

Issues and Opportunities in a time of change

***A PwC report on
the Australian
Pharmaceutical
Industry***



Welcome



Issues and Opportunities – in a time of change

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

PwC has undertaken its second survey of the Australian Pharmaceutical Industry and we are pleased to present our findings in this Report – *Issues and Opportunities – in a time of change* (Report).

We undertook a confidential survey of a wide cross-section of industry participants between June and August 2010 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.

Respondents surveyed represented companies engaged in activities ranging from sales & marketing to manufacturing, research and development (R&D), distribution, wholesaling, retailing and services. Respondents held approximately 70 percent of the Australian prescription market and employed some 15,000 people across Australia.

This Report follows the global projections we made in *Pharma 2020 – The vision – Which path will you take?* based on our 2007 global industry survey and our 2008 thought leadership publication titled *The Australian Pharmaceutical Industry – Issues and Challenges (Issues and Challenges)*, which reviewed risks and opportunities in the Australian pharmaceutical sector at that time.

In this Report, as well as providing our qualitative and quantitative findings, we include comparisons with trends we discovered in 2008 and with our global projections in the *Pharma 2020* series (the *Pharma 2020* series is set-out on page 31 of the Report). Our goal is to assist the Australian industry, as well as regulators and governments, with up to date information to support sound business strategy and public policy development.

This is a critical time for the industry. With a wide range of new regulations, health reforms and demographic trends occurring, the Report discusses how businesses will need to make far reaching changes to deal with these trends.

We hope that our analysis and the 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 the future challenges.

A stylized, handwritten signature in black ink, consisting of several overlapping loops and lines.

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10%

Survey respondents that said they fully understand the implications of the wider healthcare reforms on the pharmaceutical industry



1,950

The number of brands that will be subject to price disclosure under the coming price disclosure legislative reforms

\$10 trillion

The amount that OECD countries are expected to spend on healthcare by the year 2020



59%

The percentage of respondents that indicated they did not fully understand the implications of the price disclosure regime

Executive Summary

The industry is seeing significant and accelerating change. Companies will need to respond effectively in order to thrive in a radically changing and more intensively regulated market. The main findings of our recent industry survey are outlined in this summary.

Responding to reforms: Only 10% of respondents reported that they fully understood the implications of wider healthcare reforms on the pharmaceutical industry. Pharmaceutical companies will need to move quickly to improve their understanding of how the reforms will affect their businesses. Some of the likely changes the industry may have to address include bulk drug purchasing by groups of hospitals, extension of prescribing rights to nurses and the evolution of multidisciplinary care.

Improving regulatory processes: Respondents were generally positive about the reforms to the regulatory regimes of the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC). However, respondents suggested that the differing regulatory regimes need to be harmonised, streamlined and made more transparent in order to improve access to drugs for patients.

Understanding price disclosure: Current and planned price disclosure rules will strongly affect the industry's fortunes. Less than 50% of respondents said they had a full understanding of the implications of price disclosure. To improve business certainty, companies will need to develop a better understanding of the reforms and respond decisively.

Meeting the generic challenge: Substitution rates of around 72% were confirmed by the industry. The dramatic increase in generic drug sales following the end of patent protection periods will over the next few years cause further disruption. More companies are expected to enter the generic market or expand their existing generic sales.

Greater compliance and increasing costs: Regulatory compliance is improving. However, in an era of ongoing regulatory reform, compliance costs are expected to rise.

Adapting to the rise of E-health: The rapidly emerging global trend towards E-health will radically change Australian healthcare. Respondents indicated that they still have not fully leveraged the use of E-health opportunities. Companies will need to adapt to advances such as the greater use of mobile technology by therapists and patients, the implementation of electronic medical records, and the advent of electronic prescribing.

Learning to collaborate more: With the growth in personalised medicine, the industry sees collaboration as critical for the future success of pharmaceutical companies. Australian companies, to date, have been slow in fully exploiting collaborative opportunities and would benefit from increased collaboration.

Promoting innovation: Survey respondents indicated that pharmaceutical companies need greater incentives to perform innovative R&D in Australia. The Federal Government will play a key role in creating incentives to risk capital and promoting Australia as a leading centre for R&D.

The following sections of the report discuss the above issues and include comparisons with the trends we discovered in the 2008 Issues and Challenges publication and the global projections made in the Pharma 2020 series.

Findings

Wider healthcare reform:

How Australia is improving the system

The forces driving health reform in Australia are being felt around the world. Health reform is a global issue. All developed countries are grappling with how to organise and fund their health care systems to address the changing demands arising from ageing populations, the shift in the burden of disease from acute to chronic conditions, the development of medical and information technologies, and increasing consumer expectations to not only have access to the benefits of the latest medical advances but also to take more control in the management of their health.

