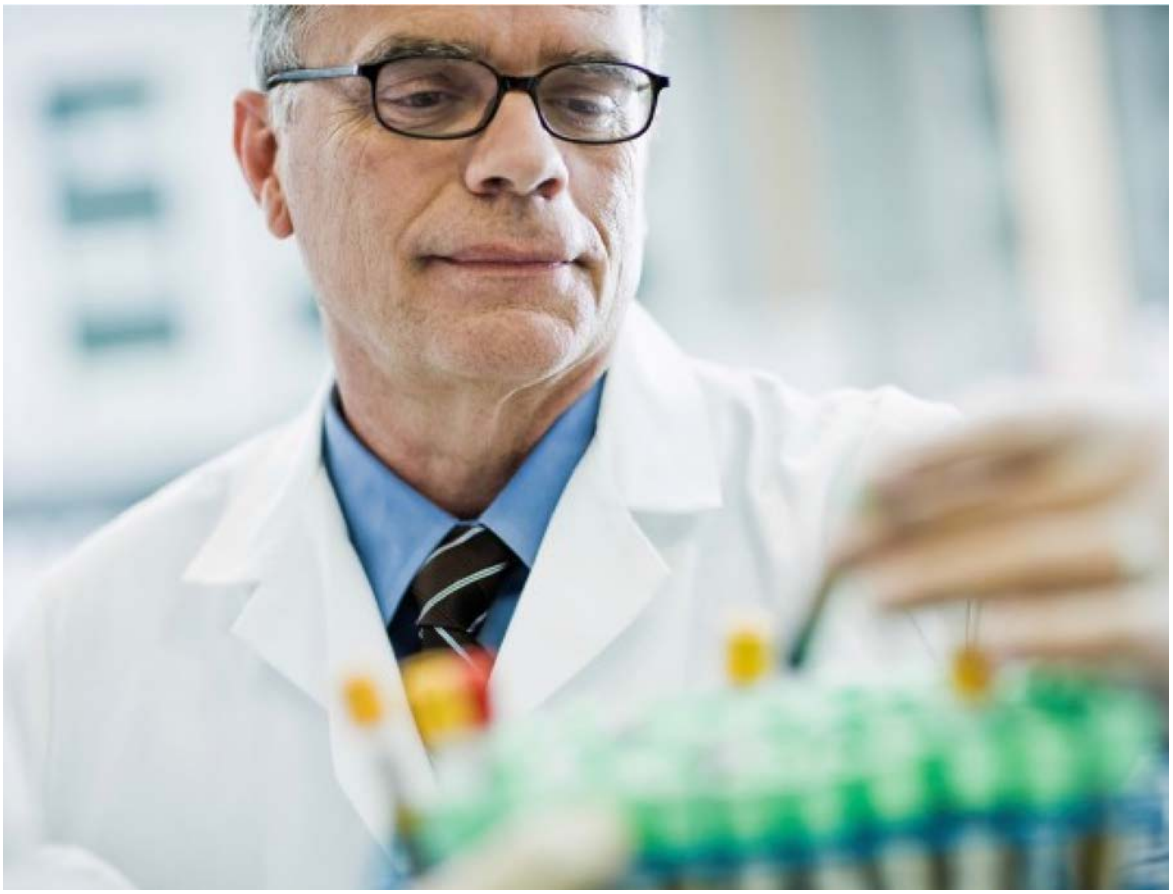
Since our last Pharma Industry survey in 2010, we have witnessed a period of change, reform and uncertainty with new pressures and challenges for industry; but industry participants have also demonstrated adaptability, resilience and a positive vision of the future

Issues and Decisions

A Report on the Australian Pharmaceutical Industry



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As well as reporting on the 2012 picture, we include in this report comparisons with trends we discovered in 2010 and with our global projections in PwC's Pharma 2020 series.

Welcome

John Cannings OAM
Pharmaceutical & Life Sciences Sector Leader
PwC Australia

PwC's pharmaceutical sector is dedicated to providing the industry with valuable strategic insights as well as leading service.

This is PwC's third survey of the Australian pharmaceutical industry, the first in conjunction with Medicines Australia, and we are pleased to present our findings in this report – '*Issues and Decisions*'.

Our goal is to assist the Australian industry, as well as regulators and governments, with up-to-date information that supports sound business strategy and public policy development.

We undertook a confidential survey of a wide cross-section of industry participants between December 2012 and March 2013 to prepare this report. The current and emerging issues that we identify have evolved and escalated from trends already apparent in recent PwC industry reviews across the globe.

Survey respondents represented companies engaged in activities ranging from sales & marketing to manufacturing, research and development (R&D), distribution, wholesaling, retailing and services.

Our survey respondents represent:

- 17 of the top 20 pharmaceutical companies in terms of PBS value (78%);
- 14 of the top 20 pharmaceutical companies in terms of total PBS volume (72%)
- Over $7.1Bn of the $9Bn pharmaceuticals market in Australia.
- Over 139,575,577 scripts dispensed;
- Employers of over 13,000 people across Australia.

This Report follows the global projections we made *in Pharma 2020 – The vision* which was based on our 2007 global industry survey, our 2008 publication titled *'Issues and Challenges'* and our 2010 survey and report *'Issues & Opportunities'*, which reviewed risks and opportunities in the Australian pharmaceutical sector at that time.

In this Report, as well as reporting on the big picture of the Australian pharmaceutical industry, we include comparisons with trends we discovered in 2010 and with our global projections in the Pharma 2020 series (the Pharma 2020 series is set-out on page 32 of this report).

This is a critical time for the industry, with a wide range of new regulations, health reforms and demographic trends occurring. The Report represents and reflects the current views and concerns across the industry, identifies emerging issues and trends requiring attention and examines how different segments are responding and dealing with these trends.

We hope that the analysis and informed views we provide will assist industry participants. Please feel free to contact me if you would like to know more about how we can help your business to manage and thrive amid these current and future challenges.

John Cannings OAM
Pharmaceutical & Life Sciences Sector Leader
PwC Australia

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Foreword

Dr Brendan Shaw
The Chief Executive of Medicines Australia

It's no secret that the Australian medicines industry is going through tough times. Globally, the industry is having to grapple with changing business models, a more competitive market, major patent expiries, shifting technology, constrained budgets, increasing scrutiny from payers and regulators, and fundamental questions being raised about the validity of what the industry does. Australia has not been immune from these pressures. Many of the challenges the industry is facing around the world are being replayed here in Australia and it is incumbent upon the industry to collectively articulate the value of what it does and the issues it needs to pursue.

This is why this survey by PwC is particularly pertinent. It comes at a time when the industry is grappling with a range of issues here in Australia, not least of which is the tough reimbursement environment. Overwhelmingly the Australian medicines industry has signaled its frustration with a system that appears to be getting more difficult to navigate for various reasons. Against the backdrop of major price reductions and restructuring, the difficulties in delivering new medicines and vaccines are a major disappointment. The reforms to the Pharmaceutical Benefits Scheme over the last 10 years or so were always about generating more competition and savings in the off-patent market to provide headroom for new medicines to be listed on the PBS and made available to Australians. While the savings are being delivered, there is still some way to go to securing the timely access to new medicines and vaccines that Australians demand.

The survey also highlights the industry's changing fortunes in areas such as the transparency of its operations. Clearly the world is changing here, and companies are having to grapple with changing community expectations about what companies do and how they report what they are doing. The industry has rightly identified this as both a challenge and an opportunity. If the industry can rise to the challenge of providing the information the community wants, it can use this to better explain the value it adds to the health system generally.

Innovation is a fundamental part of what drives this industry and this comes through in the survey. Whether it is the importance of respecting and rewarding intellectual property, or responding to the opportunities from greater collaboration with public sector researchers, the critical role that innovation plays in this industry is evident in the response Australia's medicines companies have provided in this survey. It is testament to what the Australian industry has achieved and what potential there is to build on further. Already the industry is one of the leading R&D performers in the Australian economy and each year earns Australia more money exporting medicines than the country earns in exporting cars or wine. There are a world of opportunities for the Australian medicines industry to further develop if we can get environmental and policy settings right.

The PwC survey provides a great snapshot of the views of the Australian medicines industry and the issues the industry faces. It also provides a roadmap for how to resolve these issues and help improve the business environment for the industry in the future.

I congratulate PwC on the report and commend it to you.

Dr Brendan Shaw
Chief Executive
Medicines Australia

The biggest issue in the last two years is the growing uncertainty and unpredictability of access to new drugs and the pricing of those new drugs.

Executive summary

"The PBS listing process has slowed substantially – especially for medicines with high sales (cost to government) forecasts. There now appears to be little certainty over the listing process, with decisions made based largely on cost, as opposed to the previous cost/benefit test."

Survey Respondent

60% of our survey participants see future growth in the market

Since PwC's last Pharma Industry survey in 2010, we have witnessed a period of change, reform and uncertainty with new pressures and challenges for industry; but industry participants have also demonstrated adaptability, resilience and a positive vision of the future.

The biggest issue in the last two years is the growing uncertainty and unpredictability of access to new medicines and the pricing of those new medicines. Access has, for the majority of respondents, become more difficult – the financial reward has decreased while cost and regulatory burden has increased; industry members are feeling the pinch.

This is set within a context where the financial pressure on government has impacted the environment for the Pharma industry. With an imperative to fund new policies and advance reforms in education, disability and health, the industry must compete with other priorities within a difficult economic environment.

A result of this, clearly identified by survey participants, is a lack of efficiency of processes, as the attention of Government is diverted; regulatory and other bodies were assessed as bureaucratic and slow. The impact of deferrals, delays and red tape are job losses, reduced investment and the withholding of access to medicines for consumers.

With the number of major submissions getting through PBAC on first application approaching zero, and with some having to apply up to four times before they satisfy the reviewer, negativity around PBAC, its predictability and access, was a major theme of discussion by respondents to the survey.

Another prevalent theme of respondents was a desire for transparency in government processes and its regulatory regimes, with an overall aim of improving patient outcomes. Many questioned how they could improve demonstrating value to consumers and Government, how to build better relationships and how to shift the Government's focus from costs and budget impacts to better health outcomes.

Patent expiries, as exemplified in 2012 by the blockbuster drug atorvastatin, and the introduction of a direct-to-pharmacy supply model were two of the largest developments over the last two years for the Australian Pharma industry. Other developments were the Government's deferral decision, the expanded and accelerated price disclosure amendments to the PBS and the number of therapeutic group reviews being undertaken.

Still, the Pharma industry shows resilience. Their profits and growth are positive; 60% of survey participants see growth in the market. In response to these changes, the clear view is that they are prepared to adapt, but want a level of certainty so they can adapt and respond to these industry developments. They are now focusing more on their consumers, not just selling products, but providing patient support programs and trying to engage them as communities of consumers. They are exploring new collaborations, new pipelines, innovation and the use of mHealth and other opportunities such as health outcomes data to ensure their health and dynamism into the future.

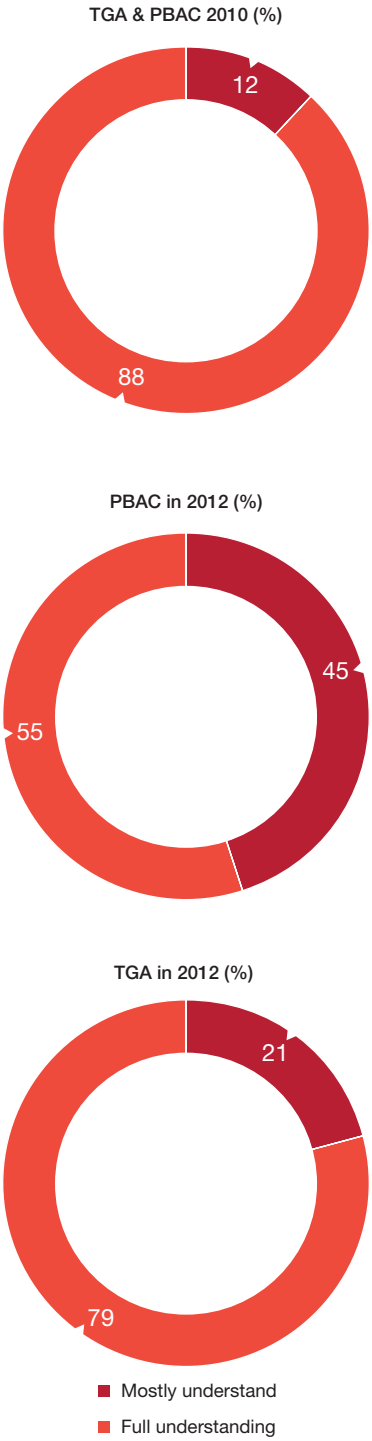
Findings

Reforms to the TGA and PBAC have resulted in limited or no improvement for patients or industry.

