- Excludes anyone who has achieved 100% final mark via resubmission or supplementary assessment.
- Among finalists, the winner is determined through review of learning log book and online participation by UTAS panel; MA to make final decision if it is difficult to identify a clear winner.



The Code of Conduct Award was presented to:

Ms Sharon Wong from Sanofi (pictured receiving the award from AMA President, Dr Steve Hambleton).

### CEP ACHIEVEMENT AWARDS

CEP Achievement Award winners are the students who achieve the 10 highest aggregate marks for the five core programs (out of a possible total aggregate of 500).

Program 3 Human Anatomy and Physiology is not included in the aggregate calculation as not all students are required to undertake this program.

The award evaluation excludes anyone who has achieved their marks via resubmission or supplementary assessment.

CEP Achievement Award recipients in 2012-2013 were:

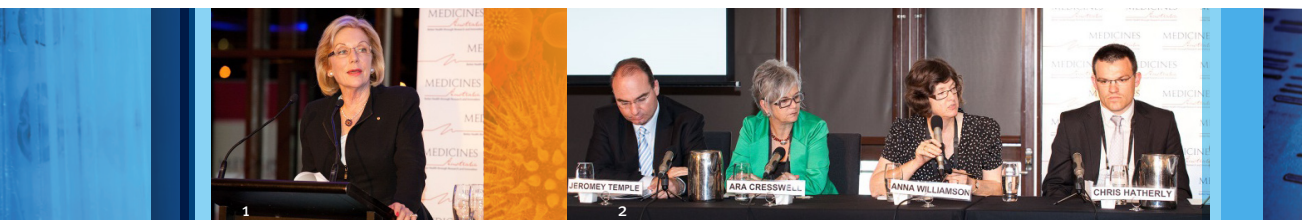
- Ms Helen Duck – GlaxoSmithKline
- Ms Jessica Ellershaw – Pfizer
- Mr Rodney Foong – Novartis
- Mr David Tran – Boehringer Ingelheim
- Mr Blessed Ramos – GlaxoSmithKline
- Ms Rachael McGregor – Abbott
- Ms Clair Morris – Sanofi
- Ms Sharon Elliott – AstraZeneca
- Ms Jamie Gunther – Merck Sharp and Dohme
- Ms Andrea Blank – Boehringer Ingelheim
- Ms Sally Bishay – Merck Sharp and Dohme

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

For more information on the Continuing Education Program, visit the [Medicines Australia website](http://www.medicinesaustralia.com.au).



## Working with the community



1. Ms Ita Buttrose AO OBE, President of Alzheimer's Australia, speaking at the 2012 MA Conference Dinner.

2. HCO representatives on the panel for the 2012 Medicines Australia Conference session 'Ageing better and the role of medicines: patient perspectives'.

Health consumer organisations (HCOs) and the industry have collaborated for many years in areas of mutual interest with regard to the needs of health consumers and improving health outcomes. The voice of the health consumer is widely acknowledged as contributing valuable insights into the health policy debate, reinforced by public comments, funding, and engagement from government.

The greater rigour now being applied to how these relationships are being established (based on the [Working Together Guide](#)) is a positive step. The *Working Together Guide* contains the basic framework from which industry should engage with consumer groups and organizations. The key principles for any engagement are: honesty, integrity, trust, and respect. Underpinning these principles is:

- Respect for independence
- Achieving and maintaining public trust
- Fairness
- Openness and transparency
- Accountability

Over the past year the Medicines Australia HCO working group has been in contact with many HCOs delivering key messages on behalf of the industry, and encouraging these organisations to take action on certain issues of mutual relevance to both the industry and health consumers.

Through 2012-13 Medicines Australia continued to support a range of partnerships between industry and HCOs that encouraged collaborative work in a number of areas. Partnerships that Medicines Australia supported included the Arthritis Australia Community Chest, the Heart Foundation Pharmaceutical Roundtable and the Mental Health Council Pharmaceutical Collaboration.