In Australia the national health reform agenda is focused on three key elements of structural redesign to address these challenges:

1. Devolved models of governance for public hospital services which move decision making closer to the clinical coal face and support local solutions to address individual patient and community needs;
2. A national system of Activity Based Funding or case based payments for all aspects of public hospital services – inpatients, outpatients, emergency departments, and sub acute services – under which the Commonwealth Government becomes the majority funder, paying 60% of an independently determined efficient price; and

3. The development of Primary Health Care Organisations to support co-ordinated, multidisciplinary care models in the community, particularly in relation to the management of chronic disease. The reforms recognise that a large part of the pressures on hospital services can be addressed by more effective community based care.

In addition to these structural changes, the national reforms incorporate two key enablers which will support a more effective health system:

1. Investment in E-health capacity to support secure, interoperable electronic health records which support safety, efficiency, and more personalised patient management supporting co-ordination across care settings; and
2. The establishment of Health Workforce Australia, a national agency responsible for addressing the expansion and redesign of the health workforce to meet the growing and changing health and aged care needs of the Australian population.

The national reforms are in keeping with the recommendations of the National Health and Hospitals Reform Commission which recommended “well designed funding and strategic purchasing” as a key reform plank.¹

Under a national system for Activity Based Funding, the money essentially follows the individual patient to fund the

hospital episode rather than funding the standing capacity of the hospital. This will allow system funders and managers to see what is being funded at the individual patient level, what are the comparative costs across different settings for the same service, how efficient and effective is the care (for example variances in relative length of stay on a case weighted basis can indicate the effectiveness of different care models as well as the quality of care), and the distribution and relative access of individuals to services. The funding model also has the potential to create strong incentives to consider whether the patient is being cared for in the right setting, promoting a focus on patients before, during and after they are ill or injured and on how to connect care between hospitals and other providers.

Australia enjoys an excellent health system. The Commonwealth Fund of New York 2010 international survey of 7 countries’ health systems ranks Australia at number 3 after the Netherlands and the UK, with a rank of 1 for “Long, healthy, productive lives”² and a rank of 2 for “Patient centred care”. The challenge as Australia moves into reform implementation is about how we continue to meet the changing health needs of the Australian community.

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1. A Healthier Future For All Australians, Final Report June 2009, National Health and Hospitals Reform Commission.

2. Mirror, Mirror on the Wall – How the Performance of the U.S Health Care System Compares Internationally, The Commonwealth Fund, June 2010.

Wider healthcare reform

In Pharma 2020 – The Vision, PwC predicted that by 2020 the OECD countries, excluding the US, will spend 16 per cent of their GDP on healthcare, while the US will spend 21 per cent. In all, it was anticipated that OECD countries will spend \$10 trillion on healthcare by the year 2020.

Governments everywhere have recognised this trend and are introducing reforms to fund the healthcare needs of their inhabitants over the near future.

Understanding and dealing with the broader healthcare reforms will be vital for the pharmaceutical industry.

90%

Survey respondents that did not fully understand the implications of the broader healthcare reforms on the pharmaceutical industry

The planned healthcare reforms listed below are among those that will directly and indirectly affect the pharmaceutical industry:

- **Efficient pricing:** The Federal Government will supply the States and Territories with 60 per cent of the efficient price of every public hospital service provided to patients;
- **Devolution:** Responsibility for hospital management will be devolved to local hospital networks, giving communities and clinicians a greater say in how their hospitals are run;
- **Primary care focus:** There will be greater investment in general practitioner (GP) and primary health care, which will help reduce demand on the hospital system;
- **Better mental health:** Improving capacity to deliver care in mental health services will offer patients better access to the services they need;

- **National reporting:** Higher national standards will prevail, with transparent, consistent reporting requirements for hospitals;
- **Intervening earlier:** More investment will be made in early intervention and preventive health programs; and
- **Deploying IT:** Investment in E-health initiatives will provide better access to health information centred on the needs of patients.³

Having regard to the scale of the looming changes, 53 per cent of survey respondents described their understanding of the reforms as limited. Only 10 per cent indicated that they fully understood the implications of the reforms for the pharmaceutical industry.

3. Australian Government, A National Health and Hospitals Network for Australia's Future – Delivering the Reforms.



44%

Survey respondents that saw primary care as a reform theme that will have a major impact on the pharmaceutical industry

11%

Proportion of survey respondents that viewed local hospital networks as having a major impact on the pharmaceutical industry