Regulation and access

Industry participants consider that reforms to the TGA and PBAC regimes have resulted in limited or no improvement for patients or industry; confidence in them has fallen over the last two years. Greater collaboration between regulatory bodies and a more streamlined regulatory approach is required to improve access for patients.

Understanding of regulatory regimes:



In 2010, the Australian pharmaceutical industry expressed strong confidence in their understanding of the TGA and PBAC regimes. Over the last two years, this confidence has fallen, indicating that this period of reform has led to more uncertainty.

The previous survey indicated 88% who fully understood the regimes with 12% who mostly understood. Understanding of the TGA regime is slightly less than in 2010, but understanding of the PBAC regime has fallen significantly. This year's survey disaggregated the regimes, resulting in 79% who fully and 21% who mostly understand the TGA regime, and 55% who fully and 45% who mostly understand the PBAC regime (nil responded with 'none' or 'limited' understanding).

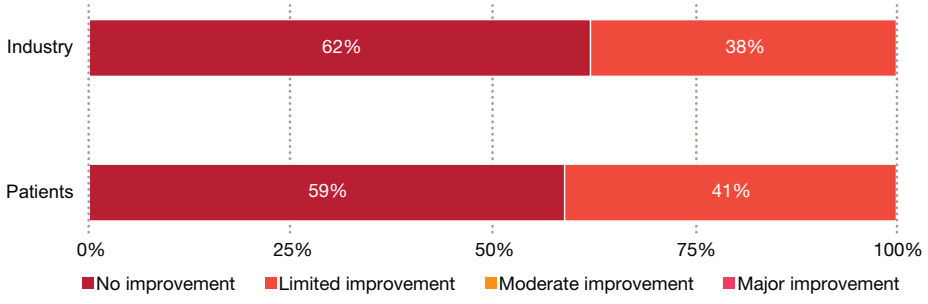
While respondents were generally positive about reforms in 2010, observations of their implementation over the last two years has seen any positive assessment disappear. Reforms to PBAC are clearly seen by respondents as a failure. No major or moderate improvements are considered to have taken place for industry or patients; the majority of respondents assessed that no improvements were made. TGA reforms were seen in a marginally better light, though most assessed them as resulting in limited or no improvement, with a small percentage considering that moderate improvement was achieved for industry (14%) and patients (5%).

In response to these concerns, respondents made clear and emphatic their recommendations around process improvement, consistency and timing. They asked for:

- More and greater transparency in processes, and less bureaucracy
- Appropriate resourcing for the TGA to meet their timelines and milestones
- Reduced and predictable timelines, and the introduction of fast-track mechanisms for breakthrough drugs.

As in 2010, it was recommended that harmonisation with overseas submissions and regulatory bodies in North America and Europe for regulation and pricing would improve efficiency and consistency, and minimise duplication and delay.

To what extent did the current Government reforms to PBAC improve access?



Comparator erosion

For the pharmaceutical industry, comparator erosion refers to situations where a new medicine has greater difficulty in demonstrating cost-effectiveness when compared with older medicines, due to price reductions in older generic medicines that are used as comparators against the 'new' medicine. These price reductions in older generic medicines, driven by changes in Government policy like the introduction of Price Disclosure, have the effect of making it more difficult to have new medicines recommended for listing on the PBS. That is, this occurs not due to any changes in the clinical effectiveness or any increase in price in the new medicine.

The introduction of Price Disclosure in Australia in 2007 has led to major price reductions for a range of older medicines, making it more difficult for companies to bring new medicines onto the PBS when compared in price alongside those older medicines which are subject to price disclosure.

Regulatory burden

Survey respondents indicated slightly more regulatory burden in 2012 than 2010, particularly relating to the Medical Services Advisory Committee and Human Research Ethics Committees; this indicates that they are spending more time addressing these regulations.

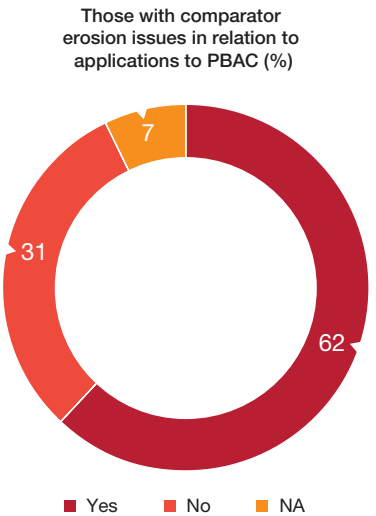
Comparator erosion

Some respondents feel that the listing process is not working, and is preventing health benefits from reaching consumers by a too stringent application of categories that prevent some pharmaceutical innovations being considered in F1.

62% of survey respondents indicated that they were affected by the comparator erosion issue in relation to their applications to PBAC. 31% were not affected and the question was not applicable to the remaining 7%.

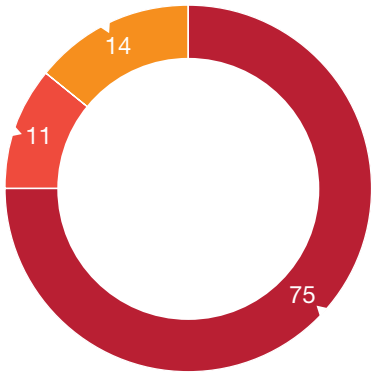
Comparator erosion is a key issue of concern for survey respondents, with one calling it 'the most serious issue that will have a devastating impact on the industry in the future'. It is an ongoing issue for pharmaceutical companies' R&D, and has affected both originator and generic sides of businesses. While it has not affected some companies, many see that it might in the future.

Related to this issue are examples of new formulations of existing F1 drugs that are brought into the market and are viewed as being 'incorrectly' treated as a new brand, triggering movement to F2 and a price reduction. An example cited was of a new delivery device to benefit people with diabetes. This technological improvement was not considered as F1 (although the device is delivering a medicine that is in the F1 category and was still under an existing patent) and was classified as F2 with an automatic 16% price reduction.

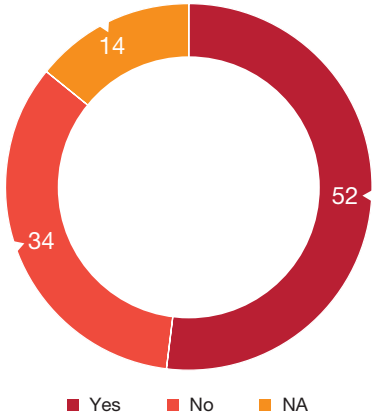


75% of survey respondents have products which are not being listed on the PBS given the current PBAC approval rates and price conditions.

Extent to which products are not being listed on the PBS in 2012 (%)



Rate of products being withdrawn or not applied for reimbursement in 2012 (%)



Lower return for companies

Respondents said that comparator pricing was resulting in lower returns for companies and that this, combined with a lack of transparency and clarity in processes, is resulting in companies reconsidering whether to even list their products in Australia. It affects a range of new products in various therapeutic areas, and may prevent research into areas such as antimicrobial drugs. As mentioned above, many respondents were of the view that Australian patients may not be benefiting from technological advances if products are withheld due to price pressure or financial non-viability caused by the 16% price reduction applied when a line extension of an originator brand is launched.

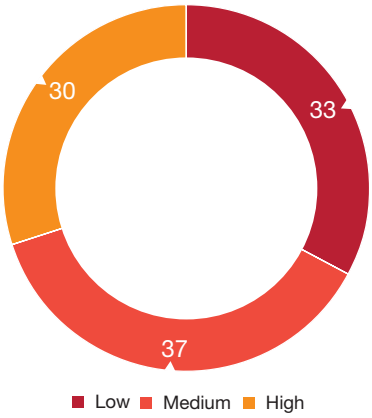
Recent experience with PBS

In describing their experiences with the PBS listing process in the last 12 months compared to the previous 1–5 years, survey respondents were generally extremely negative. While a minority described a positive or neutral experience, others found faults in their interaction with the PBAC, the process (notwithstanding the recent reforms) and the results. Interactions were described as less pragmatic and less constructive. The process was seen as slow and ad hoc and not always dispassionate; instead they were referred to as adversarial, painful and difficult. The process was seen as more conservative, and with an increased focus on financial impacts with the result being an erosion of access for patients and industry, and a strong sense of frustration.

Products withdrawn or not applied for reimbursement

A majority of survey respondents (52%) indicated that they had withdrawn products from submission or had not applied for reimbursement for new products. This was principally due to the company believing that they would not achieve either reimbursement success or the target price through the PBS submission process. Of the 34% who indicated that they had not withdrawn products, some indicated that they are not currently launching a new product but this may be an issue in the future.

Quality of PBAC responses in 2012 (%)



Quality of PBAC responses

Survey respondents gave a number of examples of new products that are not being brought to Australian consumers through the PBS. Instead, many of these products have been introduced as private prescriptions. Some companies are simply considering the bottom line: Will the price be sufficient to make a profit? But an equal number find the lack of consistency and the burden of the approval process enough to deter them for applying for PBS listing.

Survey respondents can be divided into three categories in terms of their ratings of the quality of the PBAC reimbursement evaluation and decision-making processes for independently assessing and reflecting the clinical attributes of their relevant product. Roughly a third each assessed it as 'high' or 'moderate quality' with the remaining third rating it as 'low quality'.

Canvassing government?

To address the issues described above, survey respondents were generally proactive in canvassing new ideas with Government in 2012, with about three-quarters responding they had done so.

However, in general, they felt they had little influence and saw limited impact, even if lobbying was through Medicines Australia, the industry body. A perceived government focus on fiscal restraint was seen as a factor in limiting dialogue. A few respondents, conversely, felt they were able to impact the Government as they felt that the Government was open to new approaches on policy issues, and that they had influence on TGA reforms.

After the deferral announcement in February 2011, a number of companies indicated that they would suspend their applications for listing new medicines on the PBS due to the ongoing uncertainty. 11 out of 26 companies, or around 42%, responding to a Medicines Australia member survey conducted in 2011 indicated that they were considering delaying submissions of new medicines for the PBS because of the government's decision to defer the listing of some medicines.

Deferrals

The Australian Government decided in February 2011 to defer the listing of seven medicines and one vaccine on the PBS; a decision which appeared to ignore the advice of the Government's own independent, expert advisory committee, the PBAC.

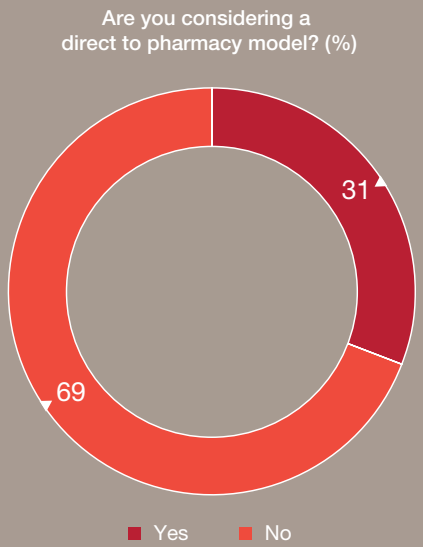
The Government openly acknowledged that the reason it deferred these medicines and vaccines was not through any lack of efficacy in the medicines themselves, but because of its concerns about its own financial situation. By denying Australians subsidised access to new medicines that had been assessed by experts to be clinically and cost effective, concern was raised that we run the real risk of creating a two-tier health system. High-income patients can afford the most effective and convenient treatment options (even if they are not on the PBS), while the rest will have to make do with treatments already on the PBS.

The impact on companies of the Government's decision to defer listings of medicines on the PBS included direct impacts on staffing and supply, timing of launches, increased uncertainty and a lack of confidence in the process. Other causes of delays to access for medicines in the process, besides Cabinet include: poor communication, the need to make new or multiple submissions because of higher rejection rates or being asked to resubmit as a major or minor submission, and timelines which were expanded because of poor adherence to them, and finally what respondents see as increased bureaucracy.

The impacts of these delays are wide-ranging and serious. Survey respondents spoke of direct negative impacts on jobs, budgets and revenues and more indirect impacts on the ability to plan and invest. Companies are currently even reconsidering whether Australia is an attractive market to invest in.

Others gave specific examples of losses, for example, two months of lost sales or making staff redundant. The additional costs of these processes mean lower revenues, fewer jobs created and ultimately, fewer benefits for patients. On a broader level, the uncertainty affects business in terms of being able to plan more effectively, including for cost savings, revenues, performance and employment. All of these factors were seen as adding up to less access to medicines for patients.

Operations and Supply



In March 2007, Pfizer introduced its first direct-to-pharmacy distribution scheme in the United Kingdom; a similar business model was launched in February 2011 in Australia. It introduced a new model to what was a well-established supply chain, bypassing full-time wholesalers by going direct to pharmacy.

Among industry, the response is mixed: 31% are considering this model, while 69% are not.

Most are saying that this model is not for them: they don't see the value, don't have distribution expertise, and don't have the interest.