Medicines Australia engaged with a broader range of HCOs through 2012-13 on a range of issues and as part of a more general contact plan. Assisting HCOs with queries on different policy issues and industry's views on these has been a key part of the program through 2012-13. This work was supported by the Health Consumer Organisations Working Group and the Reputation Committee.

HCOs took an active role in the 2012 Medicines Australia industry conference in Sydney. Many attended and actively participated in the event. Ms Ita Buttrose AO OBE, President of Alzheimer's Australia, was a guest speaker at the Conference Dinner. Consumer Health Forum CEO, Carol Bennett, chaired a session on 'Ageing better and the role of medicines: patient perspectives' which had several consumer representatives on the panel.

## Working with our Members

### STRATEGIC COMMITTEES AND WORKING GROUPS

\* Committee and working group representative companies are current at 30 June 2013. 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 Access, Regulatory Affairs and Vaccines.

##### Members at 30 June 2013:

- Michelle Burke . . . . . Bristol-Myers Squibb, Co-Chair
- Elizabeth de Somer . . . . . Medicines Australia, Co-Chair
- Sue Alexander . . . . . Roche
- Alissa Brown . . . . . Sanofi
- Andrew Carter . . . . . Commercial Eyes
- Steve Crowley . . . . . Janssen
- Mendel Grobler . . . . . Pfizer
- David Herd . . . . . GlaxoSmithKline
- Sara Pantzer . . . . . Amgen
- Christian Sellars . . . . . MSD
- Peter Vermeer . . . . . Eli Lilly
- Charles Waterfield . . . . . AstraZeneca

#### 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 2013:

- Sue Alexander . . . . . Roche Products, Co-Chair
- Elizabeth de Somer . . . . . Medicines Australia, Co-Chair
- Helen Critchley . . . . . Sanofi
- Brian Hewitt . . . . . Pfizer
- Elizabeth Joshi . . . . . Bayer
- George Lillis . . . . . Novartis
- Anastasia Moisidis . . . . . BioCSL
- Michael Parker . . . . . AstraZeneca
- Mark Rowland . . . . . Amgen
- Ron Sinani . . . . . Shire
- Elizabeth Thompson . . . . . Abbott

#### 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 2013:

- Greg Cook . . . . . Bristol-Myers Squibb, Co-Chair
- Alissa Brown . . . . . Sanofi
- Susan Phillips . . . . . Commercial Eyes
- Peter Germanos . . . . . Boehringer Ingelheim

- Geoffrey Chin . . . . . Novartis
- Louise Graham . . . . . Amgen
- Gary Hamann . . . . . Servier
- Julie Van Bavel . . . . . MSD
- Jodie Thomas . . . . . Eli Lilly
- Alison Wright . . . . . Janssen
- Carlene Todd . . . . . Roche

#### PBS Reform Access 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 2013:

- Mendel Grobler . . . . . Pfizer, Co-Chair
- Greg Cook . . . . . Bristol-Myers Squibb
- Steve Crowley . . . . . Janssen
- David Grainger . . . . . Eli Lilly
- David Herd . . . . . GlaxoSmithKline
- Christian Sellars . . . . . MSD
- Mike Smith . . . . . AstraZeneca

#### 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 2013:

- Alissa Brown . . . . . sanofi, Co-Chair
- Andrew Wheatley . . . . . Janssen
- Jodie Wilson . . . . . Abbott
- Steve Quinn . . . . . Amgen
- Michael Haberl . . . . . GSK
- Jonathan Tan . . . . . Allergan
- Carolyn Cameron . . . . . Novartis

#### 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 2013:

- Louise Carter . . . . . GlaxoSmithKline, Co-Chair
- Elizabeth de Somer . . . . . Medicines Australia, Co-Chair
- Helen Concilia . . . . . CSL
- Lauren Conyer . . . . . Pfizer
- Christoph Kaufmann . . . . . Novartis
- Andrew Shelton . . . . . Sanofi
- Tony Shelton . . . . . Baxter
- Paul Vilner . . . . . Abbott

