
Challenges and Change

A report on the Australian pharmaceutical industry



Welcome

to PwC's 2015 pharmaceutical industry survey



John Cannings
PwC National Health Leader

“The more things change the more they stay the same” is an apt description of where the pharmaceuticals industry is at in Australia today.

Since our last survey of the industry *Issues and Decisions 2013* we have seen a lot of change across the industry. There's been the development of new and targeted therapies for Hep C and immuno therapies for cancer, regulatory changes in pricing and reimbursement, changes to the regulatory environment and marketplace through M&A activity and loss of exclusivity on some major brands.

Despite these changes, we still see a system not operating as efficiently or as effectively for stakeholders – taxpayers, government, suppliers and patients – as it could. There continues to be some lack of trust between originators and government that impacts access to new, innovative and specialised treatments. The recent failure to reach agreement between the peak body Medicines Australia and the Department of Health underscores

the challenges and difficulties in present relations.

In 2013 we put forward the view that all parties needed to find a way to work more collaboratively and to rebuild positive relationships in a transparent and ethical manner. This continues to be our view two years on.

Encouragingly, there have been a number of positive developments. The Pharmacy Guild entered into a historic 6th five year agreement with Government, albeit with give and take on both sides. The Generic and Biosimilar Medicines Association (GBMA), formally the Generic Medicines Industry Association (GMiA), also concluded its first agreement with Government and have as a consequence positioned themselves as a distinct player in the market. And pharmaceutical wholesalers have secured funding and certainty around the Community Service Obligation (CSO) for another five years.

The industry also continues to be the major developer of new life saving and life improving drugs and has made significant gains in the areas of cardiovascular disease, malignancies (solid and liquid) and infectious diseases where some diseases which were previously killers are now treated as chronic conditions or in fact can now be cured.

As a society we want access to these new drugs at affordable prices and to do this we have created one of the world's best health care systems. However the system is starting to show signs of wear and tear. It is incumbent on all stakeholders to find ways to work together, to bring

forward access to new drugs when appropriate, to reduce costs when and where appropriate, and to ensure a viable and sustainable industry in which taxpayers and patients have a say.

In other words, we are all in this together.

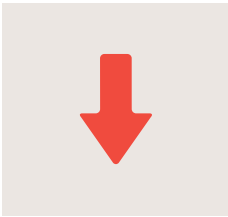
We are pleased therefore to present the findings of our fourth survey of the Australian pharmaceutical industry, which we conducted in association with Medicines Australia. It should be noted the survey was conducted before the commencement of negotiations with the pharmaceutical sector surrounding the 6th Community Pharmacy Agreement. The resulting PBS Access and Sustainability Package, announced in May 2015, brought about a number of structural reforms to the PBS and savings measures.

Our goal is to assist the pharmaceutical industry, as well as regulators and governments, with up-to-date information to support sound business strategy and public policy development. Our views on the current and emerging issues are supported by trends already apparent in recent PwC industry reviews across the globe.

PwC's pharmaceutical practice is dedicated to providing industry with valuable strategic insights as well as leading services. We hope that the analysis and informed views we provide will assist all industry participants. Please feel free to contact me if you would like to know more about how we can help your organisation to manage and thrive amid these current and future challenges.

John Cannings OAM
PwC National Health Leader

Key findings



80%

felt that the PBAC reimbursement process has not improved or deteriorated over the last two years



65%

felt that the TGA processes have either not improved or deteriorated over the last two years



87%

have considered not applying for reimbursement in the last two years



89%

feel that further investment in compliance will be needed in the near future



80%

expect to use a risk sharing agreement in the next two years



63%

plan to develop biosimilars in the next two years



89%

have high priority on strategic alliances and joint ventures



45%

still consider ehealth/mhealth a potential future competitive advantage



66%

are anticipating growth

Foreword

from Medicines Australia



Tim James
CEO, Medicines Australia

The 2015 PwC Pharma Industry Survey comes at a challenging time for the Australian pharmaceutical industry. Recent years and months have been characterised by a more competitive market, significant advancements in technology, constrained budgets, major reform and increasing scrutiny from payers, regulators and the community. This has led to pharmaceutical companies reassessing business models to ensure they remain responsive.

Companies are facing challenges from an increasingly difficult reimbursement process and tight fiscal circumstances, which has in turn led to delays in access to some new medicines.

Importantly, since the survey was conducted, the industry is being subjected to the largest reforms since the separation of formularies and the introduction of price disclosure. The 2015 PBS Access and Sustainability Package will create added pressure on the already strained industry and

lead to downsizing for many companies and further access pressures. However significant savings will be delivered from these and existing reforms and the PBS is more sustainable than ever. There is a commitment by government to ensure innovative, new medicines continue to be made available to the Australian community.

On top of this, the report highlights that ad hoc pricing measures, the introduction of appropriate policy for biosimilars and early access to medicines through Managed Entry Schemes remain but a handful of the complex challenges facing the industry. The Australian industry also faces an increasingly competitive international investment environment, calls for greater transparency of its operations and increasing compliance pressures.

Overwhelmingly the report identifies that there remains a feeling of uncertainty, and a desire for predictability with respect to market access and the business operating environment since the previous report. It is an imperative now more than ever that the industry and government together focus their efforts on achieving stability and ensuring Australians receive timely access to the latest and safest medicines.

At the same time, the challenges identified in the report also raise opportunities and the Australian pharmaceutical industry will have a key role in delivering a smarter, stronger, healthier Australia now and well into the future. However to achieve this, it is incumbent upon industry to cohesively and more effectively articulate the

value and significance of its work, the broader benefits it delivers, and the dynamics needed to deliver even more for Australia.

Australia needs to leverage its highly educated and skilled workforce to ensure its success in the post mining boom economy and it is anticipated that health and medical research will be a key area for growth. Shifting the narrative from the cost of medicines to the value they provide to the health and wealth of the nation will be important for the industry over the coming year. It is also important that the community and government recognise that medicines have a broader value to the economy by ensuring the population continues to participate and remains productive.

The 2015 PwC Pharma Industry Survey provides an important and timely insight into the collective views of the Australian medicines industry and the issues of considerable challenge as well as opportunity. The findings are all the more poignant given the ongoing importance of the industry to the health and wealth of the nation in this decade and indeed century.

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

Tim James
CEO
Medicines Australia

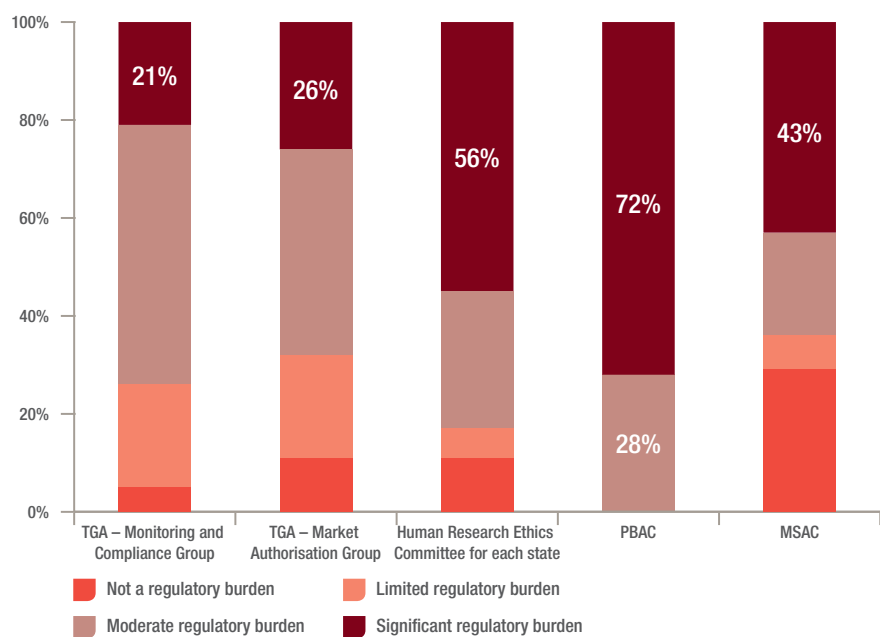
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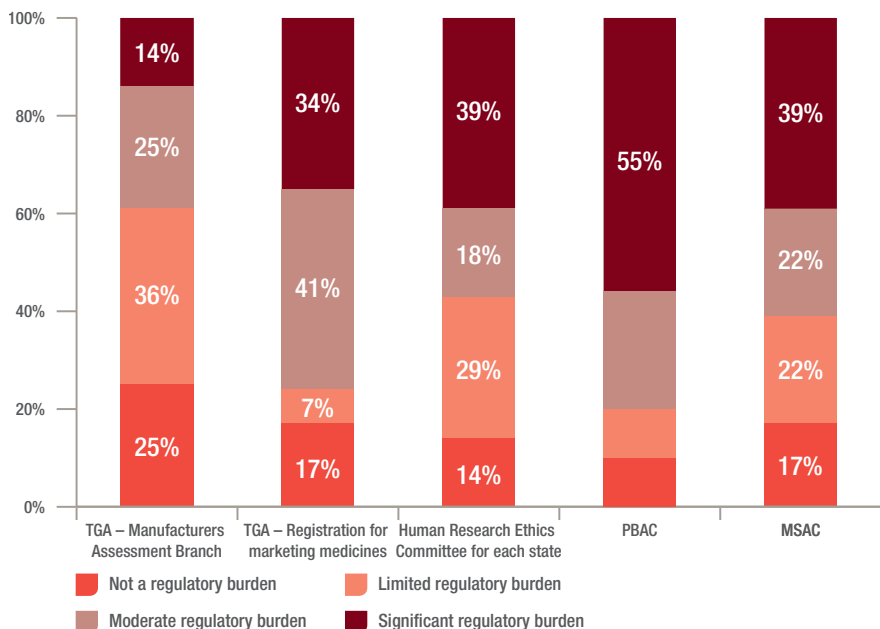
Regulation and access: looking for clarity and consistency

Regulation and access remain key challenges for the pharmaceutical industry in Australia. Companies say they are experiencing increased regulatory burden across many areas, with a clear increase in burden from Pharmaceutical Benefits Advisory Committee (PBAC) since 2012. There appears to be a theme emerging from the comments by survey respondents that transparent decision-making and access to new medicines is being hampered by a lack of collaboration between industry and government.