Some feel the current model works for them as they still have healthy operating margins.

Still, some are open to explore this model to see if they can receive more value from it in relation to existing or specific products.

Wider healthcare reform: Are we there yet? Australia's health reform journey to date

Professor Christine Bennett
is the Dean of Medicine, University of Notre Dame and former Chair National Health and Hospitals Reform Commission

Three years on from the release of the National Health and Hospital Reform Commission's Final Report – *'A Healthier Future for All Australians'* in 2009, Australia's health reform journey is well underway.

The case for reform in Australia features many challenges common to health systems around the world: the growing health burden of chronic diseases; an aging population; rapid developments in medical and information technologies; increasing consumer expectations and involvement in health and health care decisions; and the questions of financial sustainability and affordability with rising health care costs. In addition, inequities in health care access and outcomes as well as challenges with health workforce distribution are critical in Australia. Structural flaws and complexity in governance and financing systems are further challenges in leading effective national action.

The Australian Government's response to the Commission's blueprint has seen some shifts in direction with the changing political landscape, in particular the reshaping of Commonwealth and state roles and responsibilities. A centerpiece of the 2010 National Health and Hospitals Network Plan was the shift of responsibility for financing which was to see the Commonwealth take full public funding responsibility of primary health care and outpatient care, and the majority funding of public hospitals – paying a 60% share of the cost, using an efficient activity-based funding approach. In the revised National Health Reform Agreement ultimately signed by all First Ministers in 2011 and currently being implemented, the Commonwealth does not take responsibility for primary health and outpatient care. It will however be providing increasing funding to public hospitals with a 45% share of the growth using an efficiently priced, activity-based funding approach from 2014/15; and a 50% share of growth from 2017/18.

Some of the other reforms currently being implemented are described below under the reform themes presented in the Commission's report.

Taking responsibility *– individual and collective action to build good health and wellbeing by people families, communities, health professionals, employers, health funders and governments*

An important and much anticipated initiative was the establishment of the Australian National Preventive Health Agency in 2011 (ANPHA– www.anpha.gov.au) to target effective prevention of obesity, use of tobacco and harmful use of alcohol. This focus on prevention recognises that there is more to good health than health care and that prevention and health risk management are vital contributors to health status and longevity.

The development of the My Hospitals website in 2011 and the publication of Healthy Communities reports for each local community in March 2013 are part of new public reporting on health system performance and health status to help inform consumer choices and community action and policy.

The introduction of the Personally Controlled Electronic Health Record (PCEHR) is underway with registration available to individuals through www.ehealth.gov.au since 1 July 2012. This is a useful a start. Further system enablement and increased engagement and participation of medical practitioners will be followed by a more comprehensive uptake and adoption strategy.

Connecting care *– comprehensive care for people over their lifetime*

Strengthening primary health care has been a reform priority with the establishment of 61 Primary Health Care Organisations across Australia – titled Medicare Locals – to support action on prevention in local communities, more coordinated care for chronic disease, and to bridge and connect care across health care settings in particular with hospitals, mental health and aged care services. Stronger devolution of governance to Local Hospital Networks has been implemented by each state as part of the National Health Reform Agreement. Across Australia, more than 55 substantial Local Hospital Networks have been formed with a number of smaller networks in rural areas. Boundaries of Medicare Locals and Local Hospital Networks are generally reasonably aligned in most states, which should assist local planning, service collaboration, sharing of resources and achieving goals.

Subacute care services were described as the 'missing link' in the continuum of health care by the Commission. The significant investment by the Commonwealth to support development of subacute care such as stroke recovery, rehabilitation services and palliative care has been part of a National Partnership Agreement with the states with funding due to expire in June 2013 and June 2014.

End-of-life care and advanced care planning initiatives are being developed and aged care services reforms were the subject of a further Productivity Commission inquiry 'Caring for Older Australians'. A series of recommendations are being implemented to expand community and home-based care options and simplify the assessment process.

***Facing inequities** – recognise and tackle the causes and impacts of health inequities.*

The health of Aboriginal and Torres Strait Islander peoples is a focus of the national 'Closing the Gap' strategy. Mental health care received significant focus with creation of a National Mental Health Commission and significant new investment. Dental health care has received an injection of funding to reduce public waiting lists and a more substantial investment to provide benefits to children in lower income households has been foreshadowed. Addressing health care access problems for people living in rural and remote areas has led to the strengthening of rural clinical schools to recruit from and train doctors in rural areas and the development of multipurpose centers and telehealth services.

The National Disability Insurance Scheme is an important health and social justice initiative for people living with disabilities and their carers.

***Driving quality performance** – leadership and systems to achieve best use of people, resources and evolving knowledge*

A new transparent, nationally consistent approach to Commonwealth financing of public hospital services by efficient activity-based funding is a major element of the reforms. Greater clarity of the Australian Government contribution to the growing costs of public hospitals is also important to the financial sustainability of state health systems.

To support the new arrangements two independent, national bodies have been formed: the Independent Hospital Pricing Authority which is determining the national efficient pricing for public hospital service activity; and the National Health Performance Authority which reports on almost 50 measures of across the continuum of health care through Hospital Performance and Healthy Communities reports.

Health Workforce Australia has provided a platform for a national, coordinated approach to health workforce planning, training and innovation. Meeting the demands for training places across the system including postgraduate and advanced training is a national challenge currently being explored across public and private sectors and various health settings.

Knowledge management systems, and the smart use of health information through data linkage and analysis of patterns of health service utilisation and unwarranted variation are receiving some attention and will be vital to informing future reforms. Addressing waste and inefficiency across health care will be greatly aided by health data analytics and health systems research to support both local and systemic solutions. The Government's response to the recent McKeon Strategic Review on Health and Medical Research more generally is pending.

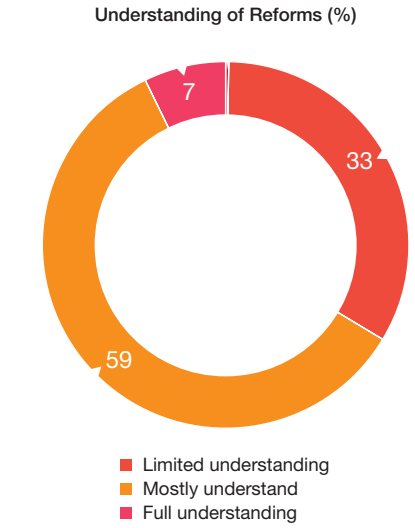
Even with this extensive and complex package of reforms across Australia's health system, some major challenges remain requiring further discussion and action. Three in particular are issues being grappled with by nations around the world: ensuring financial sustainability by tackling, in a systemic way, waste and inefficiency in health care as well as innovating to get value-based purchasing into how we pay for health activity; coordinating and connecting care for patients across service settings and over time; and how to best leverage the benefits of public and private health financing and care provision.

Health reform is a journey with a long horizon. It is important to share and learn from experiences here and internationally, to review progress and evaluate whether we are achieving the policy objectives, and continue to innovate and respond to the changing health needs of the Australian community.

Professor Christine Bennett
Dean of Medicine, University of Notre Dame Australia and Strategic Advisor to PwC

Wider healthcare reform

As in 2010, over 90% of survey respondents in 2012 did not fully understand the implications of broader healthcare reforms on the pharmaceutical industry.



Australia has been through an intense period of healthcare reform in recent years and survey respondents were asked to consider their understanding of these reforms and the importance of a range of reform themes. In general, understanding has risen with the percentage of those who at least 'mostly understand' climbing from 37% to 59%, with a corresponding drop in those with limited understanding from 53% to 33%, as compared to 2010.

Concern for primary care reforms dropped from 94% to 72% among those who considered the impact as 'very' or 'moderately important'; a similar drop in concern was seen for shifting care to the home.

Reform of the primary health care system, including increased investment and the establishment of Medicare Locals, was considered as the most important theme relating to their companies, while alternative prescribing rights for professions such as nurses, Activity-Based Funding for hospitals, and increased expenditure on prevention and wellness (including in the workplace) were also seen as critical. Reform of local hospital networks was seen as important, but not as much so; shifting care to the community and people's homes and increasing choices to older people to access aged care services were seen as less relevant. In comparison to 2010, across all themes, healthcare reform was now seen as less important.

Importance of specific health reform themes

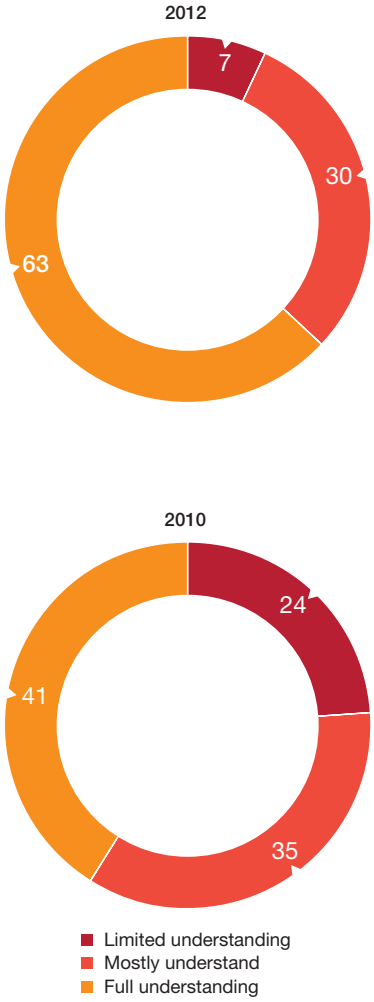
In considering the top opportunities that healthcare reform offers the pharmaceutical industry, the key areas identified were the establishment of Medicare Locals, the introduction of eHealth, and Activity-Based Funding. Other opportunities mentioned were the community pharmacy agreements, partnerships on quality use of medicine, shifting care to the home, and a more holistic provision of services with the aims to increase transparency, communication, sustainability and medication management.

62% or respondents have seen a decline in market share of existing mature products since 2012.

Price disclosure

A majority of respondents indicated a full understanding of the implications of the price disclosure regime though nearly 37% lack this full understanding. It is essential that companies increase their understanding of the current regime in order to increase business certainty.

Understanding of Price Disclosure regulation implications (%)



In recent years, major pricing reforms were agreed in order to manage increasing PBS costs and ensure the viability of the medicines industry. The National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010 introduced mandatory price disclosure for all drugs on the F2 formulary. At the time of its introduction, it was expected to increase the number of brands subject to price disclosure from approximately 176 to almost 1950.

The percentage of survey respondents who indicated that their company has a 'full' understanding of price disclosure increased from 41% to 63% from 2010 to 2012, with a similar drop in percentage in those who indicated a limited understanding (24% to 7%). Nearly one-third of respondents indicated that their companies mostly understand the implications of price disclosure.

74% of respondents indicated that their company is currently price disclosing or expect to do so in the next five years; 22% answered negatively. A similar number of respondents (78%) had prepared internal modelling of the financial and competitive impact of price disclosure on their business with a smaller number (68%) noting that price disclosure has had a major impact on their business in 2012.

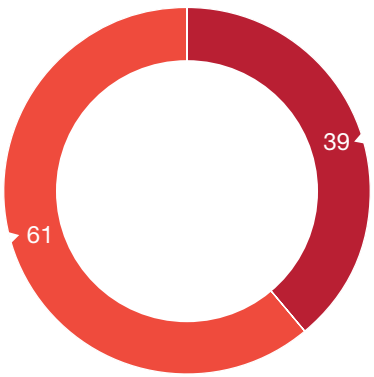
Discussions about price disclosure were consistent with the overall theme of the pharmaceutical industry accepting a regulatory environment but wanting it to be timely, transparent and to provide certainty. Only 39% of participants in the 2012 survey found the Government's price disclosure calculation transparent.

Industry participants want to understand and be prepared; therefore, early notification is desirable rather than after the fact. 62% of participants have seen a decline in their market share of existing mature products since the April 2012 price cuts, and yet, a similar percentage (64%) say that there is no concern for the industry given the price cuts to atorvastin that came through on 1 December 2012.

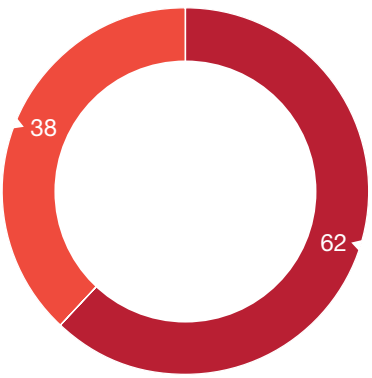
The focus, therefore, should be on getting the process right to ensure industry-wide understanding upon which to build. Still it is early days and full-round price cuts under the Expanded and Accelerated Price Disclosure cycle have not yet taken place.