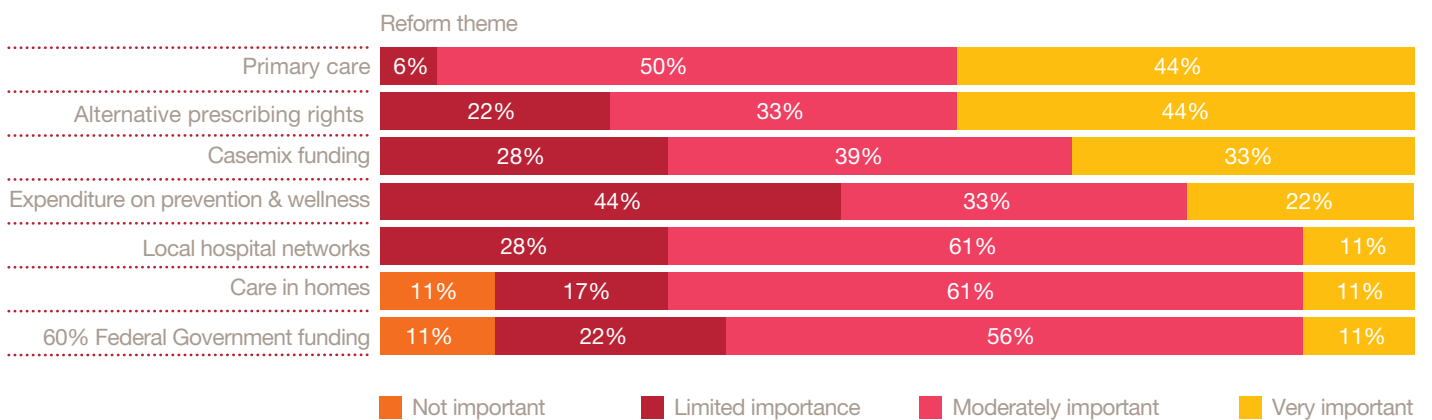
44 per cent of respondents to our survey saw alternative prescribing rights – such as nurse practitioners being allowed to prescribe Pharmaceutical Benefits Scheme (PBS) medicines – as highly important. However, less than one-quarter of respondents rated local hospital networks as having a major impact on their company (see Figure 1).

Companies will need to increase their understanding of the broader healthcare reforms and consider the effects of

changes in funding and in the range of customers they will serve. In particular, industry participants will need to address questions such as:

- How will drugs be treated in the context of national activity-based funding and the setting of an efficient price for care delivery?
- Will there be further moves to bulk purchasing and centralised tendering within the hospital sector?
- As alternative prescribing rights continue to evolve, who will the customers of the future be?
- What role does the pharmaceutical industry have in the delivery of co-ordinated, multidisciplinary care?
- Will hospital formularies be standardised?
- What will be the role of the industry in rolling out the reform agenda?
- Is the GP’s role as gatekeeper ending?

Figure 1: Rating the impact of major reforms on the pharmaceutical sector



A challenge to the industry to speed the release of new drugs

Live licensing is authorisation to market a product on a limited basis, once the drug has demonstrated sufficient efficacy, value and safety in an initial trial population. This contrasts with the traditional licence granted after a long regulatory approval process. PwC's publication *Pharma 2020 – The Vision* forecast that live licensing will be more prevalent in the future, in order to make more therapies available sooner to a wider group of patients.

The PBAC appears to support the implementation of live licensing based on post-market surveillance of drugs (commonly referred to as Coverage with Evidence Development or CED). The implementation of CED principles would mean that

clinically important drugs could be made available to patients earlier. The chair of the PBAC, Professor Lloyd Sansom, has challenged the industry to outline how it intends to conduct and report on post-market surveillance of drugs to enable earlier access to drugs and subsidies.⁴

Despite Professor Sansom's view, respondents did not raise CED as a major issue in the survey. Given that access for new drugs is still a top priority for manufacturers, the industry will need to find new ways of engaging with the regulator earlier to facilitate faster access to new drugs.

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4. Medicines Australia Conference – June 2010.

Regulation and access

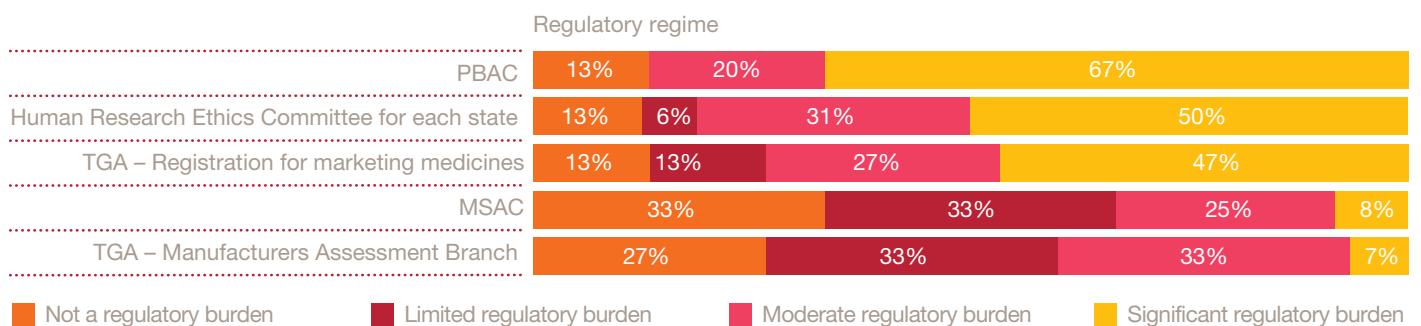
Industry participants are confident in the policies and procedures of our regulatory bodies. However, greater collaboration between regulatory bodies and a more streamlined regulatory approach is required to improve access for patients.