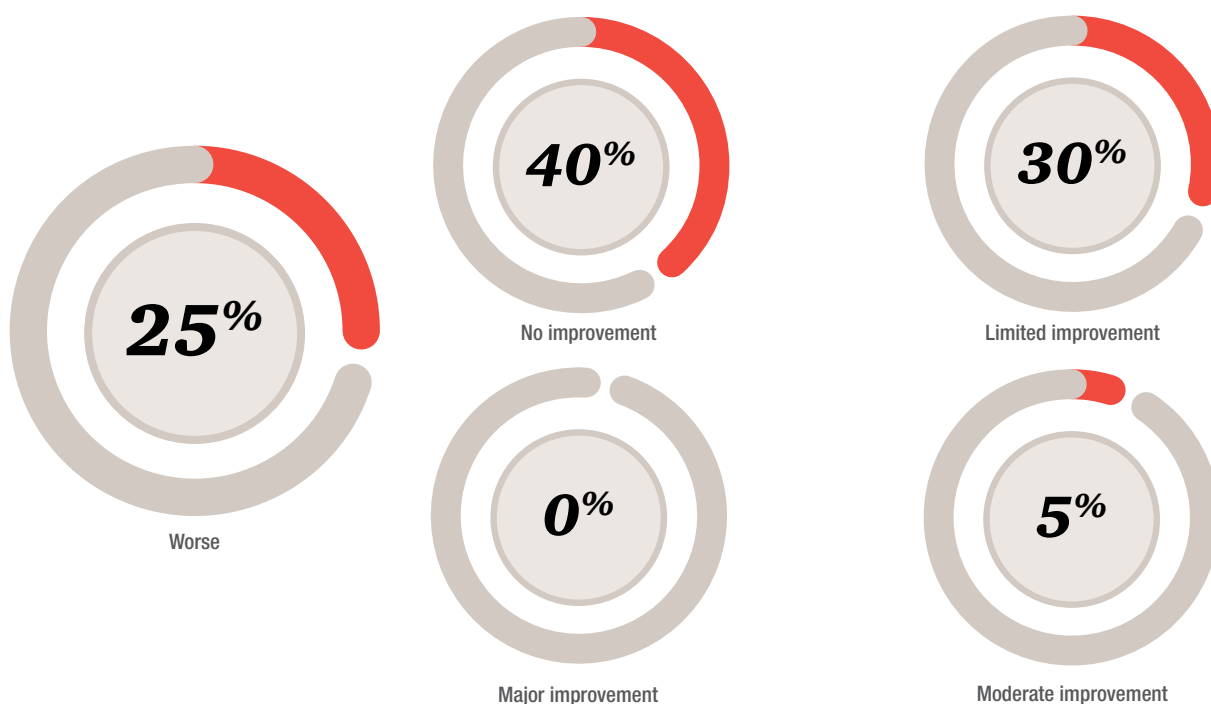
Extent of regulatory burden in 2014



Extent of regulatory burden in 2012



TGA Registration process over last 2 years



Registering products remains a challenge

On 24 October 2014 the Minister for Health announced the Expert Review of Medicines and Medical Devices Regulation or the Therapeutic Goods Administration (TGA) review. In light of this review, respondents agree that it's important to keep an independent, Australian regulatory agency for approvals. However, 65% of the industry believe that the processes managed by the TGA have either not improved or have worsened over the last two years.

An under-resourced TGA and an unnecessarily bureaucratic approach are perceived as the main factors contributing to this. The responses highlight that the industry believes that there could be more opportunities to collaborate and work with the TGA to increase the scope for companies to submit supporting documentation to address any issues raised.

Respondents also acknowledge a few improvements. Some say timelines are more predictable and the decision-making process more transparent. Others consider the ability to make online submissions a plus. Good Manufacturing Practice clearance prior to submission appears to have improved since the last survey was conducted.

It's worth noting that Australia appears to be middle of the road compared to other international regulators in terms of approval times, slower than the Food and Drug Administration (FDA) in the US but faster than Europe's European Medicines Agency (EMA)¹.

As mentioned in previous surveys, respondents are again looking for a more efficient process and greater collaboration between the TGA and international regulators. This would help to streamline approvals where agencies such as the FDA have already approved a product. It would also limit the requirement for Australian specific data.

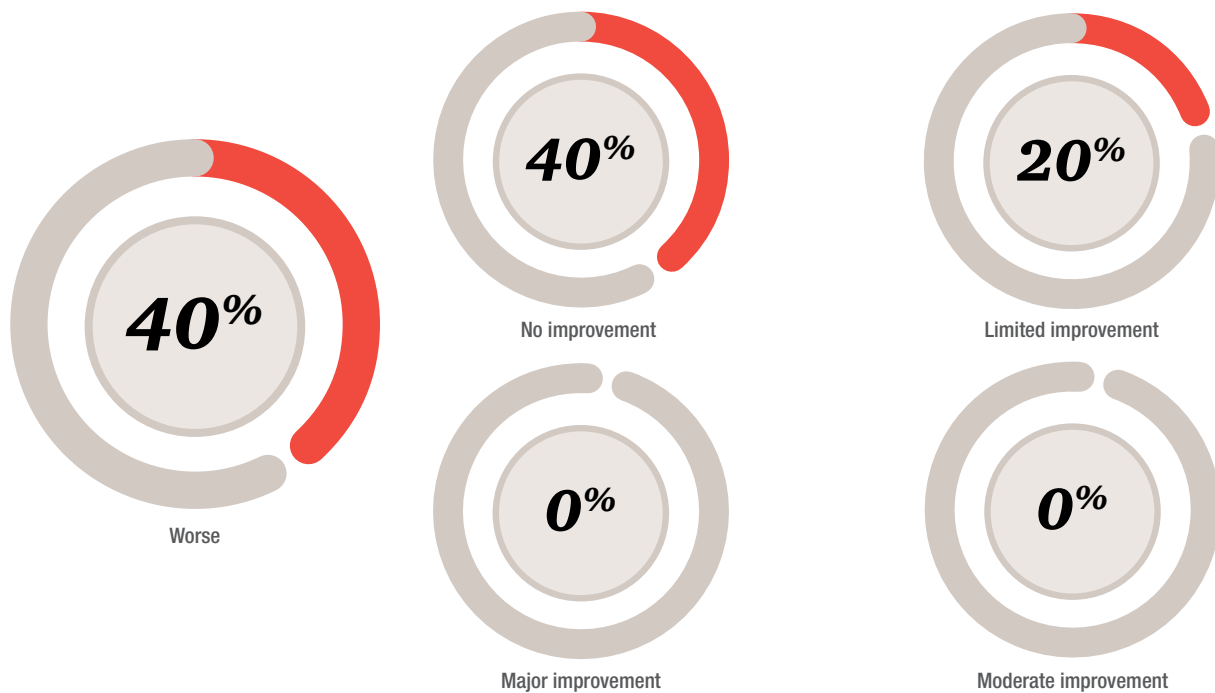
There is independent support for change on this issue. The recent Review of Medicines and Medical Devices Regulation report made suggestions to utilise assessments conducted by comparable overseas regulators, and for expedited assessments in defined circumstances².

Companies say the regulatory approval process would also benefit from fast track or priority mechanisms for certain drugs for high clinical need or lifesaving therapies. Accelerated approval mechanisms are available through both the EMA and the US FDA. Recent examples are Novartis' heart failure medicine, Entresto, and Eisai's thyroid cancer drug, Lenvima. Such outcomes can only be of benefit to people in need of breakthrough treatments and PwC, the industry and a majority of patients groups and other stakeholders supports the development of similar fast-track mechanisms in Australia.

¹ Sansom, L., Delaat, W., Horvath, J. (2014). *Review of Medicines and Medical Devices Regulation – Discussion Paper*.

² Sansom, L., Delaat, W., Horvath, J. (2015). *Medicines and Medical Devices Regulation – Report on the regulatory framework for medicines and medical devices*.

PBS Reimbursement process over last 2 years



PBS reimbursement has become more difficult and riskier

Respondents found that the PBAC has the highest regulatory burden of all regulatory bodies. 80% of respondents felt that the PBAC reimbursement process has either not improved or has deteriorated over the last two years.

Pharmaceutical companies in turn are becoming increasingly reluctant to apply for reimbursement through the Pharmaceutical Benefits Scheme (PBS).

87% of respondents have considered not applying for reimbursement for some products in the last two years and 82% expect again not to in the next two years. This is significantly higher than the reported 52% of products being withdrawn or not applied for in 2012.

Companies are now more seriously examining cost effectiveness and viability before presenting drugs for PBS listing. If the risk is too high that the resulting PBS price will be unviable, companies are often not even going through with the cost of an application.

Comparator erosion is still cited by sponsors of medicines as a barrier to listing. Respondents say an over-emphasis on price at the expense of delivering improved clinical benefits to patients and the health system more broadly is marring the process.

While this frustration is understandable, PwC believe it's important to recognise that it makes good business sense for companies to critically assess the value of a product before bringing it to market, and that the government must inevitably balance the cost to taxpayers against clinical benefit.

Pricing and reimbursement pressures in pharmaceutical schemes are however, somewhat inevitable and this is not just an issue in Australia. Trends towards cost cutting and value based assessments can also be seen in other areas of healthcare (e.g. outcomes based reimbursement) and in other countries with public healthcare funding.