The significance of market share decline will vary from product to product due to factors including market size, ease of production, and whether there are competing products in the same therapeutic area which may still have exclusivity. Survey respondents indicated that they have been affected differently, from 'not massive' to 'very significant'. One participant stated that 'the industry signed up to a structural change that would result in price reductions in drugs post-Loss of Exclusivity (LoE); this would then

Considers Government's price disclosure calculation transparent (%)



Decline in market share of existing mature products (since April 2012) (%)



Yes No

Mandatory price disclosure has generally not changed companies' strategies of developing or acquiring mature products and/or a generic business

make head room for new products…this does not appear to be happening so we are being squeezed from both ends'. Another commented that 'Lipitor was a candle to the moths' as the April cuts haven't driven a reduction in market share; it has been the volume of new competitors that has driven a change in pharmacies' expectations.

In considering the 1 April 2012 Weighted Average Disclosed Price cuts (WADP), respondents answered that these adversely and directly impacted their company's profitability (71% yes, 29% no) and similarly, they did cause their companies to reconsider how they manage the late-stage life cycle of their existing mature products (70% yes, 30% no).

Managing late – stage drugs

For the majority who viewed price cuts as having caused their company to reconsider how it manages the late-stage life-cycle of its existing mature products, these companies have considered a full range of options including third party licensing, the introduction of competing brands, engaging in earlier planning around LoE, phasing out or selling products, disinvesting in products or withdrawing them from the market, partnering with generic companies or third parties. Among other views on the impact of WADP were that they significantly reduced profits, had a broader impact than expected, and changed the way in which the company values the potential return on investment for a product over its life cycle.

New acquisitions?

Mandatory Price Disclosure (MPD) has generally not changed companies' strategies of developing or acquiring mature products and/or a generic business (59% no, 41% yes). A slight majority feel that MPD has not impacted their company's strategy on bringing new products to Australia that may otherwise have a generic comparator as a reference price (56% no, 44% yes).

Various feedback on the impacts of MPD on business strategy ranged from a global strategy to stay out of generics, to reducing focus and investment in mature products, and that outlicensing and promotion are less attractive with the basic economics of decision-making having changed.

Future impacts?

Looking to the future, survey respondents see the longer-term impacts of MPD on the PBS as having some positive outcomes for the consumer and government, but in the far future, a troublesome possibility. The reduction in costs of drugs was specifically noted, which was seen both as 'managing' and 'limiting' growth. The scenario was then painted of barriers created to the entry of new products for public subsidy and hence, fewer products getting listed onto the PBS. The PBS may one day resemble a limited formulary of older cheaper products while newer therapies (if they can be launched at all) may be restricted to a private setting. This may lead to less generic competition over time as the number of players decline.

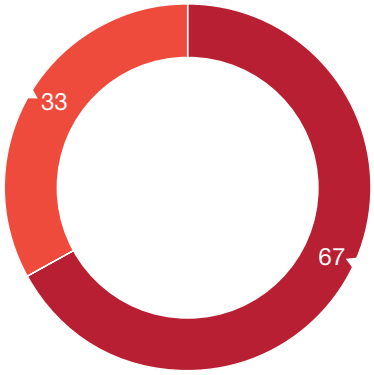
Similarly, in terms of the longer-term impacts on the availability of drugs, while a few survey respondents see no or limited impact, and that the size of the Australian market is large enough to guarantee continued supply, others see that, over time, there may be delay or limits to access to new products as manufacturers reconsider PBS listing, or if they consider Australia a lower priority country due to the challenges of costs and regulation. The possible end results may be fewer competitors in the market place and less access to new innovative medicines by Australian consumers.

Impact on wholesalers

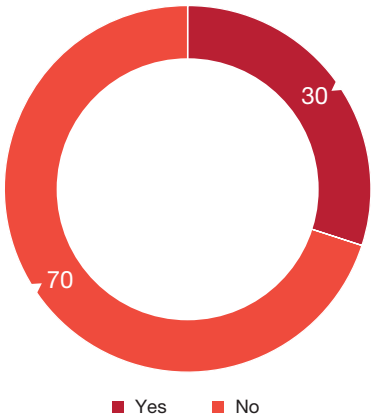
It is predicted that pharmaceutical wholesalers will suffer in the longer-term as a result of MPD. As PBS prices decrease, the wholesale revenue declines as the percentage margin is claimed on a lower price. This financial impact of reduced margins was a key theme in the comments of survey participants. While MDP may create a more competitive environment, wholesalers are then likely to review which services and products they offer, and if they survive, will require additional business strategies to cover lost revenue.

In 2012, 67% of survey respondents were not in favour of directly linking future price cuts to making provision for the introduction of new drugs onto the PBS.

In favour of directly linking any future price cuts to making provision for the introduction of new drugs onto the PBS in 2012 (%)



Decline in price discounts or rebates being sought by customers (since April 2012 price cuts) (%)



Impact on pharmacies

Similarly, community pharmacy will be required to examine new business strategies and revenue streams to counter the loss of revenue from PBS items. As the Government pays less and patients pay the same for medicines, it is pharmacy that will suffer reduced margins and profitability, particularly for those that rely on revenue from generic drugs – therefore threatening their ongoing and future financial viability.

Other reforms

Some survey participants consider data collection no longer relevant and would like it not to be done. Others would like the frequency of submissions to be reduced. Some understand the need for it, or consider it important but see some forms of data (i.e. public hospital data, classification of non-monetary benefits) as difficult to obtain. One participant suggested that market accuracy would be improved by collecting information from the supply chain (i.e. individual pharmacies) rather than at the manufacturer-level.

Clearer guidance was requested from Government on separating public hospital sales data from PBS sales data; on the definition of 'incentives' and how to collect that data; on how data is adjusted prior to submission for public hospital sales; the time lag between data sources; and the reduction dates for each data cycle.

The majority of survey participants who commented on Weighted Average Disclosed Price calculations indicated a desire for change, noting that the current process is 'too complex' and that clarity was still needed with regard to the recent changes following the Federal Court consideration in 2012 of the appropriateness of some determinations, that the price disclosure mechanism is designed for pills and not injectables, that the current formula misses some costs, and that price disclosure should be around the 'total delivered cost to consumers'.

Earlier notification

While a number of survey respondents found no changes needed to the notification of price variations, an equal number asked for earlier or more timely notifications, or a published schedule so as to avoid wasting time and effort on unnecessary readjustments. Industry needs more certainty as to when reductions will be known, and the management of F1 has become problematic over the last two years.

Price premiums

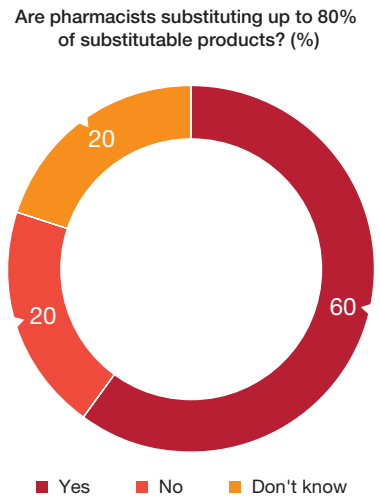
Maintaining and adding price premiums was seen as a complex issue. Suggestions included that legislation should be changed to allow these to occur, and to allow concurrent price reduction (premium adjustments would be convenient for sponsors but is unlikely to interrupt continuity of services). There should be greater flexibility in charging premiums, CPI increases, and more windows of opportunity. The need to remove the premium and then add it back in the following book causes additional administrative burden and potential patient confusion; the inability to apply and change a price premium at the same time as a price change is occurring also, remains an issue.

70% of survey respondents did not see price discounts or rebates sought by customers. For the 30% that did see them, they commented that pharmacists want more price discounts, and that these discounts and rebates are being sought by customers at significantly higher rates in order for them to offset the reduced profit margins that have already been driven by MPD.

60% of respondents are seeing substitution by pharmacists of up to 80%, with some up to 90%.

Substitution

PwC's Pharma 2020 reports have forecast that generic substitution will continue to increase and lead to changing business models. Current results confirm this trend.



The level of generic substitution has increased substantially since the PBS reforms in 2007. In 2008–09, member companies of the Generics Medicines Industry Association had a share of 33.8% of PBS prescriptions, up from 27% in 2005–06. Today they represent 35–37% by volume of the PBS.

PwC's own anecdotal enquiries suggested that the level of substitution increased from around 25% before 2007 to around 72% over the period to 2010. This rate was confirmed by 68% of respondents. In 2012, PwC asked whether pharmacists are now substituting up to 80% of substitutable drugs. Only 60% of survey respondents agreed with this estimation. While other respondents suggested that for some products, i.e. new molecules that have lost exclusivity, substitution could be as high as 90%, other substitution rates are considered to generally be around 50% to 60%.

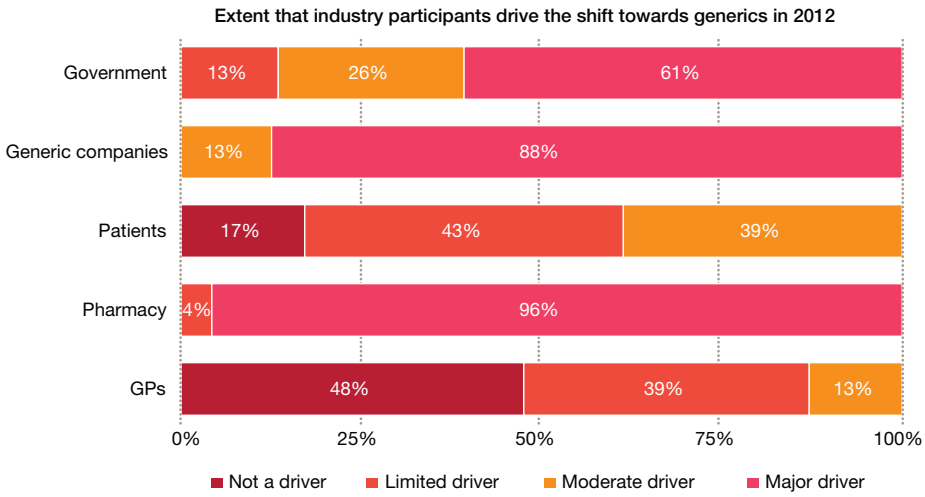
What has this meant for industry? Survey participants had a range of responses with some indicating little or no impact of substitution on their companies. Generally though, substitution has had a clear financial impact on companies with a rapid loss of revenue from mature brands and their corresponding decline in market share. This has spurred some companies to do long-term planning and rethink their strategies. Some have partially offset losses to originator brands through acquiring or growing their own generic business. There is increased pressure to focus on pipeline products, growth brands and innovative medicines.

Which industry participants drive the shift to generics?

As in 2010, pharmacy remains the major driver (at 94%); the reason noted was the discounts and incentives offered to them by generic companies. Patients are considered to have increased in influence as a driver in 2012, with a slight increase for generic companies themselves. The big shift is relating to the Government: rather than being considered a moderate driver, over half of respondents now consider them a 'major driver' of the shift to generics.

How will it impact pharmaceutical companies if generic suppliers increase their level of discounting?

Survey participants see a range of possibilities. Most seriously, it could *'threaten the whole business model'* as, discounting has already increased to *'levels that are completely unsustainable'*. If this continues, some see that this would lead to *'consolidation and smaller generic companies pulling out… potentially posing risks for quality and supply reliability in Australia.'* Others see increased price erosion through price disclosure, the further reduction in sales of mature products, and general loss of market share. Some see no impact, or limited or unclear impact, pointing out that patients and GPs are typically loyal to a brand. Still, another survey participant wondered if it was possible at all to increase discounting, noting that generic suppliers are currently discounting up to 95% on large molecules that have undergone Loss of Exclusivity (LoE): by year four the volume has rapidly eroded and the price has also been dramatically eroded.

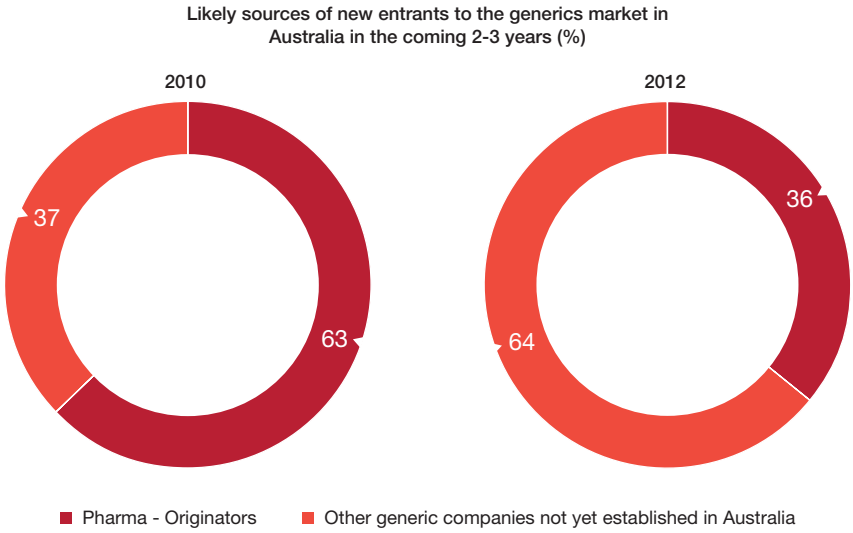


A respondent noted that 'under the terms of PBS reform and the Medicines Australia Memorandum of Understanding (MOU), increased competition in the generic market should deliver increased savings to the PBS and create more "headroom" for the Government to fund new treatments.'