The Australian pharmaceutical industry is confident of understanding the TGA and PBAC regulatory regimes, despite recent reforms in these areas. Of respondents to our survey, 88 per cent said they fully understood these regulatory regimes and 12 per cent mostly understood.

Respondents were also generally positive about recent reforms to the TGA and PBAC, which were seen as improving access for patients and the industry. However, most respondents saw room for improvement across all regulatory regimes. In particular, the TGA's processes for registering medicines for marketing, the human research ethics committees in each State, and PBAC requirements were all seen as imposing substantial regulatory burdens and costs on pharmaceutical companies (see Figure 2).



Figure 2: Rating the extent to which selected regulatory authorities are a burden for companies



In response to these concerns, respondents said they would like to see some of the following changes:

- further streamlining the TGA process, making the process more efficient and increasing transparency;
- creating greater alignment between the TGA and PBAC processes, and
- increasing the TGA's use of overseas submissions and making better use of lessons learned by regulatory bodies in North America and Europe when assessing the acceptability of new drugs.

In order to achieve greater efficiency and consistency in regulatory approaches, the TGA and PBAC processes should be run in parallel where possible. This would allow overall faster processing times for reimbursement listings. This is one of the principal proposals contained in the memorandum of understanding (MoU) reached on 6 May 2010 between Medicines Australia and the Federal Government on the management of the PBS.

The PBAC has already moved to improve the transparency of its decision-making process by publishing details on their website.

Australian regulatory bodies would benefit from increasing their reliance on data and decisions made by European and North American regulatory bodies when they have already assessed submissions for equivalent drugs. The TGA and US Food and Drugs Administration (FDA) have already entered into co-operative arrangements that facilitate more efficient regulation and information sharing.⁵ Greater collaboration between international and domestic regulatory bodies will minimise duplication in regulatory efforts. It will also lead to a harmonised regulatory regime that will enable patients to use new medicines sooner.

88%

Survey respondents that said they fully understand the TGA and PBAC regulatory regimes



5. TGA News Issue 54 (November 2007).

Price disclosure

Many respondents indicated that they do not fully understand the implications of the price disclosure regime. It is essential that companies increase their understanding of the new regime in order to increase business certainty.

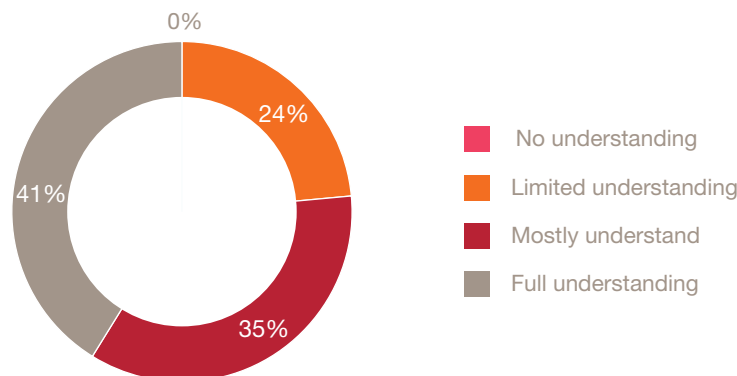
Since the last set of major medicine pricing reforms in 2007, the growth rate for the Federal Government's PBS expenditure has increased from 4.3 per cent in 2006–07 to an estimated 10.5 per cent for 2009–10.⁶ Savings from the earlier reforms, although greater than originally estimated, will be outweighed by higher growth in PBS costs, which are expected to increase from \$9 billion in 2010 to \$13 billion in 2018.⁷

Under the MoU, further major pricing reforms have been agreed in order to manage the increasing PBS costs and ensure the viability of the medicines industry. *The National Health Amendment (Pharmaceutical Benefits*

Scheme) Bill 2010 is expected to be passed by the Senate, following the Senate review, introducing mandatory price disclosure for all drugs on the F2 formulary. This will increase the number of brands subject to price disclosure from approximately 176 to almost 1950.⁸

Given the far-reaching impact of price disclosure, a surprising result of our survey was that about one-quarter of respondents had only a limited understanding of the implications of the change. Of respondents, 41 per cent said they had a full understanding of the implications of price disclosure, whilst 59 per cent said they did not fully understand them (see Figure 3).

Figure 3: How would you rate your company's understanding of the implications of price disclosure regulations?



6. Health Minister Nicola Roxon, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 – Second Reading Speech.
7. Health Minister Nicola Roxon, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 – Second Reading Speech.
8. Australian Government, Department of Health and Ageing – RFT 017/1011, p 33.