In 2011 Germany instituted the Act on the Reform of the Market for Medical Products (AMNOG), which mandated more stringent benefit assessment requirements for new pharmaceuticals to help control costs. Canada has also been known for a stringent value analysis and budget focus for publically funding medicines. The UK's Pharmaceutical Price Regulation Scheme helps contain costs by limiting the profit that companies can achieve through National Health Service (NHS) medicines. Since 2003 the prices of branded pharmaceuticals in the UK have dropped considerably compared to global price points³.

³ Association of the British Pharmaceutical Industry. (2014). *Understanding the 2014 Pharmaceutical Price Regulation Scheme*. London. http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf

Industry split on PBS listing processes

On a positive note, half of the Australian pharmaceutical companies surveyed feel that there have been some improvements to the PBS listing process in the last two years. They cite the availability of a parallel approval process, acceptance of some electronic documents, transparency of public summary documents, some increased flexibility with PBAC processes and increased recommendation rates. A recent report supports this view showing that the current Government has placed an average of 24 new or amended listings on the PBS per month, compared to the eight per month added under the previous Government⁴. However the report does not outline if these are new innovations, generic competitors or extensions of indication to current PBS listings or innovative new medicines.

However, half of those surveyed believe that there has been no improvement in the PBS listing process. Perceived causes of this are a lack of resources to manage overly complex processes, lack of transparency on risk sharing, unreasonable expectations of clinical evidence and a skewed focus by PBAC on setting the lowest price.

While the approach taken by PBAC of granting conditional approvals has the benefit of boosting recommendation rates, companies say it places greater onus on them to undertake more costly additional submissions. Department of Health data shows that while overall approval rates are up, the success rate for initial PBAC submissions dropped from 89% in 2010 to 51% in 2013⁵.

⁴ Harvey, R., de Boer, R. (2015). Growth in expenditure on high cost drugs in Australia. Canberra: Parliamentary Library. http://parlinfo.aph.gov.au/parlInfo/download/library/prspub/3599565/upload_binary/3599565.pdf;fileType=application/pdf

⁵ Medicines Australia. (2015). Medicines Australia Facts Book – Fourth Edition. https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/11/MAFactsBook4_update2015.pdf

Increasing the frustration to companies, these requests for follow-up data and submissions are not always consistently used by PBAC to inform further price changes, and have not necessarily led to a listing. Such delays in access cause uncertainty for launch planning, employment of local staff, delays to investment in R&D and cost blowouts, not to mention delays in access to medicines for patients. Flexibility in being able to meet with the PBAC and discuss issues through the submission process has been suggested as one way to avoid confusion, time and expense.

Industry calls for improvement

Companies appear to be losing confidence that these submissions have much impact in changing the process – 42% of companies surveyed have canvassed their ideas with government on how to improve the PBAC submission process, down from 75% in 2012.

Respondents say that the process would improve if PBAC were better resourced and companies were given more open and consistent access to PBAC officials during the submission process. They say a more collaborative approach, where companies are given greater clarity on assumptions, calculations, methodologies and comparator selections would help them to better know where they stand.

Respondents also feel that there could be improvement in the government's Health Technology Assessment (HTA) process by including further information and valuing broader societal and patient outcomes. PwC believe that the inclusion of evidence around societal and patient outcomes, such as reduced hospitalisations and economic impact from productivity improvements, could make for a more comprehensive impact analysis. For example, Australia has a high rate of melanoma, which typically affects younger patients, compared to other malignancies. Appreciating the high morbidity and mortality rates, new targeted medicines such as PD1 Inhibitors should be assessed on their broader economic benefits such as workforce participation and productivity for young patients diagnosed with melanoma.

Clearly, it's in everyone's interest for regulators to find ways to increase the efficiency, clarity and certainty of approvals processes, particularly in relation to breakthrough and life saving medicines. Fast-track solutions or exceptions, for example, could help increase patient access to medicines for special cases.



Pressures on price

Comparator erosion is rising

Respondents say that comparison with generic products when listing a product is the primary reason why the majority of the industry will not consider some products for the PBS. Comparator erosion impacts the majority of surveyed companies and as more patents expire, this effect will continue to grow. The general agreement within industry is that there is an over-emphasis by PBAC on benchmarking the price as low as possible by using F2 medicines as comparators.

Price disclosure supports PBS sustainability

71% of companies currently believe that the government's price disclosure calculation is transparent, up significantly from 39% back in 2012. However, some also suggest that there needs to be independent verification of calculations. Many companies believe that no further price reductions can be sustained and that their market share will be further eroded under Simplified Price Disclosure (SPD).

A substantial majority of respondents (83%) say that the price cuts associated with price disclosure have caused their company to reconsider how it manages the late stage life cycle of its existing mature products, up from 2012 survey. Companies are responding by considering delisting original brands, increasing brand premiums, renegotiating supply contracts and partnering with generics and third parties.

Three-quarters of companies believe that the original intent of the price disclosure mechanism has not been achieved. This intent was to manage PBS costs, ensuring it could be financially sustainable while enabling the continued listing of new innovative medicines on the PBS.

Many believe that there is little transparency about how the savings are being reallocated. There are misgivings that savings are not being used for new medicines or being re-invested back into the PBS. Some suggest that a specific funding pool should be set up so that price disclosure savings are transparently allocated for reinvestment in new listings.

The pharmaceutical industry on the whole feels that the current model of price disclosure is sustainable only if resources are allocated appropriately to new medicines and comparator erosion can be dealt with. Most are concerned that further price cuts will stifle innovation and reduce patient access to medicines.

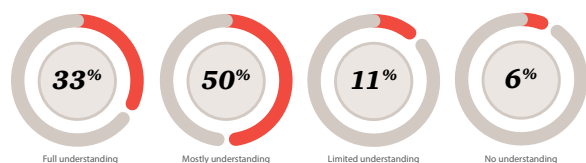
So, while industry supports price disclosure, they also want increased certainty about price as well as transparency about how savings are being re-invested.

Worryingly, there appears to be less understanding about the implications of price disclosure currently compared to our last survey in 2012.

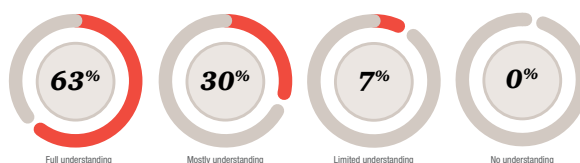
Comparator erosion

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.

Understanding of Price Disclosure regulation implications in 2014



Understanding of Price Disclosure regulation implications in 2012



Post market reviews

58% of companies surveyed have been involved in a post-market review.

Whilst the stated intent of post-market reviews mostly relate to improving Quality Use of Medicine (QUM), based on the outcomes to date many believe it has limited benefits in supporting patients. The process is largely believed to be neither collaborative nor transparent. Most respondents suspect that the primary agenda of the process is to reduce price. Some cited the recent post market reviews of diabetes and Alzheimer medicines that resulted in price reductions.

The industry and government have sought to improve the process over recent years and a framework for the conduct of post-market reviews was jointly published in early 2015.

Cessation of PBPA

Since cessation of the Pharmaceutical Benefits Pricing Authority (PBPA) in early 2014, pharmaceutical companies surveyed feel that PBAC is now acting as price negotiator. Companies report compromised PBAC independence and poor clarity around the pricing of products as a result.

There is a sense that the process is more adversarial and less cooperative than it was when the PBPA was still in operation. According to respondents the potential for improvement in time to listing following PBAC recommendation, given the removal of the extra step of PBPA consideration, has not been achieved. Industry has also expressed frustration that the post – PBAC process is now less transparent following the disbandment of the PBPA.

While the frustrations of industry are understandable, the reality is that pricing pressure is here to stay. PwC believe that a greater focus on joint solutions between regulators and pharmaceutical companies on the many regulatory issues facing industry is urgently needed. The lack of trust generated by the current adversarial situation benefits neither industry, the Government nor patients.

Impact of the Pharmaceutical Access and Sustainability Package and the 6-CPA

On 23 June 2015 the *National Health Amendment (Pharmaceutical Benefits) Bill 2015* was passed by the Australian Parliament. The Bill gave effect to the PBS Access and Sustainability Package (PASP), which is a set of reforms to the PBS and medicines supply chain. The PASP accompanied the signing of the Sixth Community Pharmacy Agreement (6-CPA) which set the funding arrangement for community pharmacies for the next five years. The PASP and the 6-CPA will continue to add to price pressure within the wider industry by:

- Lifting the number of times a year a PBS medicine price can change from three times to five time per year
- A one-off statutory price reduction of 5% to all brands on the F1 formulary once the medicine has been listed for a minimum of six years
- Further accelerating price disclosure by removing originator brands from the price disclosure calculations following three years listed on the F2 formulary
- Application of price disclosure reductions for single ingredient medicines (e.g atorvastatin) to related combination items (e.g amlodipine and atorvastatin)
- Freezing of the indexation on the Community Service Order (CSO) for the duration of the agreement period
- Removing certain Over The Counter (OTC) medicines from the PBS⁶

These measures are likely to significantly hit the revenue of originator pharmaceutical companies the most, and similarly generic manufacturers and upstream wholesalers will likely be impacted. Companies will need to make strategic decisions as to the products they launch into the Australian market, which will ultimately influence the health outcomes of Australians through access to novel therapies.

⁶ PBS Access and Sustainability Package including the Sixth Community Pharmacy Agreement. (2015). <http://www.pbs.gov.au/info/general/pbs-access-sustainability-package>

Risk sharing or risk shifting?

Pharmaceutical companies and the government are exploring different mechanisms to provide patients with faster access to new medicines whilst also distributing the risks more evenly. With the increasingly specific actions of novel drugs on smaller patient populations, alternative approval processes can provide earlier access to medicines for patients and additional usage data and outcomes for government.



50% of respondents considered applying for a managed entry scheme

Managed entry scheme

The intent of the managed entry scheme (MES) is to facilitate the PBS listing of a product which may have limited clinical data, thereby expediting patient access. Subsequent price alterations are to be made as more supportive data becomes available. This process is sought by PBAC as a mechanism to insulate government from risk should the real world data not match the clinical data.