New entrants?

With some $2.3 billion worth of medicines coming off patent over the next 5 years, it is likely that the trend to substitution will continue.

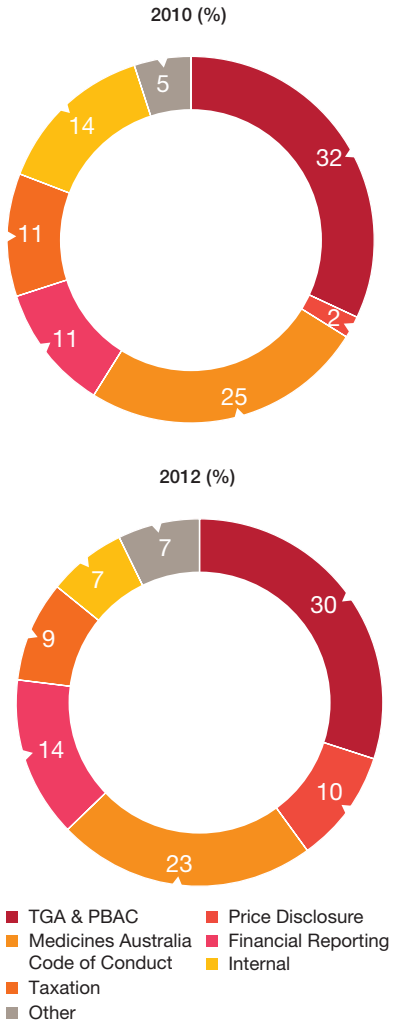
Among survey respondents, big pharmaceutical companies were viewed as the most likely to enter the generics market over the next two to three years (as foreseen by 64% of respondents) though 36% predicted it would be other generic companies not yet established in Australia. 17% of companies have acquired or are seeking to acquire or expand a generic portfolio into their product mix by alliance or company acquisition.



The cost of compliance in 2012 is markedly greater than in 2010.

Regulatory compliance

The cost of compliance is generally greater now than in 2010, and companies are clearer about their compliance costs. Survey respondents reported that they have continued to make improvements in their compliance programs to meet the increasing demand for transparency and regulatory compliance, with price disclosure a growing compliance cost for companies since 2010.



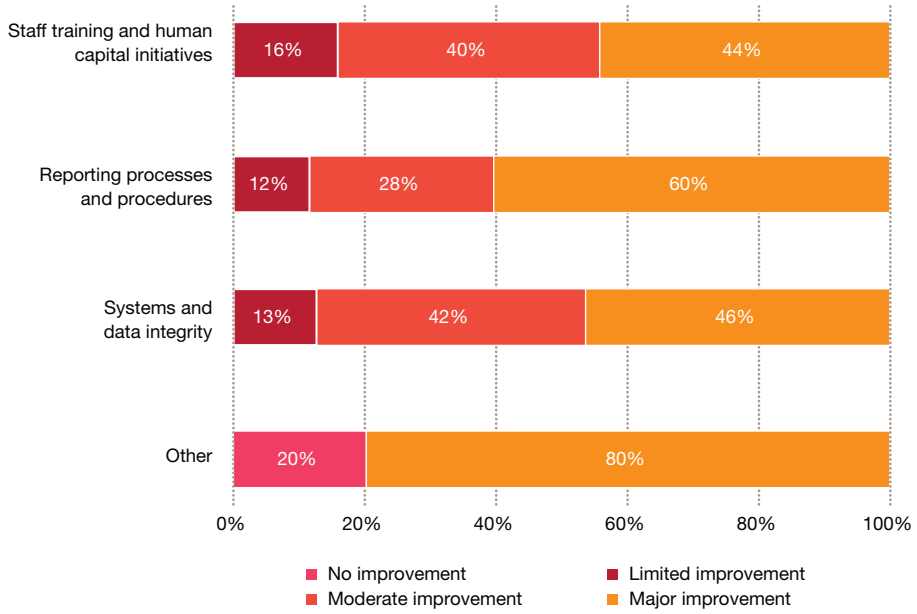
Respondents across the board saw improvements in each of the key compliance areas – 'Staff training and human capital initiatives', 'Systems and data integrity' and 'Reporting processes and procedures', with 'major improvement' scores ranging from 44 – 80% of survey respondents across the compliance categories. When you include 'moderate improvement', the percentage range increases to 80 – 88% of respondents.

In estimating the costs of complying with legislation, regulations and industry codes, a majority (64%) estimated their compliance costs to be over 2% of total costs, up from 57% in 2010. Of this 8% (2010: 0%) were now estimating costs between 10–15% and 16% (2010:13%) compliance costs as between 5–10%.

Largest costs of risk and compliance

TGA continues to be the largest compliance costs to businesses (32% in 2010 and 30% in 2012). From 2010 to 2012, Price Disclosure has increased from 2% of total compliance costs to 10%, consistent with the heightened activity in this area in the industry. The Medicines Australia Code of Conduct is the second highest compliance cost, at 23% of total compliance costs (down slightly from 25% in 2010).

Most survey respondents (64%) foresee increased investment required for the updated Medicines Australia Code of Conduct (Edition 17 which came into force in January 2013) but at the same time, the same percentage see no significant impact on their operations by this updated code. Half of respondents (50%) see increased investment required for the US Sunshine Act, for group entities with US operations, mostly with regard to the costs of training and changing systems.



Transparency

Daniella Dickson **is a Director in PwC's Forensic Services team and Medicines Australia Code of Conduct Review Panel member 2013/2014**

Regulation in the pharmaceutical sector globally has continued to increase as a result of calls from industry stakeholders and consumer groups for increased transparency around the testing, promotion and marketing of pharmaceuticals to Health Care Professionals (HCPs).

Significant global fines, $11bn in the last three years alone, have been handed out to global pharmaceutical companies for dishonest behaviour and criminal activity going back a number of years, relating to the approvals and promotions of drugs, including withholding safety data, off-label advertising, and the promotion of drugs without adequate evidence of their effectiveness. This dishonesty will continue to erode public trust, unless additional measures are taken to deter this behaviour.

Promoting the transparency of the relationship between HCPs and pharmaceutical companies is a key part of achieving increased transparency in the industry. The prescribing of drugs that are appropriate for patients and their circumstances is an important part of achieving better health outcomes for patients and will help to curb global health costs that are set to substantially increase in years to come.

In January, the US introduced the Physician Payments Sunshine Act (the Sunshine Act), which will require all pharmaceutical companies to report all payments or transfers of value to HCPs. In Australia, the Medicines Australia (MA) Code of Conduct was updated in January 2013 to require additional reporting – however, it does not contain the same onerous obligations to report all payments to HCPs as required in the US.

Nevertheless, MA is currently reviewing the challenges and risks around the public reporting of all payments to HCPs, to ensure that the benefits of increased transparency through reporting all payments are realised while managing the challenges of reporting personal information regarding HCPs.

There is likely to be continued increases in regulation that aim to improve transparency and deter dishonest behaviour in the industry globally. Further, Australia will likely implement a similar HCP reporting requirement as the US in the next 2–3 years.

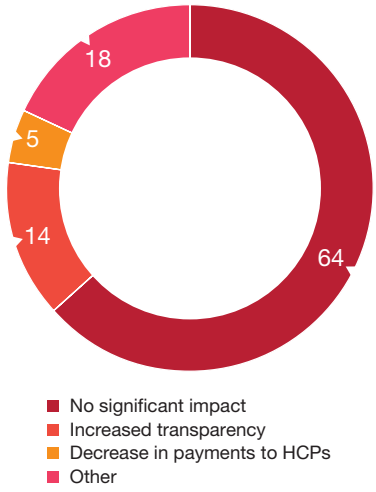
The increased regulation will require pharmaceutical companies to review their operating models and specifically in Australia, how they engage with HCPs to provide educational information relating to new products. Australian companies will need to consider:

- data accuracy and reporting,
- disclosure of personal information and dispute resolution mechanisms,
- stakeholder and contract management; &
- adopting an organisation wide approach where legal, compliance, operations, field force and sales are working together in a systematic way to ensure the regulations are met, and that the right outcomes are achieved for patients.

What aspects of your business will need to change to promote and encourage transparency into the future?

"Disclosure of payments to compensate HCPs for their involvement in medical education may improve perceptions of the legitimate relationships between companies and HCPs and dispel some misperceptions."

What do you think the impact of the new Medicines Australia Code of Conduct will have on your business? (%)



Only 19% of respondents think that increased transparency in reporting payments to Health Care Professionals (HCPs) will lead to better customer knowledge or health outcomes for individuals.

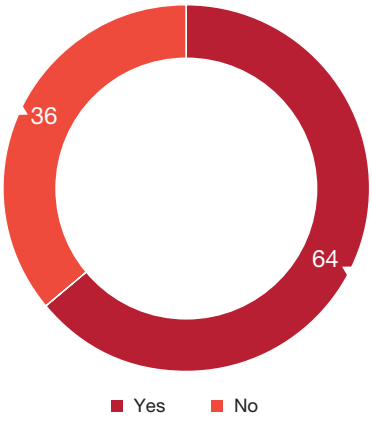
In addition, only 14%, believe that increased transparency in the pharmaceutical sector (the US Sunshine Act, and additional transparency measures in future Editions of the Code of Conduct in Australia) will positively impact their marketing initiatives; while 5% believe that the expected future decrease in payments to healthcare providers will impact their marketing initiatives.

Interestingly, there are now fewer complaints made in relation to the Code of Conduct than in previous years. In 2011–12, Medicines Australia received 12 new complaints (2010–11: 14, 2009–10: 39, 2008–09: 59) with 11 of these finalised. Of the 11 new complaints finalised, 5 were found not to be in breach of the Code.

Survey participants commented that increased transparency in and of itself was important and could lead to increased trust between patients and HCPs. One respondent even stated that in the long run the increased transparency would contribute to improved patient adherence and potentially better health outcomes. Conversely, a number of respondents see the risk in reporting individual payments to HCPs, concerned that it may lead to:

- individuals and patients questioning the reputation of HCPs,
- embarrassment for HCPs
- less training with HCPs, and
- less willingness by HCPs to work with industry.

Increase investment required for the Updated Medicines Australia Code of Conduct? (%)



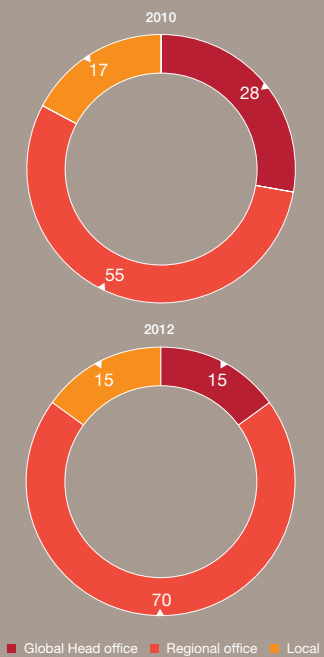
Anticipating growth and the degree of local decision-making

The industry's view of growth in Australia is extremely positive in 2012. A full 82% anticipate growth in their company's presence over the next five years, 11% answered 'no' with 7% answering 'don't know'.

Companies anticipating growth have new products and new indications in the pipeline in a range of areas. Some of them are new areas for the companies involved. Companies also expect to increase their market share in key segments. Some are expecting to grow through acquisition; expanding manufacturing, increased market share in wholesaling; organic growth; and sales and marketing. A few comment on uncertainty, lack of growth, delays in listing products, pricing pressure on profitability and the inability for new products to make up for the decline of old ones. But the general assessment of their companies is positive.

Organisations were asked about their reporting structure. Compared with 2010, power has increased significantly to the regional level (up from 55% to 70% reporting to regional offices) with only minor decreases in reporting to local (17% to 15%) whereas global/head offices fell the most (28% to 15%). Local decision-making is usually related to marketing, PBS listing and strategic initiatives; the least amount of decision-making was seen in R&D and new products and licensing.