“Under the price disclosure regime, the Government will be inundated with too much data and may be overwhelmed”

– Survey Respondent

PwC’s report on the impact of PBS reforms, commissioned by the Department of Health and Ageing and tabled in Federal Parliament in February 2010, found that savings for the Federal Government from the existing price disclosure regime would be between \$2 billion and \$4.1 billion over the ten years to 2017–18.⁹

The Federal Government estimates that the proposed accelerated and expanded price disclosure would save approximately \$1.9 billion over the forward estimates period of five years.

In PwC’s 2008 survey of the industry, two-thirds of respondents said that they would withdraw their products if the comparator price for their drugs fell

below the global benchmark prices, compared to around one-third of respondents in this survey (see Figure 4).

Most respondents were critical of the current price disclosure regime’s calculations citing procedural errors and lack of transparency. Respondents proposed independent audits, sample audits and dispute resolution processes as ways to promote an accurate and efficient price disclosure regime.

In addition, the outsourcing of data collection and calculations, a central plank of the MoJ, was commonly favoured among respondents.

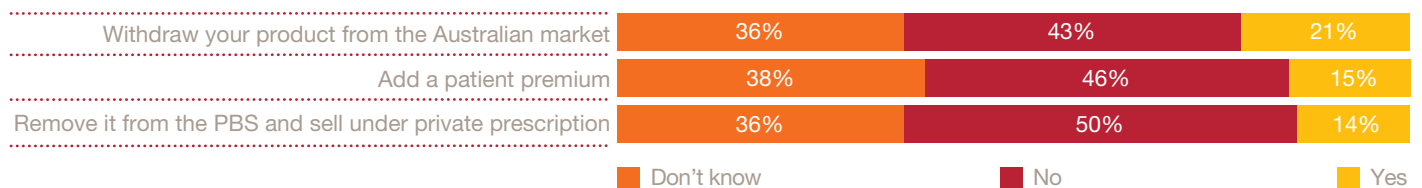
The Federal Government has already moved to outsource data collection,

validation and analysis as well as the calculation of the Weighted Average Disclosed Price (WADP) and Guaranteed Average Price (GAP) under the proposed new price disclosure regime by issuing a request for tender.

Most respondents said that the industry needs to have confidence in the system and that outsourcing data collection and calculations to a third party would go a long way towards achieving this.

Based on the forecast impact of price disclosure, all affected industry participants should model the financial impacts of the new regime so that they are better positioned to forecast the revenue and budgeting implications of price disclosure on their businesses.

Figure 4: Likely company actions if the prices of your products fell below the global benchmark



9. PwC – The Impacts of the Pharmaceutical Benefits Scheme Report (February 2010).

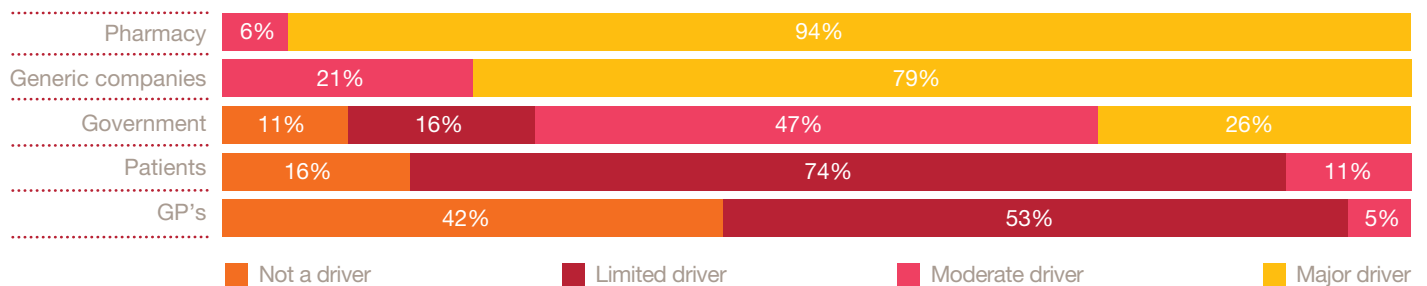
Substitution

The Pharma 2020 reports 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 per cent of PBS prescriptions, up from 27 per cent in 2005–06.¹⁰ Anecdotally, PwC’s own enquiries suggest that the level of substitution has increased from around 25 per cent before 2007 to around 72 per cent over the period to 2010. This rate was confirmed by respondents.

Respondents to the survey said pharmacists were the largest single cause of the shift to generic medicines, most likely because of the discounts and incentives offered by generic companies. It will also be interesting to see what impact the introduction of nurse prescribing will have on the level of generic substitution over the coming years (see Figure 5).

Figure 5: To what extent has each of the following industry participants been causing the shift towards generics?