Only half of the companies surveyed have considered applying for a MES. For some companies, it's not desirable because the parameters are not well understood. Some say that the MES is not that different to accepting the PBAC price within the PBS, and then undertaking real-world studies to justify a higher price for the product.

Scepticism exists about whether government will recognise positive outcomes in follow-up real world studies and accordingly increase the price of a product to reflect this. Companies say they would have greater confidence in the MES if government approached negotiations in partnership with industry rather than in the currently perceived adversarial manner.

Additionally, some companies say it's very hard to prove an impact with real world evidence, as there are multiple confounders that potentially obscure the direct effects of the medicines alone. Follow-up research and collection of

real world evidence is the onus of the sponsor company and undertaken at their cost. Effectively, all risk is placed on companies that this research will be supportive of a price increase.

Overall, respondents believe that they will bear the majority of the risk burden under the current arrangements and that industry would have a higher incentive to apply to list products under the MES if pricing at entry is at the requested sponsor price and the required evidence to maintain the price is agreed upfront.

Rare disease or lifesaving drug program

Only one quarter of companies have sought to list a treatment for a rare disease on the PBS or through the Life Saving Drugs program and half of these have found the process more difficult than a standard PBAC listing submission.

Some commented that the process can be fraught with delays and uncertainty. Submissions for rare diseases do not appear to be given any tailored consideration compared with standard submissions. For instance, companies noted that there is room for more pragmatism from the department and the PBAC when considering less robust data for clinical evidence. However, limited clinical data is inevitable given these drugs target smaller patient populations.

High cost drugs

There is mixed support from companies regarding the continued use of risk sharing agreements (RSAs). The majority of respondents have used RSAs for high cost drugs and 80% expect to do so in the next 2-3 years. However, respondents generally feel that there needs to be a fairer allocation of risk, as the current situation is placing the onus on companies to shoulder the majority of risk.

Companies are undertaking various activities to support the agreements such as making sure they have robust clinical development programs in place so that strong data and evidence can be delivered to evaluators.

Some are restricting access to the most cost effective population or targeting drug therapy using biomarkers to identify those patients who are most likely to respond to certain drugs. By restricting access or using biomarkers, companies are reducing the risk of Government paying for drugs for less responsive patients.

Others are entering price/volume arrangements, confidential rebate agreements, introducing their products via the private and hospital sector or using a managed entry scheme.

Suggestions for how the government could better manage expenditure on high cost drugs include finding alternative funding streams, reinvesting savings from products coming off patent and establishing dedicated funds such as the UK cancer fund.



7 Commonwealth of Australia. (2015). *Out-of-pocket costs in Australian healthcare*. http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Australian_healthcare/Report

Improving access to high-cost drugs

The Australian Institute of Health and Welfare has predicted that from 2003 to 2033 expenditure on pharmaceuticals is likely to increase by 163%. Part of this increase is due to the impact of highly specialised and higher cost medicines as a proportion of PBS expenditure. Additionally, based on AIHW private prescription data, it seems that patients are also increasingly paying more for medicines that are not covered by the PBS⁷.



Nathan Schlesinger
Health Consulting Partner

Whilst there are ongoing debates around the sustainability of the PBS, there can be no doubt that bringing new, high cost medicines to market in Australia will be increasingly challenging for the biopharmaceutical sector.

It may be time to consider innovative approaches to ensure that patients get timely access to new treatments, while meeting the investment returns that innovators of new products inevitably require.

Here are several options that we believe warrant further exploration:

- **Resolving the constraints faced in ‘pay for performance’.** While the appetite for the use of risk sharing approaches is on the rise, there remain some fundamental issues that constrain its use. A concerted strategy and program of work is required to work through these challenges in a collaborative way such that Australia could become a global leader in the application of these models.
- **The role of Private Health Insurance (PHI).** PHIs have constrained their coverage for pharmaceutical products over the last 10 years. We have seen coverage for high cost drugs not listed on the PBS “pushed down” to hospitals who have increasingly required patients to cover some of these costs. Industry should be engaging with these payers to better understand their needs and the value proposition they have in this industry.
- **Personal medical savings accounts.** The concept where people or employers contribute a portion of their income to a tax-deductible savings account that can be used for medical costs has been tried in various countries including Singapore, China, the United States, and South Africa.
- **National Drug Fund.** In the UK there is a separate fund that was introduced in 2011 for cancer patients to access medicines that are not subsidised through the NHS. The fund’s costs have increased by over 50% since 2011, however, and some criticise the fund for prioritising cancer over other diseases. Medicines Australia recently rejected a UK style cancer fund solution as they feel a capped funding pool would not necessarily solve the access issues in Australia in the long term.
- **Public Private Partnerships and Social investment strategies.** Taking a lead from developments in the UK, the health system in Australia is increasingly looking to social investment strategies (e.g. social impact bonds) to fund growth in services and innovation. A recent example is in NSW where the Premier has launched a program seeking social impact bonds for multiple service areas including health.
- **Financial services sector’s role.** Personal investment products such as superannuation or life insurance policies could potentially be adapted to make access to funds for life saving drugs easier for patients.
- **Employer benefits.** Employers are increasingly seeing the value of creating a healthy work environment for employees, including the impact on productivity. With this trend towards increased focus on wellness in the workplace, there is potential for employers to play a role in supporting coverage for life saving drugs.

Biosimilars: a complex challenge

The biosimilars market lacks certainty for industry and patients alike.

All companies surveyed believe that the TGA's approach to determining biosimilars is not providing sufficient certainty, compared with 41% back in 2012, a significant rise in concern. This no doubt reflects the recent and expected growth in this market and the fact that existing frameworks are inadequate to deal with biosimilars.

With many biologic's patents expiring soon, the market for biosimilars is ripe for growth. However, it seems the regulatory environment is not equipped to cope with the complexity that biosimilars present compared to the processes for small molecules.

Biosimilars are more complex and expensive to manufacture than small molecule products. There is no guarantee that the same therapeutic effect will result from biosimilars unless the formulation and manufacturing process are identical to that of the originator. This makes decision-making about how to classify biosimilars under the F1/F2 regime a significant issue.

Industry is especially concerned about pharmacovigilance in cases where biologics and biosimilars are considered potentially substitutable. Recently, in August 2015, the PBAC recommended that pharmacists be allowed to substitute biosimilars with the reference biologic without consent of the patient or their GP.

A lack of clarity around the defining and naming of biologics is exacerbating this complexity in Australia. The TGA has changed its naming conventions several times while awaiting finalisation of the World Health Organisation (WHO) policy on this issue.

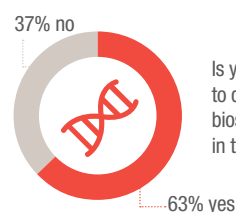
The pharmaceutical industry is seeking certainty on this issue now and some respondents suggest that the TGA need to set out a clear and transparent timeline for policy finalisation on biosimilars, perhaps reaching an interim position before the WHO policy is released.

All companies surveyed believe that the PBAC approach to determining biosimilars for the purposes of reimbursement is not providing certainty, up from 86% in 2012.

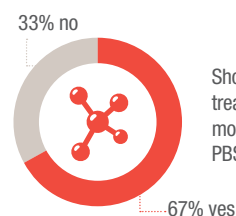
More than two thirds of respondents feel that biosimilars should be treated the same way as small molecule generics for PBS reimbursement. This is largely because the sustainability and competitiveness of the PBS model needs to be retained by treating all off-patent products consistently.

Of the one third who did not agree that biosimilars and small molecule generics should be treated the same, most cited concern about substitution at the patient level. Others agree that price reductions for biosimilars are entirely appropriate but that biosimilars should not be listed under the F2 regime, as they are not substitutable.

Members of the Generic and Biosimilars Medicines Association (GBMA), formerly known as the Generic Medicines Industry Association (GMiA), decided not to participate in this survey and therefore their views on this topic are not represented in the survey results. However an outline of the GBMA's position on biosimilars by CEO Belinda Wood, is detailed over the page.



Is your company likely to develop biological or biosimilar medicines in the next 2 years?



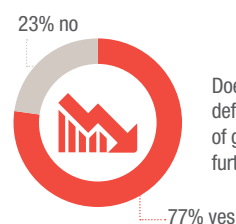
Should biosimilars be treated the same as small molecules for the purposes of PBS reimbursement?



In 2014, do you think the PBAC approach for reimbursement is providing certainty to Pharma?



In 2014, the TGA approach to determining BioSimilar/Biologics is providing sufficient certainty?



Does the lack of defined process/clarity of guidance deter further developments?



Biosimilars – an exciting opportunity

Belinda Wood

*CEO, Generic and Biosimilar
Medicines Association (GBMA)*



Belinda Wood

In an established market like Australia, it is rare that such a significant new segment emerges that offers opportunities for industry, government and patients. The next 2-3 years will be particularly exciting as biosimilars are rapidly adopted in the local pharmaceutical market.

Biosimilars are not exactly new, and traditional generic companies are ahead of the curve in Australia with epoetin, marketed since 2010, and filgrastim, since 2011. But momentum is building as the patent expiry dates draw closer for some of the most expensive brands on the PBS such as Remicade, Humira, Mabthera and Enbrel.

The Australian biosimilars opportunity is drawing attention from local and international stakeholders as it blurs the traditional line between brand and generic companies. While many companies are seeking to take advantage of this opportunity, international experience shows biosimilars don't follow the traditional generic model, where a brand patent expires and multiple generic companies compete on price for market share.

What we should expect is generic companies forging the market with the first biosimilars, new players in the market who will focus purely on biosimilars, and some brand pharma companies taking a step into the post-patent space for the first time. The end result is more affordable medicines and increased patient access to biological treatments.