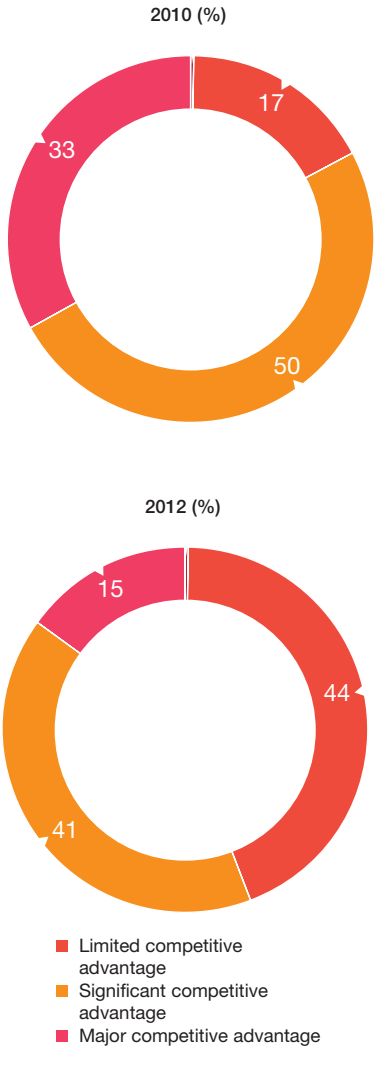
Organisation reporting structure (%)



56% of respondents see eHealth as a major or significant competitive advantage.

eHealth/mHealth

What was previously seen as an 'emerging global trend' towards electronic health (eHealth) and mobile health (mHealth) is now already influencing Australian healthcare and will continue to influence all parts of the sector.



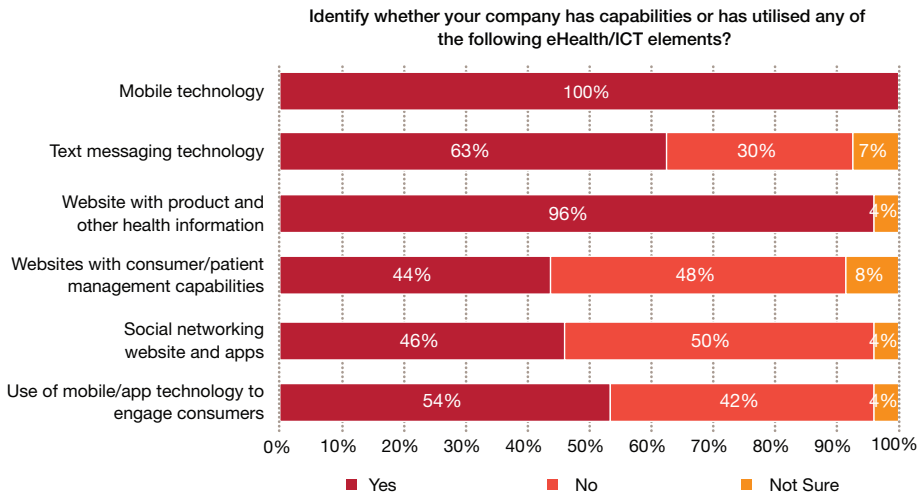
In the various Pharma 2020 reports, PwC predicted a new era of mass customisation of healthcare, advanced by technology through smart phones and electronic medical record databases as well as through home health monitoring and treatment programs.

What was previously seen as an 'emerging global trend' towards electronic health (eHealth) and mobile health (mHealth) is now already influencing Australian healthcare and will continue to influence all parts of the sector. This includes the Australian Government's launch of the personally controlled electronic health record (PCEHR) system, on 1 July 2012, and the expanded use of eHealth and mHealth for both consumer engagement by pharmaceutical companies and to support the work of their employees.

eHealth as a competitive advantage

Two years ago, with little practical experience of eHealth, 83% of respondents viewed that eHealth was a 'major' or 'mostly' a competitive advantage for their companies. Today, with many companies having entered the eHealth space, that view has become more down-to-earth. In 2012, 56% of respondents considered eHealth a major or significant competitive advantage and the percentage of those who view this advantage as limited has increased from 17% to 44%. Either the perceived competitive advantage was not there or was quickly eroded as competitors caught up.

Despite this, the use of eHealth has increased across all categories of utilisation, with 63% of companies each using mobile technology (smart phones, iPads and personal digital assistants) for their mobile workforce in the field and hosting websites with product and other health information for consumers. Companies with social networking websites have tripled. Two new categories were added in our 2012 survey with significant numbers of companies having gone on to develop more interactive websites with consumer and patient management capabilities, as well as mobile applications that are able to engage consumers and patients.



eHealth

Klaus Boehncke **is PwC Australia's eHealth Leader for Australia and the Asia–Pacific**

The national and jurisdictional push towards greater use of technology in healthcare continued throughout 2011 and 2012. Managed by DOHA and National E-Health Transition Authority, the national level saw the introduction of the Personally Controlled Electronic Health Record (PCEHR), focused predominantly on networking the primary care setting. Many jurisdictions were also continuing to invest and planning new investments in acute-care focused Electronic Medical Records (EMR) and other aspects of hospital information technology.

Of course the medication management aspects of the PCEHR and EMR projects are expected to be especially relevant to the pharmaceutical industry, as these initiatives will ensure that patients receive the drugs that are intended for them, minimise unwanted interactions and allergies, potentially increase adherence, and ultimately reduce the deaths and suffering caused by the high prevalence of Adverse Drug Events in a still widely paper-based health provider world. In addition, experience from the US shows that in the longer term, data gathered through such eHealth programs will be valuable to pharmaceutical firms, because for the first time real patient information in larger volumes may be accessible through data analytics – provided that appropriate policies around secondary data use and anonymisation are in place.

In addition to the more traditional eHealth record approaches mentioned above, the last two years also brought 'mHealth' into the mainstream vocabulary. It encompasses the provision of healthcare through mobile devices in a wide sense, ranging from simple SMS-based services through to full smartphone and sensor-dependent equipment. This development is *"the biggest technology breakthrough of our time [being used] to address our greatest national challenge"*, according to US health and human services secretary, Kathleen Sebelius. Worldwide, technology and its promise have moved up the healthcare agenda. Together with the Economist Intelligence Unit, PwC released its annual report on mHealth in June 2012, which noted further growing interest in the topic from a patient, provider and payor perspective, and also highlighted the different approaches being taken around the world.

Pharmaceutical firms will be impacted by this trend, as the first applications have already been approved by the FDA for prescriptions by doctors, and several are seen to be as effective as drugs in treating or managing certain types of conditions. However, in addition to new competition from the 'app world', these trends are also expected to open up opportunities. For example, pharmaceutical firms have leveraged mHealth to explore new ways of treating patients with a combination of mobile devices, drugs and telehealth and are also beginning to utilise technologies to increase adherence and foster closer relationships with their patients.

eHealth and mHealth are here to stay. The healthcare sector, long seen as one of the last holdouts of traditional paper-based workflows, is finally heading into the digital frontier. Driven by both a pull government on the health record front and push for patient relating to mobile devices, significant changes are underway. We expect that the pharmaceutical industry will adapt to this challenge and leverage new opportunities, and we look forward to working with our clients in the sector to optimise their strategy and help them implement new and innovative solutions.

What is your strategy to respond to the new opportunities and challenges from eHealth, mHealth and big data in healthcare?

What eHealth/mHealth elements are you using?

In qualitative interviews, survey participants viewed the use of mobile health apps for consumers and patients as a great opportunity to engage patients, adding value by improving the quality of patient care through better compliance. There were some reservations about the role of doctors in prescribing these apps, how they would be encouraged by the wider industry, and how they would link directly to a company's specific product; but generally, this area of development was seen as very positive.

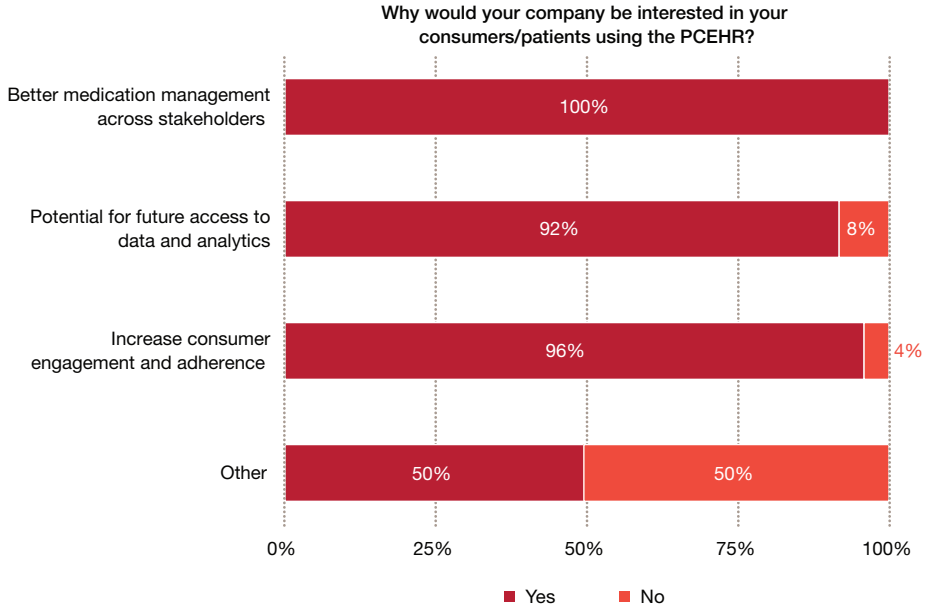
Would adverse events be reported by Facebook? Will companies monitor the channel seven days a week? Could wrong information or messages be spread through the internet?

With the national infrastructure for the eHealth record system now complete, it will now be rolled out in stages. The record system is non-mandatory. Economic modeling in 2010–11 estimated $11.5 billion in net direct benefits over the 2010 to 2025 period through more effective medication management and improved continuity of care (reducing hospital admissions, GP visits, and duplication/wastage of time and information).

As patients become more informed and actively engaged with their healthcare, they will seek information and applications to enable them to manage their health, resulting in improvement in medication management and disease control. Innovative companies are working with experts and patient groups to develop these solutions and to address issues such as patient confidentiality. As one survey participant commented, 'Anything that improves health outcomes for patients must be welcomed and seen as an opportunity'.

The interaction and intersection between the Medicines Australia Code of Conduct and the use of eHealth and mHealth channels such as social networking creates tension. While a few respondents view this as manageable, most could be seen as 'risk-adverse', and point to the dangers in operating in an area that is risky because of a lack of control about what could be written in this space. Would adverse events be reported by Facebook? Will companies monitor the channel seven days a week? Could wrong information or messages be spread through the internet? 'Very difficult but exciting and needs to be harnessed,' commented one of our 2012 survey participants.

Of survey respondents, 85% had heard about personally controlled electronic health records and 28% believe that the pharmaceutical sector should play a significant role in encouraging their uptake and use by healthcare providers (52% advocated for a limited role; 20% for none at all). Companies saw uniform benefits for patients and consumers using PCHERs: better medication management across stakeholders, increased engagement and adherence, and the potential for future access to data and analytics.

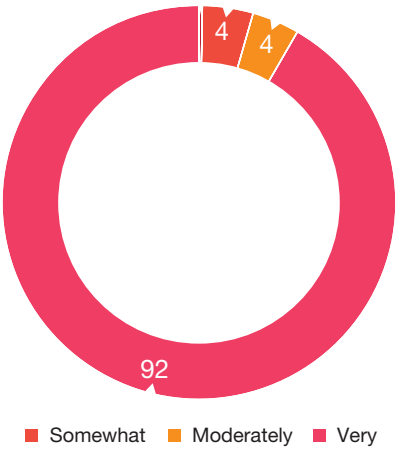


94% of respondents see protection of intellectual property as very important.

Innovation

The Australian pharmaceutical industry spends over $1 billion a year on R&D. Not unsurprisingly, the protection of intellectual property (IP) in Australia is seen as very important for 94% of survey respondents.

How important is intellectual property protection in Australia for your business currently? (%)



Despite its importance, there has been little progress or change with regards to encouraging innovation in this sector. While the Government has introduced new IP laws under the *Raising the Bar Legislation* there are still currently a number of IP-related reviews underway for the Pharma industry and enquiries into compulsory licensing, innovation patents, the economics of human gene patents and the IP Australia Pharmaceutical Patent Review, as well as a private member's bill.

Some survey participants expressed concern that these reviews would negatively impact intellectual property protection and future investments, and others worry that Australia is falling behind the rest of the world, and particularly Europe, in terms of data exclusivity. While some see no or limited changes in the IP environment, some see deterioration and that issues such as delays in PBS reimbursement and the delayed introduction of generic products result in incremental negative effects.

Improvements to IP regulation in Australia

In response to this concern, survey participants suggested a number of improvements that should be made to Australia's intellectual property regime, and suggested in particular to harmonise our data exclusivity scheme with the EU and the US. Other respondents asked for compensation or extended patent terms to address the impact of a shortening of patent life due to the PBS process. There were also requests for a predictable IP environment that gives certainty around exclusivity periods with adequate notification provisions. One commentator feels that strengthening intellectual property rights is unlikely with the current government and that the industry focus over the next 12 months should be to maintain current IP rights. Another proposed the need to resolve issues surrounding patents for biologic medicines.