72%

The level of substitution that is taking place where a generic equivalent brand is available

10. Health Minister Nicola Roxon, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 – Second Reading Speech.

“A company that wants premium prices for medicines will have to provide a range of products and services”

– Survey Respondent

With some \$2.3 billion worth of medicines coming off patent over the next 12 years, it is likely that the trend to substitution will continue.¹¹ Among survey respondents, big pharmaceutical companies were viewed as the most likely to enter the generics market over the next two to three years (63 per cent of respondents).

37 per cent of survey respondents believed that established foreign generic companies would enter the Australian market by 2013. Recent examples of this are Lupin Limited’s recent move to a majority ownership of Generic Health Pty Ltd and Watson Pharmaceutical’s recent interest in the local generics market.

In PwC’s 2008 industry survey, ‘Big Pharma’ companies were divided in their response to the question “will Big Pharma companies be looking to acquire generic portfolios?”

Sanofi Aventis (Winthrop) and Novartis (Sandoz) are among companies that have already acquired significant generic portfolios. Pfizer has indicated to the market that they intend to grow their established products business, concentrating on both their own and licenced off patent drugs. This trend towards product diversification is in line with PwC’s Pharma 2020 forecasts, which predicted an increasingly diversified business model.

Some innovative companies have additionally begun collaborating with

generics companies to deal with patent expiries, such as Glaxo Smith Kline and Aspen Pharmaceuticals.¹²

Whilst the rise of generics clearly poses threats and opportunities to the industry here and globally, it is evident that most companies have had the time to assess their response within this environment. However, this does not seem to be the case when it comes to the new wave of biologic generics, biosimilars. Our survey did not explicitly explore the biosimilar issue given the minimal activity so far in Australia. However, we fully expect this to be a larger issue in the coming years with companies like Roche and Amgen facing loss of exclusivity for some key biologics. How these companies and the Federal Government respond to this unique substitution issue is yet to be clear.



11. Health Minister Nicola Roxon, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 – Second Reading Speech.
12. Glaxo Smith Kline – Press Release, GSK extends strategic collaboration with Aspen (2009).

Regulatory Compliance

Regulatory compliance is improving. However, in an era of ongoing regulatory reform, the cost of compliance is likely to increase with new reforms.

Complying with legislation, regulations and industry codes is a significant cost to any pharmaceutical business. Survey respondents told us that they expect the trend of increasing compliance costs to continue.

Respondents rated complying with TGA requirements as the most expensive, while the cost of conforming to Medicines Australia's Code of Conduct (Code) also ranked high (see Figure 6). Interestingly, the industry is seeing increasing levels of compliance with the Code. In 2009-10, Medicines Australia received 39 new complaints, which was a decrease from 2008-09 when 59 complaints were submitted. Of the 22 new complaints finalised in 2009-10, 45 per cent were found not to be in breach of the Code.¹³

The costs of meeting price disclosure rules did not rank as significant in our survey. However, PwC expects these costs to increase significantly with the expanded price disclosure regime from 1 December 2010, as noted on page 17.

Some respondents raised concerns over the integrity of price disclosure data, which will cause increased compliance costs in the future as more companies are required to price disclose.

Among survey respondents, 87 per cent said their degree of overall compliance had improved over the past two years (see Figure 7). Many attributed this to investment in resources and systems, better training, and greater emphasis on the issue from senior executives.

Figure 6: What are the three largest costs of risk and compliance to your business?

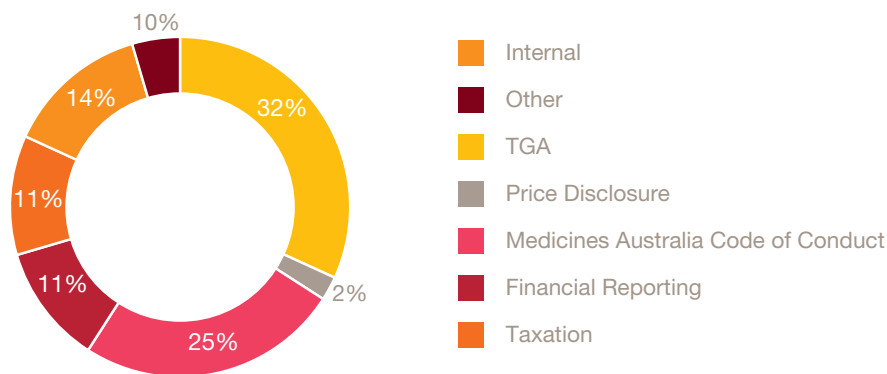
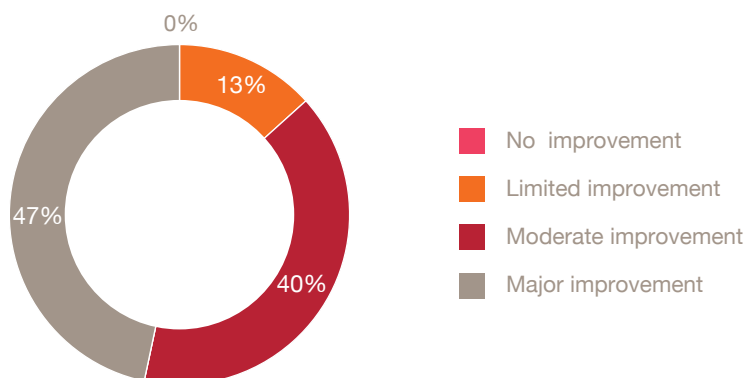


Figure 7: To what extent has your company improved on compliance in the past two years?