There is a great opportunity for Australian pharma to capitalise on the emergence of biosimilars as long as the barriers to market entry are minimised and policies are introduced to encourage uptake and a competitive marketplace. This is why it's so important to clarify aspects of biosimilar market access, particularly in the regulatory and reimbursement approaches taken by the TGA and the PBAC, and in the naming convention being discussed internationally.

The role of education can't be underestimated in delivering on the opportunity presented by biosimilars. It is essential that confidence in biosimilars is supported by factual, balanced information for doctors, pharmacists and patients. This is a fact supported by the government's commitment of \$20 million over the next 3 years to biosimilar education to promote awareness and encourage uptake.

There is no doubt that the Australian government can see the opportunity for savings presented by biosimilars. As biological medicines now account for 25% of PBS expenditure, the need to encourage biosimilar uptake and support PBS sustainability is clear. In fact, the government is counting on biosimilars to contain PBS costs.

Biosimilars offer an exciting opportunity for industry, government and patients and we look forward to seeing a competitive biosimilars market grow and thrive in Australia.

99ACB uncertainty is affecting decision-making

Almost two thirds of companies had not sought to list a second presentation of a patented PBS listed drug, because doing so would trigger a movement to F2 and a 16% price reduction under Section 99ACB of the National Health Act. There remains disagreement between the industry and the Department of Health on the intent of the legislation.

Respondents were uncertain about whether 99ACB will be triggered for innovations such as packaging or delivery devices. Some in the industry have not proceeded with innovations like this because of the potential for a price reduction where their own existing product will be used as a comparator.

More than half of those surveyed will seek to list a second presentation of a patented PBS listed drug in the next two years. Most noted that the decision to proceed to listing would depend on the risk of price reduction. If this risk is high, most companies will not proceed with listing.

Example of Biologics with patents expiring soon:

- Darbepoetin (Aranesp®) for Amgen
- Pegfilgrastim (Neulasta®) for Amgen
- Peg-interferon (Pegasys®) for Roche
- Adalimumab (Humira®) for Abbvie
- Etanercept (Enbrel®) for Pfizer
- Infliximab (Remicade®) for Janssen-Cilag
- Trastuzumab (Herceptin®) for Roche

Compliance

The current top three costs of compliance to the pharmaceutical industry identified by survey respondents were (i) the Medicines Australia Code of Conduct, (ii) TGA and (iii) internal audits and company policies.

Since 2012, it has been the cost of internal audits and company policies that has increased the most.

As a result of the above, most companies say they have made moderate to significant improvements across all areas of compliance, staff training & human capital, systems & data integrity, and reporting processes and procedures.

Some companies are experiencing an increased focus on business ethics and code compliance, representing considerable investments in both time and money. 89% anticipate further investment will be needed to comply with the updated Medicines

Australia Code of Conduct, as the reporting requirements for transparency will be significant.

Companies envisage this will require significant training, development and implementation of new tracking systems, along with increased monitoring and auditing to allow companies to deliver accurate reporting of the required data of expenditure at the Health Care Professional (HCP) level. These will be additional burdens. Communicating changes within companies and ensuring 100% compliance will be a challenge.

Medicines Australia Code of Conduct

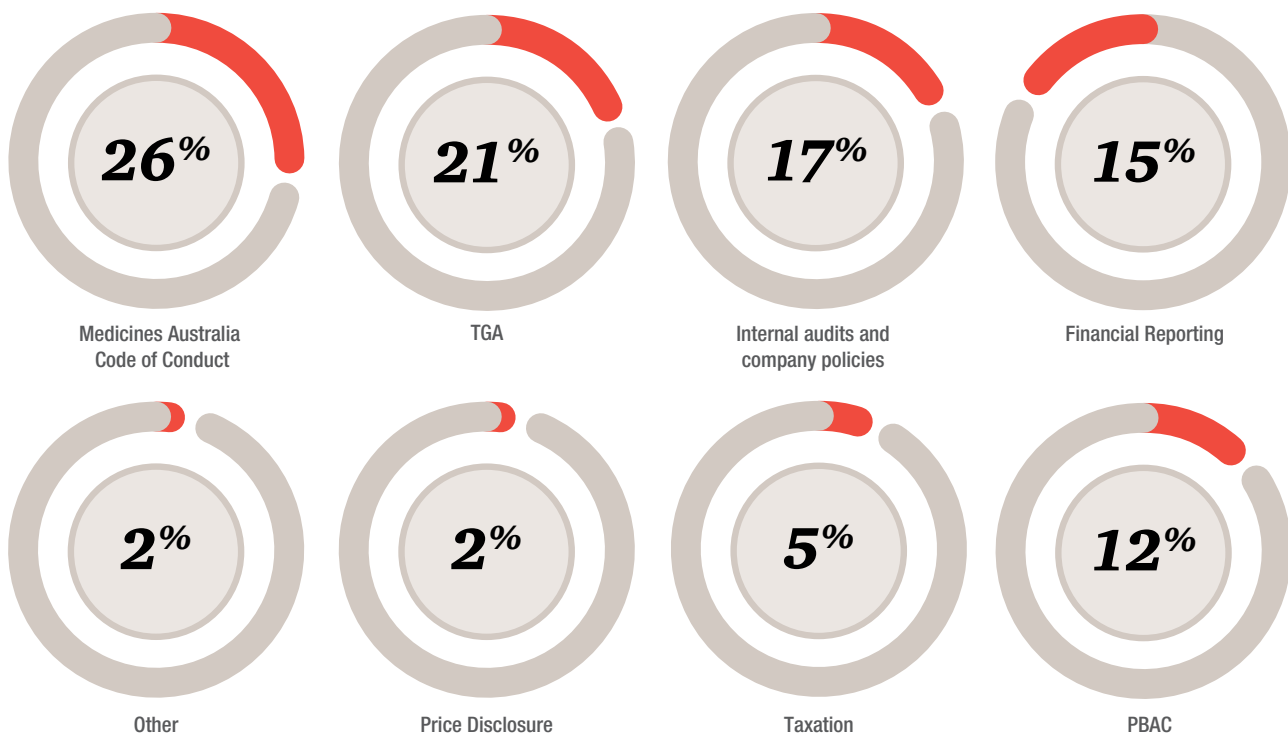
There are mixed views about the likely impact of the new Medicines Australia Code of Conduct. Some say the impact of increased transparency is difficult to gauge and may be

marginal. Others believe it could reduce collaboration between health care providers and industry, as HCPs may be unwilling to get involved if there is any risk they will be seen as accepting funding from industry.

If barriers are created between the medical community and the industry there are concerns it will consequently limit transfer of education.

Most companies do not believe that transparency will have an impact on health outcomes for individuals one way or another. Rather, the main benefit of increased transparency is that it will improve the industry's reputation.

Risk and compliance measures rated in the top 3 in terms of costs in 2014





A growing focus on compliance

Compliance is becoming an increasingly important issue for the pharmaceutical industry globally. This is a result of:

- the global trend towards transparency reporting
- additional government requirements regarding the registration of medicines
- recent scandals regarding bribery and corruption, increasing the internal and external regulatory focus on payments, and
- increased scrutiny of relationships with third parties.

Transparency reporting, in particular, has continued to gain momentum globally with the introduction of the APBI Code of Practice for the Pharmaceutical Industry in the UK, the EFPIA Code of Practice in Europe, and the continued reporting in the US under the Sunshine Act.

In Australia, the main introduction to the Medicines Australia Code of Conduct is the requirement for member companies to report payments or transfers of value to healthcare professionals (HCPs), for sponsorships, consultancies, travel and accommodation costs. Companies will need to collect relevant information from October 2015, with reporting commencing April 2016. This information must be made publically available on each company's website. The ACCC also requires that Medicines Australia consider the future development and implementation of a central database for this information.

Many member companies will have learnt from the experience of their international colleagues regarding the challenges and level of effort required to successfully implement transparency reporting. The new requirements demand a thorough understanding of a company's source systems, the availability of information

that is required to be collected, and legal documentation and contracts. To ensure the accuracy of reporting, we expect companies will need additional resources and to work more closely with HCPs.

It remains uncertain as to how both HCPs and the public will react to these disclosures. It will be important for members companies to explain to consumers the relationship between this information and patient health outcomes.

Rather than being just a burden, the reporting process should be seen as an opportunity for companies to identify improvements and efficiencies in their business, processes or systems. In the future they could consider how the reporting process could be developed to maximise its value, including measuring the impact of reporting on patient outcomes.



*Daniella Dickson
Director in PwC's
Forensic Services team*



A story to tell about tax

Taxation has become an increasingly important issue for the pharmaceutical sector in recent years. Against a backdrop of increasing public expenditure and decreasing taxation revenue, it has become increasingly evident to Governments around the world that the international tax rules have failed to keep pace with changing business models and technological developments.

With governments facing budget shortfalls and various public voices questioning whether multinational companies are paying their 'fair share' of taxes, taxation has now become a political issue. This carries with it reputational risks as companies with tax liabilities in a given country that don't readily correlate with the level of turnover for operations in that country are being subjected to aggressive income tax examinations and mainstream media attacks. This is taking place whether the taxes paid satisfy existing international tax rules, or have been approved by the relevant tax authorities.

Earlier this year, the Australian Senate's Economics References Committee commenced public hearings into Corporate Tax Avoidance, initially focusing on mining and technology

companies. From the 'Singapore profits sling' to 'Byzantine tax structures', the global tax affairs of these international companies were put under the microscope by Senators and the Press. The Pharmaceutical sector, of course, was not immune to this. Following on from earlier comments to the Senate Estimates by the Commissioner of Taxation, Mr Chris Jordan, as to the perceived risks with the sector in respect of Transfer Pricing, the Committee soon turned their eyes on Pharma. On 1 July, representatives from 9 of the largest multinational pharmaceutical companies were called before the committee to (ostensibly) testify as to their tax affairs. However the public discussion quickly moved to asking companies to justify how they pay so little tax relative to the funds they receive through the Pharmaceutical Benefits Scheme.