The R&D tax credit

The Government's current Research & Development tax credit programme is seen as providing value to the survey respondent's companies. Allowing for R&D claims in respect of overseas-owned Intellectual Property was seen as the most important (with 96% considering it 'very' or 'moderately' important), while the 40% tax credit and ability to claim up to 50% of R&D costs incurred overseas were also considered valuable. Refundable tax credits were seen as less or not important by survey respondents, reflecting their general ineligibility for that element of the scheme.

Greater incentive?

Survey respondents are split in their views on whether the government's R&D tax reforms will provide incentives to industry. 54% see incentives as increased, 42% with no change, and 4% with decreased incentives. This compares with 2010 where increased incentive were seen by about the same percentage (47%) but 35% saw no change and 18% saw decreased incentives. There has been a slight positive shift in opinion from seeing incentives as decreased to 'no change'.

Getting R&D 'above the line'

Tim Donald
is a Director in PwC's R&D practice and member of Medicines Australia's Innovation Strategic Committee

Support of innovation through the taxation system's Research & Development regime has undergone a number of changes over the recent years – from a system that was originally targeted at supporting the creation of Australian-owned intellectual property, through to one that supported the conduct of 'incremental' innovative activity in Australia, irrespective of the location of the ownership of intellectual property, and ultimately to the current system, which rewards locally based innovative endeavors.

While the quantum of support has also undergone its own development, moving from a 125–150% deduction, through to an incremental 175% deduction, and ultimately a 'below the line' tax credit of 40% (10c in the dollar benefit) for large companies, these developments have fallen short of the calls over successive years to move the credit 'above the line'.

The recent changes to innovation support for smaller companies provide increased rates of benefit through a 45% tax credit which is refundable where those companies are in loss. These changes are most welcome and provide a valuable source of funding to some of our most innovative small companies. However, the same cannot be said of the support offered to larger innovative companies who face the dual threats of rapid globalisation and regionalisation and cost pressures associated with a structurally high Australian Dollar. As these forces continue to put Australian businesses under pressure, the need to provide a stable and attractive research and development incentive is higher than ever.

Other nations have made positive policy decisions relating to innovation in response to these pressures, with some other competing jurisdictions super-charging their R&D credit[1] whilst others have designed their R&D incentives to be recognised above the line[2]. Innovation policies which are accounted for 'above the line' are particularly effective as they give corporate officials greater visibility of the benefits from these credits and therefore are considerably more likely to influence R&D investment decisions – the key objective of innovation incentives.

It is acknowledged, however, that the ability to lobby for further tax incentives is all the more difficult today, in the face of declining tax revenues. That said, there are other factors which provide grounds to support moves to adjust the R&D incentive so that it is accounted for 'above the line'. Moving the tax benefit associated with an R&D tax credit above the line could be achieved relatively easily and could be seen as a revenue-neutral measure that potentially adds to the Australian tax base. This could be achieved by converting the current 40% tax credit into a refundable 10% offset for R&D expenditure (effectively treating the credit like a 'grant') for all companies with over $20m turnover.

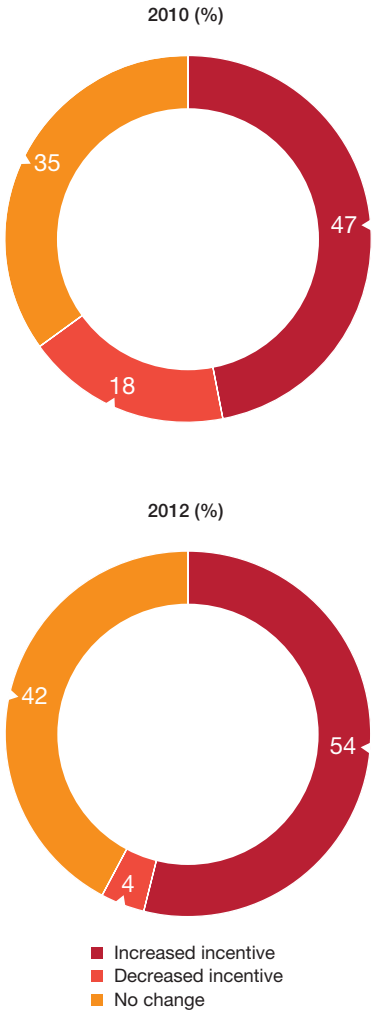
While many companies are currently availing themselves of the R&D tax credit, they are doing so without the added visibility that comes with an above-the-line incentive. Despite the concerns about making the incentive refundable, the 10% grant should be seen as both supporting and attracting profitable innovative activities to Australia along with increased PAYG withholdings from additional high-paid employment and other economic spin-offs. The new transfer pricing regime should also assist the affordability of the proposed measure since local subsidiaries of MNCs undertaking R&D under contract to offshore related companies are required to charge an arm's length mark-up for those services – generating additional tax revenues to offset the cost of R&D credits claimed for the additional R&D attracted to our nation.

The bottom line is that reforming the R&D tax credit as proposed would have the benefit of allowing senior management (and especially those bidding for finite resources within a global value chain) to recognise the reduction in the overall cost of doing R&D in Australia, thereby preserving jobs and increasing innovative activity within Australia – all without significant risk to total Government tax revenues.

1 Both China and Singapore effectively provide at least a 150% deduction on qualifying R&D expenditure.

2 The United Kingdom has provided 'above the line' R&D credits since 1 April 2013 and Australia (for small companies) since 1 July 2011.

Do you see the Government's R&D tax reforms having provided decreased or increased incentives to undertake innovative R&D in Australia?



In comparison to global incentives, many see Australian R&D incentives as less competitive (about 63%) or about the same (37%).

Competing regionally

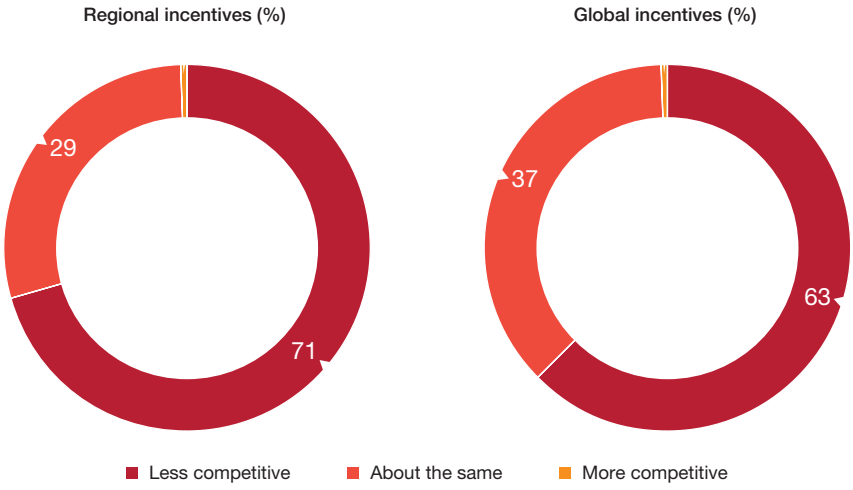
Improvements in both the IP and R&D environments could improve Australia's ability to compete in the world pharmaceutical sector so as to attract investment and to take advantage of Asia's burgeoning biotech industry. However, in general, survey respondents did not feel that the tax incentives had significant influence on the decisions their head offices make as to where to conduct R&D activities such as clinical trials and drug discovery. Most respondents pointed to factors such as cost, efficiency, quality, timeliness and capacity and hinted that lack of timeliness and high costs may count against Australia as an R&D location.

Survey participants recommended that the Government make a variety of decisions in order to improve its innovation program: they gave general guidance for the Government to take a proactive approach to support research and development in Australia, one that would recognise the benefits to health outputs rather than the consistently seen focus on health expenditure. It was also recommended to provide incentive for larger players to retain a presence in Australia, more direct incentive for R&D and innovative products in general, and to attract investment from multinational companies with an aggressive approach to identifying and taking advantage of opportunities.

Clinical trials

More support for clinical trials was a key theme. This support could include an efficient ethics approval system, a central national ethics committee, a clinical trials office, better organisation of patient networks to facilitate clinical trials, and cost transparency standards across states and hospitals. Investment in manufacturing was unsupported, and the unpredictability of PBS funding viewed as a disincentive to investment. Despite recent announcements by Government to support Clinical Trials in Australia, the proposed tightening of R&D eligibility appears to add only further disincentive to invest.

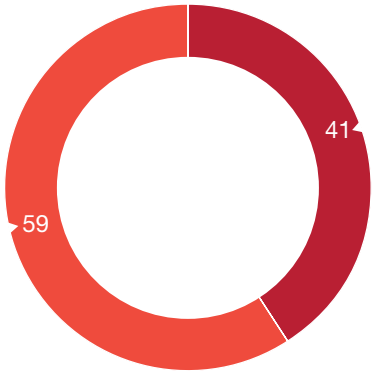
How competitive is the Australian R&D incentives compared to:



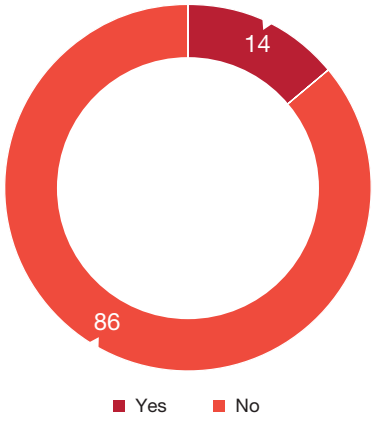
59% of respondents do not think Government has provided clarity around the differences between Biologics and Biosimilars.

Biologics

Do you think the Government's approach to determining Biosimilars/Biologics is providing sufficient certainty to Pharma? (%)



Do you think the Government's (PBS) approach to determining biosimilars for the purposes of reimbursement is providing certainty to Pharma? (%)



TGA Approach to Biosimilars

Survey respondents were split in terms of viewing the TGA approach to determining biologics and biosimilars as providing sufficient certainty to the pharmaceutical industry. Of the 41% who answered 'Yes', additional clarification included that the process for registration was clear, that it clarified their relationship with generics and that it was based on EU guidelines which their company is familiar with. Of the 59% that answered 'No', respondents felt that the Government had not defined its approach, clarified the distinction between biologics and biosimilars nor provided sufficient transparency and leadership.

Even fewer of the respondents felt that the PBS approach to determining biosimilars for the purposes of reimbursement was providing certainty to Pharma. The 14% who said 'Yes' were qualified in their answer, largely saying that it is uncertain how the legislation will work in practice and that it has not been agreed to. Of the 86% who answered 'No', respondents mostly pointed to a lack of definition of biosimilarity as well as what will be the reimbursement mechanism and approach. The general feeling is of a lack of resolution.

Data exclusivity

A large majority of 77% of respondents are familiar with the Data Exclusivity legal regime in 2012, and while a few don't want to see changes in this regime most recommend harmonisation with overseas regimes, and to extend the exclusivity period from 5 years to up to 10 years.

Risk sharing

Regarding risk sharing arrangements with the government for high-cost drugs, 69% of respondents have used them, and of the 31% who haven't, 62% would expect to do so in the next 2–3 years. Risk sharing can help facilitate companies with drug discovery and development activities and protect global reference pricing issues. However, are there better models, for example, rebates based on successful outcomes? Other approaches considered or used to overcome the issue of access for high cost drugs include cost-sharing deeds, early access and managed entry schemes, and patient co-payments.

Three-fifths of respondents are aware of conditional listings (Managed Entry Scheme) of new drugs with PBAC; 44% of companies have considered making a Managed Entry Scheme application. Currently, while some have tried it, and others are currently exploring the scheme, others are unfamiliar with it. A few are open to it being a good idea, but others lack trust for the scheme, particularly because of the high level of evidence requirements.

Lack of trust and lack of clarity are seen as barriers to the scheme's success; others ask what the commercial incentive is for companies to engage with it.

Sales and marketing were seen as a key area for local collaboration.

Collaboration

52% of respondents considered there was high or some local collaboration with pharmaceutical companies

Extent of collaboration

Companies collaborate with each other in strategic partnerships and alliances, including licensing. Active partnerships with biotech are being developed with some collaboration with university research centers. Companies are also working with biotechs with several collaborations under way, with investment taking place in Australia and at a global level.

More companies are working with other pharmaceutical companies in different global partnerships, strategic alliances and collaborations in order to optimise resourcing and leverage relevant clinical experience.