## Reputation Strategic Committee

### Key capabilities:

Provides reputation management, communication strategy, issue 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 2013:

- Lisa Maguire . . . . . GlaxoSmithKline, Co-Chair
- Dominic Barnes . . . . . Shire, Board sponsor
- Stuart Englund . . . . . Eli Lilly
- Robert Gunning . . . . . AstraZeneca
- Sharon McHale . . . . . CSL
- Lee McKerracher . . . . . Pfizer
- Maida Talhami . . . . . MSD

## 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.

The Group 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 2013:

- Sara Pantzer . . . . . Amgen, Co-Chair
- Andrew Simpson . . . . . Medicines Australia, Co-Chair
- Karen Barfoot . . . . . Bristol-Myers Squibb
- Sam Crosby . . . . . Janssen
- Stuart Englund . . . . . Eli Lilly
- Jodie Jansen . . . . . GSK
- Cameron Milliner . . . . . Abbott
- Kieran Schneemann . . . . . AstraZeneca
- Todd Stephenson . . . . . Roche
- Patrick Tung . . . . . Merck Serono

## 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 for 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 2013:

- Neil Wildman . . . . . Pfizer, Co-Chair
- Kris Ashpole . . . . . Janssen
- Zarli French . . . . . MSD
- Holly Kania . . . . . Roche
- Peter Murphy . . . . . Novartis
- Anna Karelas . . . . . Bayer Healthcare

## 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 2013:

- Lisa Maguire . . . . . GlaxoSmithKline, Co-Chair
- Libby Day . . . . . Baxter
- Adrian Dolahenty . . . . . Bayer
- Helen Corcoran . . . . . Pfizer
- Joanne Galea . . . . . Janssen
- Robert Gunning . . . . . AstraZeneca
- Lisa Julian . . . . . Eli Lilly
- Emma Keogh . . . . . Boehringer Ingelheim
- Petra Rosen . . . . . Abbott

## 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 2013:

- Deborah Monk . . . . . Medicines Australia, Co-chair
- Duncan Purvis . . . . . Janssen, Co-chair
- Graeme Blackman . . . . . IDT Australia, Board sponsor
- Alex Condoleon . . . . . sanofi
- Luke Cornish . . . . . MSD
- Tim Donald . . . . . PricewaterhouseCoopers
- Beata Niechoda . . . . . Shire
- Ian McKnight . . . . . Leo Pharma
- Bill Ketelbey . . . . . Pfizer
- Joyce Lloyd . . . . . Pretium

## 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 Trade Related Intellectual Property Rights (TRIPS) commitments.

### Members at 30 June 2012:

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

## Inside Medicines Australia



1 Mr Mark Masterson addresses delegates at the Annual General Meeting



2 Mr John Latham, Chair of the Finance and Audit Committee, presenting the Financial Report to members at the Annual General Meeting.

### MEDICINES AUSTRALIA BOARD MEETINGS

Sixteen meetings of the Medicines Australia Board were held in 2012-2013:

- 9 August 2012, via teleconference
- 4 September 2012, Melbourne
- 11 September 2012, via teleconference
- 28 September 2012, via teleconference
- 12 October 2012, via teleconference
- 23 October 2012, Sydney
- 4 December 2012, Melbourne
- 20 December 2012, via email
- 19 February 2013, Melbourne
- 4 March 2013, via email
- 20 March 2013, Canberra
- 3 April 2013, via teleconference
- 12 April 2013, Canberra (Board Retreat)
- 14 May 2013, Canberra (Federal Budget Night)
- 3 June 2013, via teleconference
- 25 June 2013, Canberra

### Finance & Audit Committee

- 1.1 Review the monthly financial statements of Medicines Australia Limited and provide advice and guidance to how finances are reported to the Board.
- 1.2 Review the draft annual budget of Medicines Australia Limited as developed by the Secretariat and provide advice and guidance on how the annual budget is presented to the Board.
- 1.3 Review the audited annual financial statements of Medicines Australia Limited and provide 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.