While much of the focus of these hearings has been on Pharma's relatively small tax payments, little has been said, other than by their industry body, about the contribution Pharma makes to the Australian economy – let alone the positive impact the industry's products have for patients. As an employer of highly skilled labour, supporter of advanced

manufacturing and driver of extensive clinical research and development, the pharmaceutical industry is critically important to the future of the nation.

Needless to say, whilst there remains uncertainty as to what specific action is needed to reform the international tax system, countries that move early and that do not act consistently with the OECD's Base Erosion and Profit Shifting (BEPS) project may produce an even more complex tax picture in the short term, and disadvantage themselves by discouraging continued investment in the industry.

At the same time, clearly there is a need for Pharma to get on the front foot about not solely their contribution to society but also the appropriateness of the tax currently paid under international and Australian tax laws. Despite this, with the Government set to introduce tax transparency reporting later this year and other BEPS initiatives, it is likely that in the short term many companies will come under increasing pressure to justify their tax affairs while the world awaits agreement on further international tax reform.



*Chris Cuthbert
Partner Corporate Tax*

Growth, strategy and innovation



Growth ahead

Despite the many challenges facing the pharmaceutical industry in Australia, two thirds of companies say they are anticipating growth in this market. Growth is expected to come largely through expansion in new therapeutic areas, increases in sales and marketing capacities, the introduction of new products in portfolio pipelines and New Chemical Entities (NCEs).

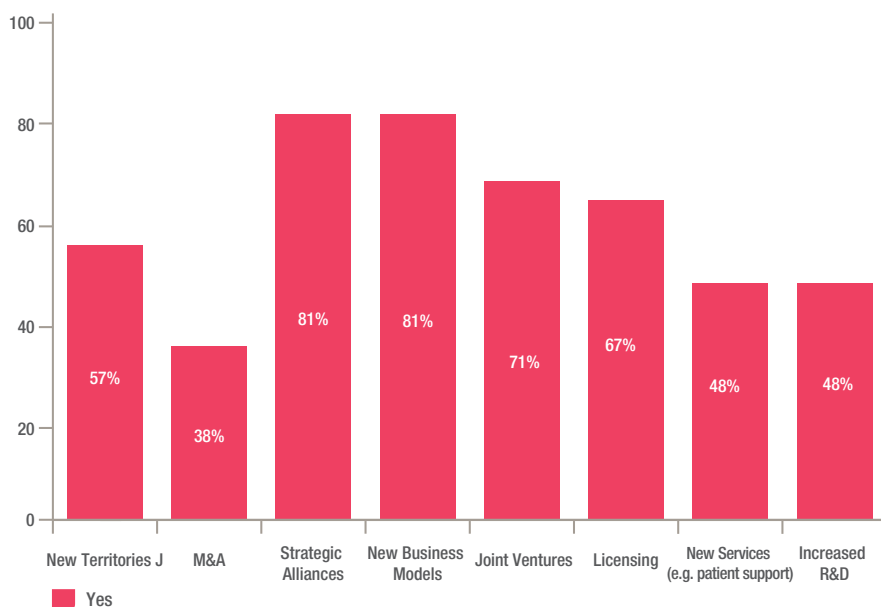
Of the 33% who do not anticipate growth or are unsure if they will grow, reasons include smaller product launches and lower PBS pricing, simplified price disclosure, lack of new products, and the impact of loss of exclusivity.

Diverse global strategies for global challenges

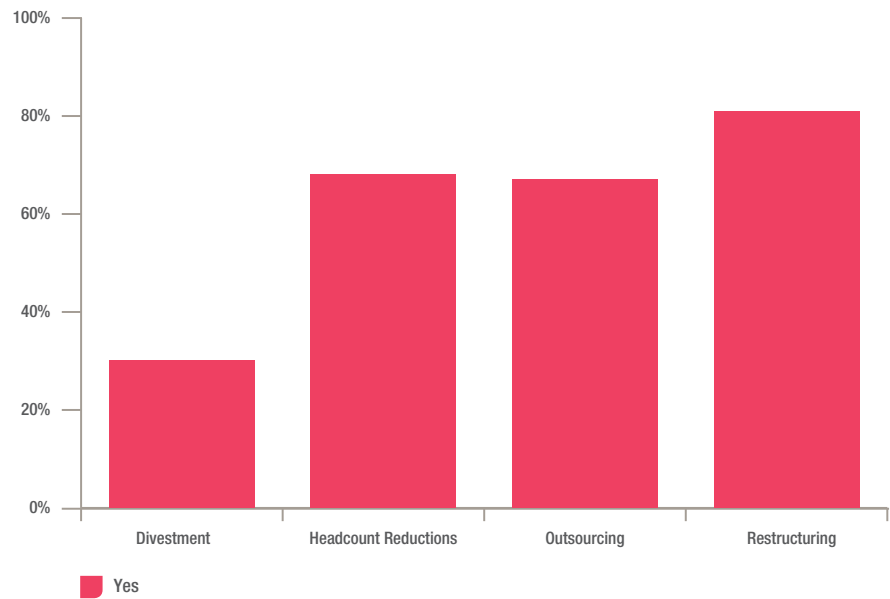
Respondents say they face a range of global challenges to growth, including: increasing regulation, higher payer and patient expectations and scrutiny on price. In response, companies are pursuing a variety of growth strategies. Some are broadening their portfolios, while slightly more report narrowing their focus to core business.

Specific strategies include maximising portfolio value, integrating research and market access functions more closely as well as building up market access and external affairs capabilities. Companies are also focusing on restructuring to increase efficiencies, manage costs, and more tightly meet their compliance obligations. Many mentioned that they are focusing on innovation, areas with high unmet clinical need, and on increasing real world evidence.

Focus/highest priority areas for the global strategy (Growth)



Focus/highest priority areas for the global strategy (Cost management)



Cost management remains very much a focus for industry with companies focusing on restructuring, headcount reductions and outsourcing.

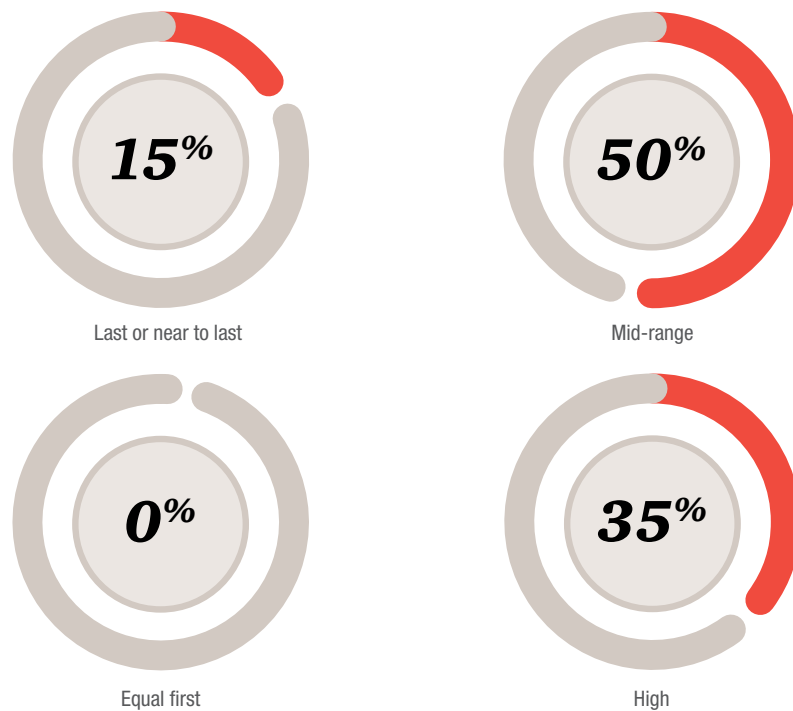
When it comes to innovation, companies are placing a strong focus on strategic alliances and joint ventures, as well as adopting new business and operating models. This reflects a similar trend found in PwC's 18th Annual Global CEO Survey, which showed that 62%

of Australian CEOs are looking to enter new joint ventures or strategic alliances in the year ahead.

It is also evident in the growth we are seeing in innovation funds, which have been set up to actively seek out alliances and partnerships with emerging innovative science and technology companies in a corporate venture capital capacity.



Australian company's rank in relation to the launch of new products compared to other developed markets



Three quarters of respondents say that their strategies overall were either mostly or very effective in increasing their company's profitability.

Adapting strategies locally

Building on global strategy, 63% of those surveyed have made additional strategic changes locally. These changes include changed business models and marketing focus, private market launches, and an increased focus on reimbursement as a critical success factor. The majority of companies (72%) surveyed have shifted from a go-to-market approach in the last two years to a disease or account focus.

Some companies expect to outsource functions like IT, supply chain, CROs and finance into the Asia Pacific region in the next five years.

Despite significant local challenges, Australia is considered by the majority of companies to be ranked high or mid-range in new product launches, compared with other developed markets.

Focusing on the patient

PwC's Pharma 2020 thought leadership reports had noted industry's burgeoning involvement in 'beyond the pill' healthcare solutions that focus on the patient journey. However, this survey suggests that the Australian pharmaceutical industry has mixed views on the extent to which they should be involved in healthcare delivery and patient outcomes.

Some believe that companies should continue to focus on what they do best, and that their responsibility is to ensure that their products deliver the best possible health improvements for patients by developing safe, innovative, effective treatments. Others feel that the industry should be more involved in the care pathway and have already started to invest in this.

However, in reality there is limited opportunity to engage at a patient level in Australia except in cases where

the public healthcare sector is unable to resource specific product-related services, for example, infusion services. Pharmaceutical companies also consider that the negative perception of the industry often held by patients and healthcare providers is a barrier to their involvement with patients.

Despite this, many have strategies in place to better focus on patient outcomes. That is, to deliver a solution rather than simply a treatment. Patient support services present the opportunity to engage in a greater proportion of the patient journey, as well as collect valuable real world evidence. This creates value for both companies and patients.