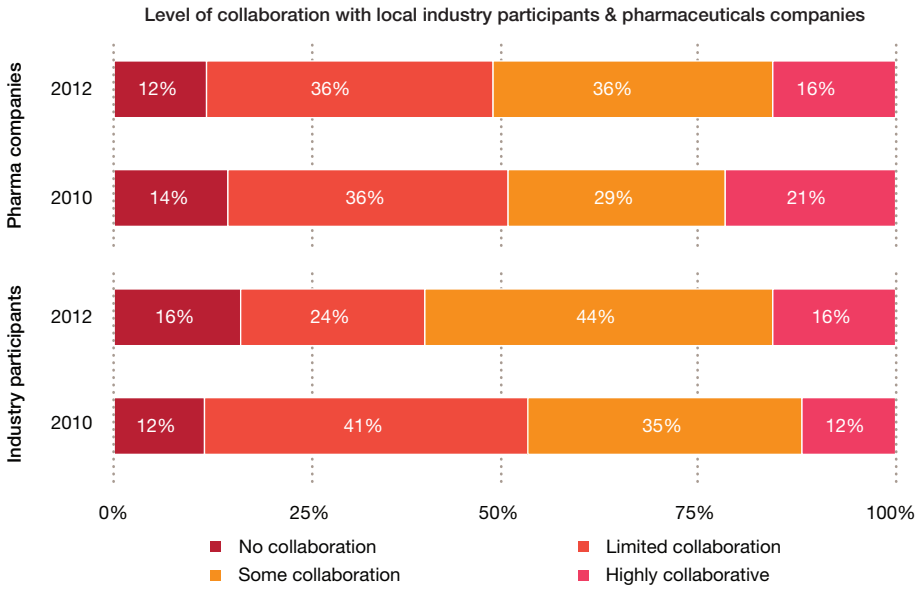
In 2012, local collaboration was seen as having improved with 52% of respondents considering there was 'high' or 'some' local collaboration with pharmaceutical companies (50% in 2010) and 60% of survey respondents considering that there was high or some collaboration with industry (47% in 2010).

While some survey respondents saw opportunities for collaboration as limited or had a lack of intent to engage in local collaboration, a number viewed sales and marketing as a key area for collaboration, as well as other areas such as partnerships and licensing, lobbying on common issues and collaboration in therapeutic areas.

Increased collaboration with payers and providers for their trials; hospitals and clinics for outcomes data and services providers for care, or seen as part of a move to new business models that was identified in PwC's *Pharma 2020: Changing Business Models* in 2009.

A new source of revenue?

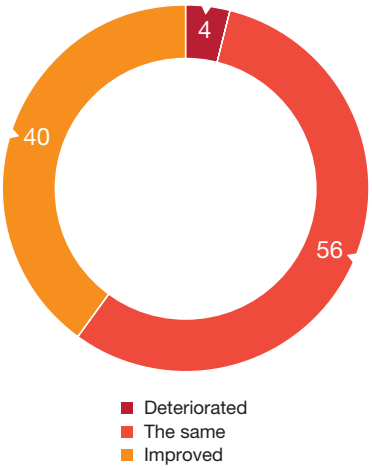
As expenditure on R&D is not delivering new products to fill their revenue gaps, most companies in the industry are looking for new drugs to fill their development pipeline as drugs increasingly coming off patent. In 2010, the most common ways to do this were through strategic alliances, R&D and licensing; in 2012, most companies aim to do this through acquiring new business, licensing, and strategic alliances.



80% of respondents are members of Medicines Australia, 10% of the Generic Medicines Industry Association and 30% other industry bodies.

State of industry representation

What is your view of the reputation of the medicines industry in Australia over the last three years? (%)



Role of Medicines Australia

As reflected by their membership, 85% of those surveyed considered the role of Medicines Australia to be very important. GMIA was viewed predominantly as moderately important (65%) and the role of NPSA was seen as mixed with 72% seeing it as moderately or somewhat important.

Industry unity

Appropriately, views among survey participants on industry unity in Australia were varied with some noting that unity does not mean uniformity of view but forums that include vigorous debate and different opinions. Unity has been expressed, therefore, in joint issues and initiatives such as on the use of deferrals, the Medicines Australia Code of Conduct and MOU with the Federal Government, and other policies and lobbying. Other participants highlighted different and competing interests depending on different factors that limit unity, for example the size of the country, the area of development and tensions between research-based and generic/biosimilar interests.

Industry reputation

In 2011, the Australian pharmaceutical industry, led by the industry organisation, Medicines Australia, launched its first consumer communications program to build trust with the Australian public, which included media placements and a website, to raise awareness of the industry's contribution to the health and wealth of the nation. Survey participants were asked to consider the reputation of the medicines industry in Australia over the last three years. Overall, the view on the medicine industry's reputation is rosy. Over the last three years, 40% of participants consider that the reputation has improved, while 56% see it as having stayed the same, and 4% deteriorated.

Some survey respondents were relatively positive, and considered that Medicines Australia had done a good job with its public relations campaign: Code of Conduct implementation has improved accountability and transparency; and the industry is no longer referred to as 'Big Pharma'. Others said that general population awareness of the industry is low; the point of care (i.e. doctors and pharmacists) is more likely to receive recognition for positive health outcomes, and that media bias and vested interests among stakeholders means that change in opinion will be limited. Some consider that the reputation of the industry will be dependent on avoiding scandal rather than on active positive campaigns.

Final comments?

In their final comments, survey respondents raised concerns about image, reputation and marketing and the level of power of both government and industry over access to medicines. They reiterated the prevalent theme of this survey of a desire for greater transparency in government processes and regulatory regimes, with an overall aim of improving patient outcomes. Their concerns can be summarised into these questions:

- How can industry improve its marketing to show the value provided to the consumer, and build better relations with them as well as the Government?
- How can industry improve working within the political process which is affecting their efficiency?
- Is it possible to shift the Government's focus from costs and budget impacts to health outcomes?

The survey's 32 responses included a number of one-on-one interviews with CEOs, Business Unit heads and directors of access and strategy.

Survey methodology

The purpose of the Pharma 2012 survey, *'Issues and Decisions',* was to elicit current views on issues facing the pharmaceutical industry. The survey was developed based on themes from the Pharma 2010 survey, *'Issues and Opportunities',* overarching themes that have emerged through PwC Industry reviews across the globe and in collaboration with Medicines Australia priority areas.

The survey was in a text-enabled PDF format and was circulated to participants through emails sent by PwC and Medicines Australia. A number of organisations were invited to undertake one-on-one confidential interviews to further explore responses provided in the survey. There were a total of 32 responses; participants included pharmaceutical companies, wholesalers as well as industry peak bodies. In terms of the 2012 PBS expenditure and prescriptions in the twelve months to 30 June 2012, survey respondents requested:

- 17 of the top 20 Pharma companies in terms of total value of costs spent on pharmaceuticals (over 78%)
- 14 of the top 20 Pharma companies in terms of total volume dispensed (over 72%)
- $7.1 bn of the $9bn Pharmaceutical industry
- Over 139,575,577 scripts dispensed

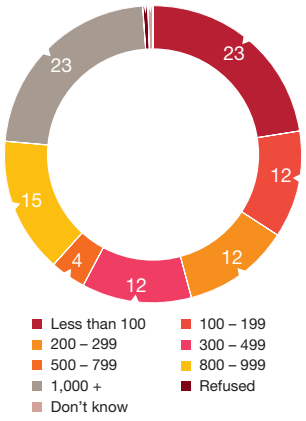
Classification

Of companies participating in the 2012 survey, 95% were multinational companies and 5% were domestic. While global headquarters of these companies were about evenly split, with slightly more located in Europe than North America, their regional headquarters were located in Europe, the USA and a majority in Asia, with a majority of those regional headquarters located in Singapore. The advantages of Singapore as a location for headquarters are clear: an English-operating environment and close reach to the rest of Asia where the government has facilitated favourable taxation, investment incentives, regulation and research as well as the creation of a biotech hub.

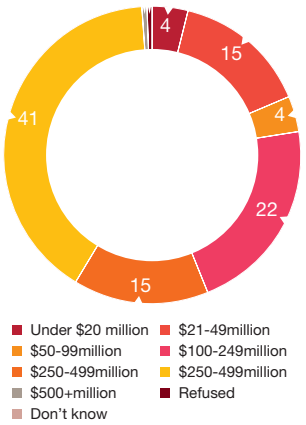
About half of the companies surveyed currently have less than 500 employees. Just over 20% have been 500–1000 employees, and 32% have over one thousand employees. Their current annual revenue has stayed about the same since the 2010 survey, showing continued strength and good revenues. About 50% of the companies turn over more than $500 million a year.

Questioned about business activities in Australia, respondents indicate that all are involved in sales and marketing, most (75%) in distribution and over half in development (60%) and research (55%). Fewer companies are involved in services (40%) and the manufacturing of a finished drug (35%).

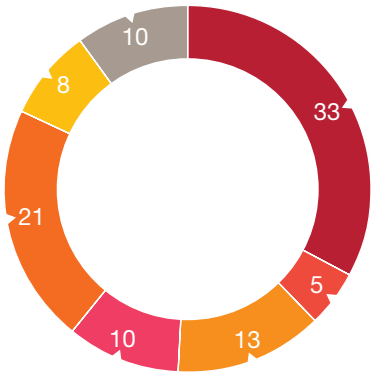
Number of employees your company has in Australia: (%)



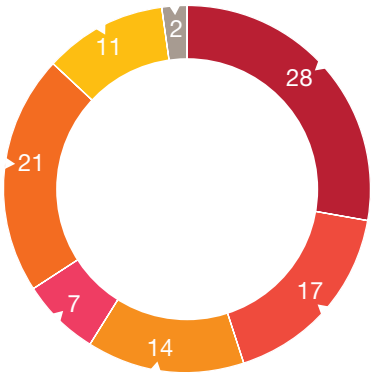
Current annual turnover in Australia in 2012: (%)



2010 (%)



2012 (%)



Sales & Marketing
Research
Development
Manufacturing of finished drug
Distribution
Other
Services

This report was produced with the assistance of survey respondents within the wider Australian pharmaceuticals industry.
Coordinating Editors: John Cannings, Tim Hogan-Doran & Jessica Li.
Contributing Writers: Andy Quan, John Cannings, Dr Brendan Shaw, Professor Christine Bennett, Klaus Boehncke, Tim Donald, Daniella Dickson, Chris Cuthbert, Eliza Penny, Tim Hogan-Doran, Nathan Schlesinger, Damian Angus, Peter Anderson, Jessica Li.

Previous PwC Publications

Pharma 2020 series:

Pharma 2020: From Vision to Decision

In this report, we focus on how companies can reach 2020 in a position to benefit from more favourable conditions thereafter. While the tools to develop remarkable new medicines are materialising, demand for its products is increasing and the barriers to free trade are falling. But pharma also faces major economic and operational challenges, if it's to capitalise on these opportunities and create more value for payers, providers and patients.

Pharma 2020: Supplying the future

In our sixth release of the series, published in February 2011, PwC discusses how pharma companies must develop different supply chain models, learn to use supply chains as a market differentiator and revenue generator, and recognise how information will drive the downstream flow of products and services.

Pharma 2020: The vision
Which path will you take?

Published in June 2007, this paper highlights a number of issues that will have a major bearing on the industry by 2020. The publication outlines the changes we believe will best help pharmaceutical companies realise the potential the future holds to enhance the value they provide to shareholders and society alike.

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Asia–Pacific Pharma & Life Sciences Newsletter

Our PwC Pharma & Life Sciences experts from throughout the region present you with regular updates on important developments within the Asia–Pacific pharmaceutical industry, with regular articles focusing on developments occurring in respect of key areas including Compliance, Pricing & Reimbursement, Regulatory and Accounting and Taxation regimes throughout the region.

India Pharma Inc. – Gearing up for the next level of growth

In this report, we look at the different types of growth levers that have fuelled the growth of the Indian market, emerging new business models, as well as the key success factors that need to be kept in mind to achieve sustainable long-term growth. The report presents an overview of the issues facing the industry today and throws light on the road ahead for all stakeholders, to realise the industry's full potential.

Issues and Opportunities – in a time of change

PwC Australia's most recent biannual report into the Australian Pharmaceutical Industry provides you with qualitative and quantitative findings from our survey of key companies and stakeholders in the industry during 2010 including companies engaged in sales and marketing, manufacturing, Research & Development (R&D), distribution, wholesaling, retailing and services

All these publications and others are available to download at: ***www.pwc.com/pharma***

For further information please contact

John Cannings
Partner
Asia–Pacific and Australia
Pharmaceutical & Life Sciences
Industry Leader
[61] 2 8266 6410
john.cannings@au.pwc.com

Eliza Penny
Partner
Assurance
Pharmaceuticals & Life Sciences
Assurance Leader – Australia
[61] 2 8266 1355
eliza.penny@au.pwc.com

Chris Cuthbert
Partner
Corporate Tax
Pharmaceuticals & Life Sciences
Tax Leader – Australia
[61] 2 8266 7957
christopher.cuthbert@au.pwc.com