13. Medicines Australia Annual Report 2009 – 2010, p 26.

E-health:

Transformative potential for the quality of care

The National E-Health Strategy, endorsed by the Australian Health Ministers Conference in late 2008, promises an incremental change that can significantly improve the quality of healthcare.

Through the National E-Health Transition Authority, the process of defining, standardising and investing in E-health strategies is under way.

Various Australian jurisdictions are defining or implementing an E-health strategy. The planned National Broadband Network will be a significant investment in the foundational infrastructure for an E-health network.

Enthusiasm for E-health is growing within the private sector. From multinationals such as Google and Microsoft to individual clinicians in small practices, investment is taking place.

A huge volume of health information about consumers is in electronic or paper form, in GP surgeries, public and private hospitals, pathology labs, imaging services, pharmacies and allied

healthcare facilities. Some information is collected as basic electronic records of treatment in hospital IT systems and in the desktops of GPs.

The introduction of a national system of individual electronic health records (IEHRs) or Personally Controlled Electronic Health Records will potentially draw on a number of sources of health information to create a comprehensive electronic record for use by patients and authorised care providers.

The National E-Health Strategy defined the IEHR as “a secure, private, electronic record of an individual’s key health history and care information, recorded by themselves and the health system.”¹⁴

Legislation passed in mid 2010 provides for a Unique Health Identifier.¹⁵ This will be assigned to patients, healthcare providers and organisations that provide health services. It will be one of the foundations for an interoperable EHR, allowing patients to have key information about their health available to share, safely and securely, with clinicians.

The information will be of most value to clinicians at the point of care. The IEHR will likely show current medications, allergies and historical diagnoses or tests, creating greater opportunities for improved safety and efficiency. Sharing this data across the health system can improve care through co-ordination and reduced duplication of information and services.

National regulation will be needed for records extending across the health sector. The gathering and storing of clinical data in a national system is likely to be incremental.

Now is the time for the pharmaceutical industry to plan its involvement in E-health as it evolves.

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14. National e-health Strategy, Australian Health Ministers Conference, December 2008, p 13.

15. Healthcare Identifiers Act, June 2010.

E-health

In the 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 home health monitoring and treatment programs.

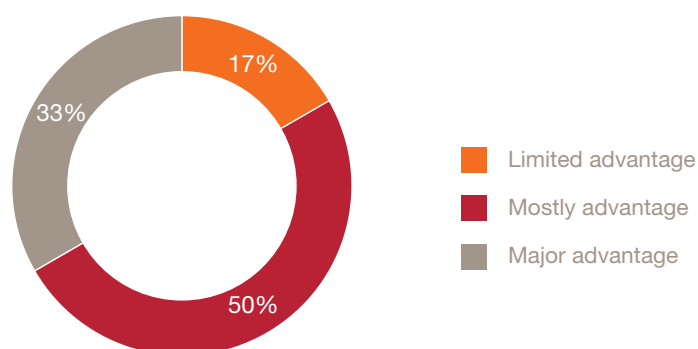
The rapidly emerging global trend towards E-health will radically change Australian healthcare.

83 per cent of respondents viewed E-health as providing a significant competitive advantage for their companies (see Figure 8). This is an interesting result considering that most respondents indicated that they have not yet leveraged the full potential of E-health.

Most respondents confined their IT use to websites that provided information to consumers and health professionals – a relatively basic use of technology that is common across the industry in Australia.

Another regular practice within the sector is the use of technology to support a more mobile sales force, for example through personal digital assistants and smart phones.

Figure 8: To what extent do you see the use of E-health as a competitive advantage for your company?





Despite the growth of social media in the general community, very few respondents reported using this medium to communicate with patients or healthcare professionals (see Figure 9).

Pharmaceutical companies will need to take account of the likely future growth of E-health in Australia.

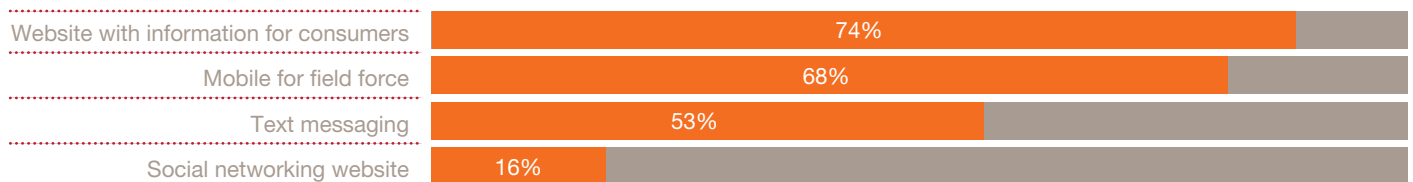
Advances in E-health have been a long time coming. However, with recent

changes to the law on unique identifiers, and with the growing investment made by health industry bodies – such as the Pharmacy Guild, the Royal Australian College of General Practitioners and the Aged Care Industry IT Council – E-health in Australia is about to become much more significant.