Examples include increasing medical teams to provide improved education to health care providers and setting up patient compliance programs to ensure optimal health outcomes. As this often needs to be conducted through third parties, it's important that pharmaceutical companies' operating models are highly collaborative.

Making the most of digital?

As expected, companies are engaging digital technologies such as web sites, social networks and mobile/apps technologies.

Interestingly, uptake of some technologies has changed little since 2012. For example, in 2012 46% said they use a social networking web site and apps, compared with 52% in 2014. Also, 54% used mobile/app technology to engage consumers and patients in 2012 compared with 62% in 2014. However, 23% are considering adopting mobile/app technology.

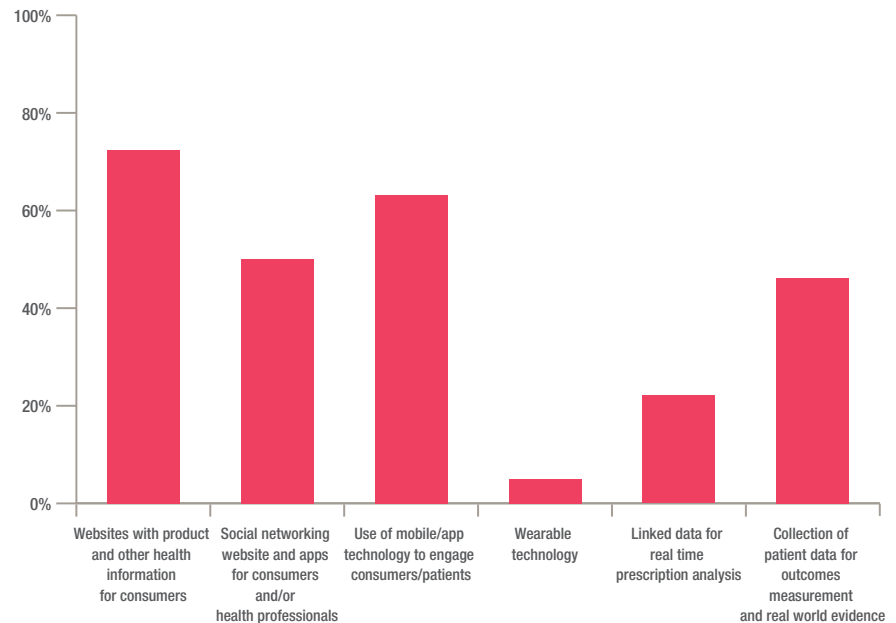
76% of companies currently utilize a web site with product and other health information for consumers. Very few are engaged with wearable technology, but some now have linked data for real time prescriptions. Almost half are collecting patient data for outcomes measurement and real world evidence, some of which would be part of MES agreements.

The majority of companies (84%) believe digital technologies to be a limited risk strategy, while 16% believe they are a significant risk.

In 2010, 83% of respondents viewed eHealth as a major or significant competitive advantage. But the perception of this advantage has dropped since then to 56% in 2012 and 50% in 2014.

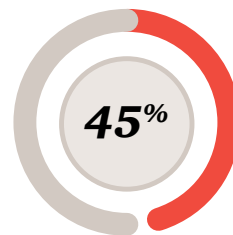
The Australian pharmaceutical industry seems a little underwhelmed by the potential of digital. This puts them at odds with the majority of Australian CEOs who, according to our 18th Annual Global CEO Survey, see digital technologies as being critical drivers of growth and adding value to operational efficiencies and customer experience.

Did respondents utilise any of the following ehealth/mhealth elements in 2014?



2014 Survey:

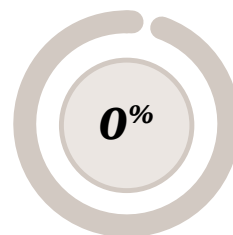
Extent that ehealth/ICT will be a future competitive advantage



Significant competitive advantage



Major competitive advantage



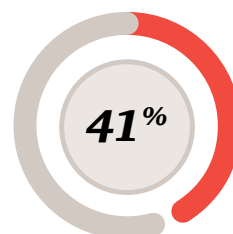
Not a competitive advantage



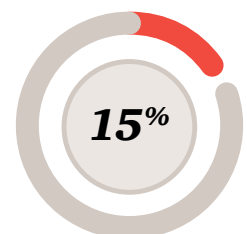
Limited competitive advantage

2012 Survey:

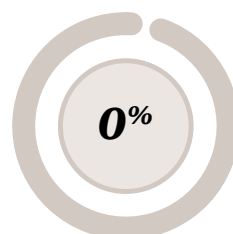
Extent that ehealth/ICT will be a future competitive advantage



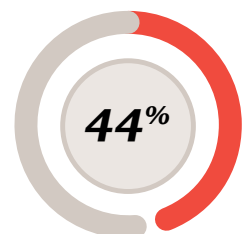
Significant competitive advantage



Major competitive advantage



Not a competitive advantage



Limited competitive advantage

How digital can help pharma

This report and many other global reports highlight that the commercial environment is not getting easier for the pharmaceutical industry. We see the key strategic priorities for companies in Australia are to:

- Ensure they have a seat at the table with policy decision makers and other stakeholders during the development and validation of integrated clinical pathways, protocols and funding models.
- Broaden and deepen relationships with consumers to drive patient activation and engagement with respect to their medication treatment.
- Anticipate and prepare for changes resulting from medical cost reduction measures and non-branded competition in the Australian market.

Digital innovation can play a critical role in supporting engagement with these priorities. It could help companies preserve their local market positioning as well as lead to the development of new capabilities or evidence that could provide leverage into other larger markets. There are three major opportunity areas of digital technology for pharmaceutical companies:

1. Build an effective Real World Evidence (RWE) based capability system

As pharmaceutical companies are shifting from a volume to value based business model, they will increasingly need to show that their drugs and services are working under real world conditions. There is a real opportunity for established companies in Australia to build their digital capabilities to collect and use Real World Evidence (RWE) as part of their own local clinical development programs. When combined with the traditional Randomised Control Trial (RCT) method of developing new products, RWE could significantly reduce the cost and time to market for new medicines.

A recent survey of global pharmaceutical leaders by Strategy& showed that less than 17% of respondents indicated they have at least minimal capabilities in RWE. Pharmaceutical companies have the chance now to develop RWE capabilities and put themselves in the drivers seat to encourage public and private insurers to provide faster patient access and reimbursement for their drugs based on comprehensive clinical effectiveness evidence.

2. Develop or participate in digital health solutions for patient engagement

Pharmaceutical companies have an opportunity to play a greater role in delivering a better experience for patients, improving clinical outcomes and reducing the total cost of care through digital health technology. The key is increasing patient activation through a patient engagement platform (PEP).

A growing body of knowledge shows that when patients are activated they have a greater understanding of their role and confidence in a care process, leading to a lower incidence of hospital readmissions and medical errors. Many of the digital health approaches and apps today remain point solutions, targeting specific patient measures such as blood pressure. However pharmaceutical expertise in medical treatments is increasingly being recognised for its potential to enable more holistic digital health solutions that would have greater success in engaging patients.

There is an opportunity for Australian pharmaceutical companies to support health insurers by developing a PEP to drive improved patient experiences, better clinical outcomes and reduce total cost of care. A holistic PEP would need to provide value through combining patient smart devices and tools, customer marketing insights, analytics of economics and medical outcomes, patient & physician communities and physician tools.

Providing that the PEP is not seen as self-serving, it has the potential to redefine pharma's place in the Australian healthcare system and evolve its commercial model by helping to address some of the industry's current challenges, for example: helping patients understand the value of their medicines, access and relevance to physicians if they see the value of their therapeutic regimen and access to design RWE studies and clinical protocols.

3. Digitise the supply chain and internal support services

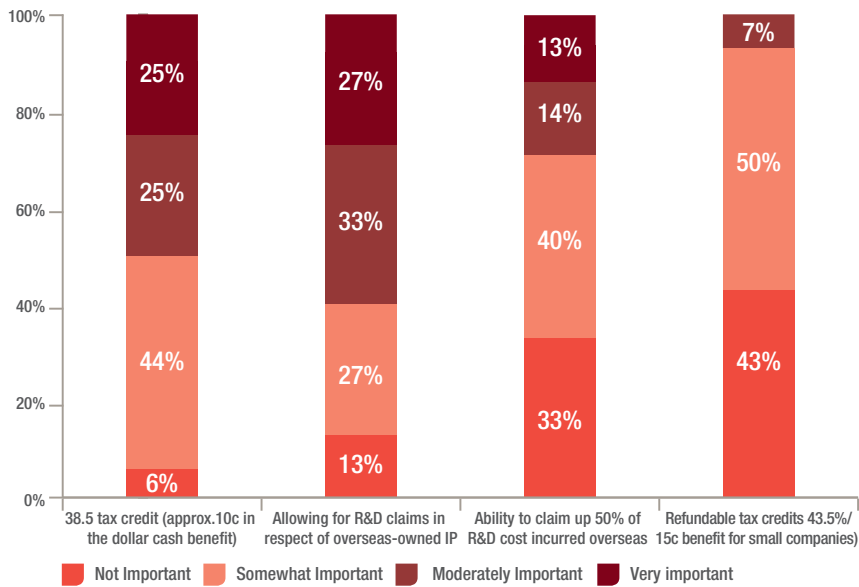
Across every sector of the economy, digital technologies are redefining the benchmark for excellence in supply chain, marketing and sales operations. The pharmaceutical industry faces a growing impetus to reduce the cost and improve the effectiveness of these activities. Companies need to ensure the ongoing optimisation of their supply chain through digital technology, as well as ensuring that their sales distribution channels are digitally enabled and supported with the right marketing and sales information.

While this survey suggests that pharmaceutical companies in Australia have been exploring some of the opportunities from digital technology outlined here, it also indicates that, at least locally, there is less recognition of the potential of digital as a differentiator. This view is not consistent with other developed markets where there remains maintained enthusiasm for innovation and investment in digital capabilities by the pharmaceutical sector.