### Members:

- Mr Chris Hourigan, Chair (from December 2012, Chair from April 2013)
- Mr Jason Smith (from October 2012)
- Mr Shaju Backer (from April 2013)
- Mr Chris Miskel (from February 2012 – January 2013)
- Mr Miskel became Chair of the Finance and Audit Committee November 2012.
- Mr John Latham, Chair (from June 2007- December 2012)
- Mr John Latham stood down as chair, pending his resignation from the Board in December 2012.
- Mr Bruce Goodwin (from June 2012 – September 2012)

### Meetings:

3 September 2012	4 December 2012	4 April 2013
14 November 2012	13 December 2012	23 May 2013
27 November 2012	11 February 2013	

### Nominations Committee

- 1.1 Identify and make 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.
- 1.2 Identify suitable people who might be nominated for the Board or its Committees.
- 1.3 Develop the policy and procedures for determining when recruitment of a Selected Director is required and conduct the recruitment process for recommendation to the Board
- 1.4 Ensure 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.

### Members:

- Dr Graeme Blackman, Chair (from February 2010 – September 2013)
- Mr Mark Fladrich (from September 2012)

### Meetings:

10 September 2012	19 November 2012	28 February 2013
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## Remuneration & Governance Committee

- 1.1 Monitor and evaluate Board Performance including duties and responsibilities of Directors, the time required to perform effectively and the range of legal liabilities applying to Directors.
- 1.2 Monitor and evaluate Chair performance and where there is an Independent Chair, make recommendations on the appropriate level of remuneration.
- 1.3 Be a consultative body for the Chief Executive on matters he/she seeks advice and guidance that are specific matters delegated to the Chief Executive.
- 1.4 Monitor and evaluate the Chief Executive performance and make recommendations on the appropriate level of remuneration.
- 1.5 Approve the remuneration of senior managers who are direct reports to the Chief Executive.

### Members:

Mr Mark Fladrich, Interim Chair (from February 2013)  
 Mr Chris Hourigan, Chair Finance & Audit Committee (from April 2013)  
 Mr Geoff McDonald (from October 2012)  
 Mr Mark Masterson, Chair (from May 2012 – February 2013)  
 Mr John Latham (from February 2010 – December 2012)  
 Mr Ian Thompson (from September 2011 – 1 August 2012)

### Meetings:

4 July 2012	5 February 2013	24 June 2013
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## MEDICINES AUSTRALIA MEMBER MEETINGS

There was one meeting of members in the 2012-2013 financial year.

- The Annual General Meeting was held on 23 October 2012, Four Points by Sheraton, Darling Harbour.
  - The Chair presented the Annual Report of Medicines Australia
  - The Chair of the Finance and Auditor Committee presented the Financial Statements and Directors' Report to members
  - Moore Stephens was appointed as Company Auditor
  - Ms Deborah Monk presented the Code of Conduct Annual Report to members
  - Mr Mendel Grobler, Pfizer Australia, was awarded the Pat Clear Award 2012

## MANAGING DIRECTORS DINNERS

Medicines Australia held three Managing Directors dinners during the year.

### AUGUST

Medicines Australia hosted Managing Directors' Dinners in Melbourne and Sydney to discuss progress on the implementation of the MoU with Government and the evolving policy landscape.

### NOVEMBER

Medicines Australia Managing Directors dinner was held in Sydney with guest speaker Malcolm Farr, National Political Editor at News.com.au.

### MAY

Medicines Australia hosted a Managing Directors dinner to discuss the membership's strategic priorities for 2013-2014.

## ORGANISATION RE-STRUCTURE

As part of the re-alignment of Medicines Australia's strategic priorities and to gain operating efficiencies, a number of internal changes were made to Medicines Australia's organisational structure, with effect on 17 June 2013.

Changes to the organisation include combining the previously separate policy and public affairs functions, together with other efficiencies in the operation of the organisation. This will allow Medicines Australia to target its operational effort to the key priority areas whilst managing constrained resources as a result of the downturn in the industry.