*Chris Bartlett
Strategy & Partner*

In 2014, what do you value most about the government's current R&D tax credit programme?



Intellectual property protection

As we found in our last survey, intellectual property protection is important for most companies, with 90% saying it is very important and 10% saying it is somewhat important.

The majority of respondents had seen no substantial changes in the intellectual property environment over the last 5 years. Government litigation to seek damages from companies trying to protect intellectual property is one exception. The intellectual property environment is considered to be inadequately competitive.

Data exclusivity protections also remain inadequate by world standards. Almost all (94%) companies would like to see changes to the data exclusivity regime and overwhelmingly this means extending the term of protection (5 years in Australia) to be in line with the U.S and the EU (between 8 to 12 years) so that there is a level playing field.

Also, respondents feel the scope of protection should be extended to include patents that cover new therapeutic indications. Companies say they should have the right to protect their patents and government should abandon the policy to claim from innovators seeking to extend their patents.

R&D

The R&D tax incentive has limited impact on influencing decisions about whether research activities will be conducted in Australia as there are many other factors that influence these decisions. These include wage and salary levels, exchange rate, patient recruitment timelines, infrastructure capabilities and how the R&D site matches with markets for the product.

R&D tax reforms have made no change to incentives to undertake innovative R&D for the majority of companies surveyed (69%). 26% said there was now an increased incentive, down from 54% in 2012.

In terms of what companies valued most about the R&D tax credit programme, there were very mixed views.

Compared with regional incentives, 71% of companies believe that incentives in Australia are less competitive, with 29% saying they are about the same. Compared with global incentives, half thought Australian incentives were less competitive and half thought about the same.

For many companies, R&D tax credit would be more compelling if available "above the line". Companies also believe that the government needs to take action to better support the clinical research environment, for example, by shortening approval timelines.



A path forward

Despite the challenges facing the pharmaceutical industry – and there are many – we believe there is a positive path forward, for both industry and regulators.

Ongoing collaboration is critical. There is a pressing need for joint solutions between regulators and pharmaceutical companies on the many regulatory issues facing the industry. It is not reasonable or sustainable for companies to take on a disproportionate burden of risk. Regulators need to find ways to increase the efficiency, clarity and certainty of regulation, particularly in relation to breakthrough and live saving medicines. For example, approval fees and processes could be more reasonable for smaller submissions, such as orphan drugs.

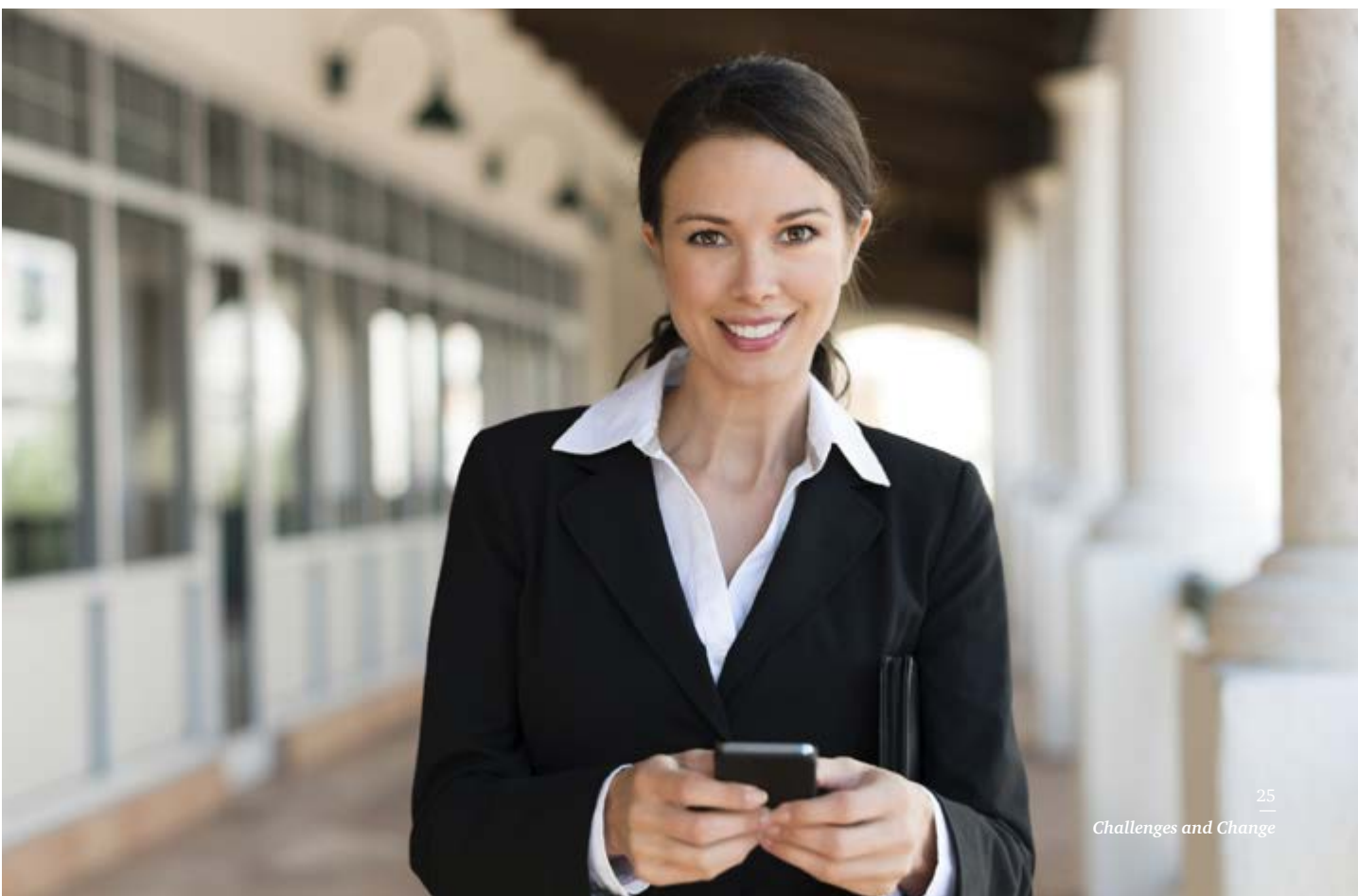
On the other hand, pharmaceutical companies must recognise that ongoing price pressure is inevitable

and they must adapt in order to grow. Although the business environment seems to have worsened, it appears that there is still room for growth. Two key areas are the support for better patient outcomes, and the use of digital technologies.

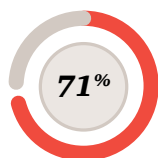
Healthcare is moving towards integrated and personalised care. Pharmaceutical companies can and should play a larger role in this transformation in healthcare, making access and outcomes more a focus. For example, Janssen Healthcare Innovation is partnering with key stakeholders on a novel patient management program designed to help optimise patient outcomes. It's an approach focusing on improving continuity of care and recovery through patient education and empowerment. Programs such as these should be encouraged and accelerated across the industry.

Digital is the other important source of innovation and growth. The development of data systems, such as real world evidence, can help support better patient outcomes, cost effectiveness cases and access, and brand perception. Investing in partnerships and technology is crucial to enable companies to collect this valuable data. Agreeing on how such data is then to be used by both Pharma companies and regulators will be critical.

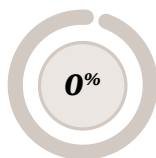
The pharmaceutical industry is ideally placed to take advantage of global transformations in both technology and healthcare. But it needs to re-imagine its traditional role in the market and ask itself where it really fits in the future business landscape. As an industry founded on innovation and imagination, we believe it can.



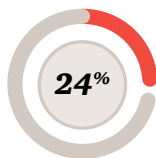
About the survey



Originator



Generics company



Both originator and generics company



Other (e.g. industry body)

The purpose of the Pharma Industry Survey, was to elicit current views on issues facing the pharmaceutical industry. The survey was developed based on themes from the Pharma 2012 survey, 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. A number of organisations were invited to undertake one-on-one confidential interviews with PwC to further explore responses provided in the survey. There were a total of 23 responses; participants included pharmaceutical companies as well as industry peak bodies.

In terms of the 2012 PBS expenditure and prescriptions (Section 85) in the twelve months to 30 June 2014, we

had 80% participation by value (costs) and volume (scripts) for originators in the top 20 for pharma market share, plus other participants that are not in the PBS expenditure top 20.

Classification

The majority of companies surveyed were originator companies, 95% were multinational companies and 60% have their headquarters in Europe.

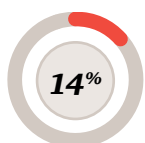
About one third of companies surveyed currently have 500+ employees and almost another third have less than 100 employees.

More than one third of respondents noted an Australian annual revenue of \$500+ million, a decrease from the 2012 survey where about half of the companies had a turn over of more than \$500 million a year. Another 40% had revenues between \$100-499 million.

Number of employees in Australia



Less than 100



100 - 199



200 - 299



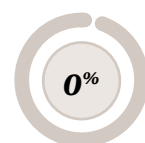
300 - 499



Under \$20 million



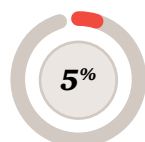
\$21-49 million



\$50-99 million



\$100-249 million



500 - 799



800 - 999



1000+

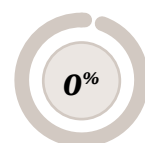
Annual turnover in Australia in 2014



Under \$20 million



\$21-49 million



\$50-99 million



\$100-249 million



\$250-499 million



\$500+ million



Unable to supply information

Members of the Generic and Biosimilars Medicines Association (GBMA) decided not to participate in this survey and therefore their views are not represented in the survey results.

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This report was produced with the assistance of survey respondents within the wider Australian pharmaceuticals industry and members of PwC's Pharmaceutical & Life Sciences network.

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