Since the restructure, Medicines Australia has three teams: Policy & Advocacy; Corporate Services; and Compliance (Medicines Australia Code of Conduct).

As part of this restructuring it has been necessary to reduce the organisation's size and scope, including a reduction in total headcount from 23 down to 19 and a reduction in the seniority of a number of positions.

The changes will help Medicines Australia to adjust to the tough operating environment facing our members and put us in good stead to progress the priorities for the industry in the coming years.

The Board is working with the Secretariat to prioritise key activities and strategic directions going forward.

## Secretariat

### Departing staff:

Mr Andrew Bruce (August 2012)  
 Mr James Turnley (August 2012)  
 Ms Zoe Morton (September 2012)  
 Mr James (Jim) Crompton (October 2012)  
 Ms Louise Collett (December 2012)  
 Mr Mathew Munro (March 2013)  
 Ms Di Phillips (March 2013)  
 Ms Julie Johnson (May 2013)  
 Ms Kayla Calladine (June 2013)  
 Ms Donna Edman (June 2013)  
 Mr Amish Chaturvedi (June 2013)  
 Mr Jamie Nicholson (June 2013)  
 Ms Prya Sonah (June 2013)  
 Ms Diana Terry (June 2013)

### New staff:

Mr Samuel Devlin (October 2012)  
 Ms Karen Patten (October 2012)  
 Mr Mathew Munro (January 2013)  
 Ms Kayla Calladine (February 2013)  
 Ms Clair Petrie (March 2013)  
 Ms Caroline Wood (March 2013)

## Medicines Australia Publications

### PUBLICATIONS AND REPORTS

- *Medicines Australia Facts Book: Third Edition – Update* (March 2013)
- *Report on Research Governance Timelines in Australia* (April 2013)
- *Report on Industry Sponsored Clinical Research in Australia* (October 2012)
- *The Impact of Further PBS Reform: Report to Medicines Australia* (May 2013)
- *Code of Conduct Educational Event Reports* (1 April – 30 September 2012; 1 October – 31 March 2013)
- *Code of Conduct Quarterly Reports* (July – September 2012; October – December 2012; January – March 2013; April – June 2013)
- *Code of Conduct Annual Report – October 2012*

### SUBMISSIONS

Submissions are available on the [Medicines Australia website](#).

- May 2013 – PIC/Medicines Australia submission to the Independent Hospital Pricing Authority on the development of a table of standard costs for conducting Clinical Trials in Australia
- April 2013 – Medicines Australia Submission To The Pharmaceutical Patents Review Draft Report
- April 2013 – Medicines Australia submission to the Therapeutic Goods Administration discussion paper entitled *The Trans-Tasman early warning system: how the process will work in Australia and New Zealand*
- April 2013 – Medicines Australia submission to the Senate Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013
- April 2013 – Medicines Australia submission to the Post Market Review of PBS Medicines to Treat Asthma in Children
- March 2013 – Medicines Australia Supplementary Submission to the Pharmaceutical Patents Review
- February 2013 – ANZTPA/Medicines Australia submission to the Therapeutic Goods Administration on the TGA/ MedSafe consultation on the *Description of a possible joint regulatory scheme under ANZTPA*
- February 2013 – Medicines Australia submission to the Productivity Commission's Draft Report on Compulsory Licensing in Australia
- January 2013 – Medicines Australia submission to the Pharmaceutical Patents Review
- November 2012 – Medicines Australia submission to IP Australia's Review of the Innovation Patent System in Australia
- October 2012 – Medicines Australia submission to the Strategic Review of Health and Medical Research in Australia's Draft Recommendations
- September 2012 – Medicines Australia submission to IP Australia on the Draft Intellectual Property Laws Amendment (TRIPS Protocol) Bill 2012
- September 2012 – Medicines Australia submission to the Productivity Commission's Review of Compulsory Licensing in Australia
- September 2012 – Medicines Australia submission to the Treasury Business Tax Working Group's Review of Australia's Business Tax System