The pharmaceutical industry will need to take account of these changes and decide how it intends to respond to developments such as:

- mobile technology and remote monitoring by sales forces, therapy support teams, and patients;
- the advent of electronic prescribing;
- electronic medical records and data collections (such as those for adverse events) being increasingly accessible by the payer; and
- the common use of a patient's medical chart across a common IT platform by a patient's healthcare providers.

Figure 9: Does your company have E-health capabilities or has it used any of the following E-health elements?



“The entire global health care system is undergoing a seismic shift. The industry is being held far more accountable – for products that demonstrate outcomes at reasonable prices – by all players across the continuum. To flourish, companies will need to invest more in research, understand and demonstrate the value of their products, lower the cost of distribution, collaborate with partners at home and abroad, and provide value-added services to customers. Effectively meeting these challenges will deliver enormous rewards in terms of human health and business success.”¹⁶

Simon Friend
PwC Global Pharmaceuticals & Life Sciences Industry Leader
11th Annual PwC Global CEO Survey



16. PwC - Canadian Life Sciences Industry Forecast 2009.

R&D:

Greater incentives likely to be introduced in 2011

With the Federal Labor Government returned to power, the proposed change from the R&D Tax Concession to the R&D Tax Credit is likely to be introduced with effect from 1 July 2011.

The R&D Tax Credit will make the following major changes:

- **Simplification:** The new tax credit will replace the existing 125 per cent concession, the 175 per cent incremental premium concession, the IPC and the tax offset for smaller companies;
- **Offsetting:** A 40 per cent tax credit to Australian incorporated companies with a grouped turnover of more than \$20 million will be able to be offset against current and future income tax liabilities. A 45 per cent refundable tax credit for Australian incorporated companies with a grouped turnover of less than \$20 million will be able to be offset against all tax liabilities; and

- **Intellectual property:** R&D services undertaken in Australia for an overseas parent company may access the new program, regardless of any cost reimbursement and IP being retained offshore.

Most existing claimants companies will continue to qualify under the proposed system, although the definition of eligible R&D will be tighter and some production activities may be excluded.

Smaller companies will benefit from the 15 per cent permanent incentive of a refundable rebate from the Australian Taxation Office. For companies with sufficient tax losses, the full 45 per cent credit could be refunded, providing substantial cash when it is needed most. This might be a significant help to biotech companies in the early stages of development.

For larger companies, the tax credit will raise the current incentive from

7.5 per cent to 10 per cent, in addition to the benefits of the normal tax deduction. This could provide them with valuable savings on large, expensive drug development projects.

Many Australian subsidiaries undertaking R&D on behalf of a foreign parent will greatly benefit under the proposed program. The existing 175% concession for foreign owned R&D is problematic in its operation in many circumstances – the proposed 40 per cent R&D credit is simpler in operation and is more likely to be able to induce increased R&D spending in Australia by multinational groups.

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“The Federal Government could assist substantially by creating greater incentives to risk capital”

– Survey Respondent

The global competitiveness of Australia for R&D investment can be improved through greater government incentives.

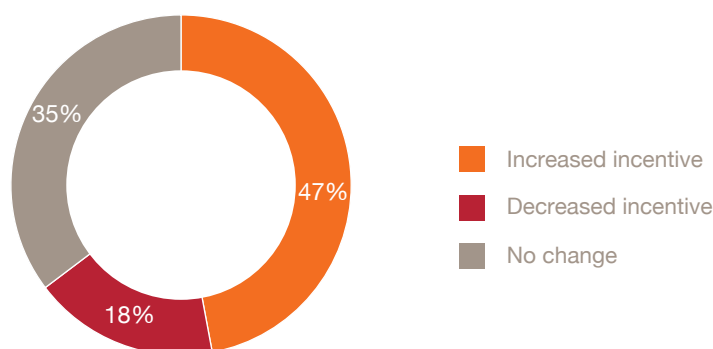
The Australian pharmaceuticals industry spent \$1.023 billion on R&D in 2008–09.¹⁷ In seeking to refocus innovation in a ‘revenue neutral’ context, the Federal Government has proposed changes to the R&D tax credit following detailed consultation with industry, including Medicines Australia and various member companies. Despite this, over half of survey respondents did not see the proposed reforms as providing an increased incentive to undertake innovative R&D in Australia, with 18% of the total respondents expecting these changes to provide a decreased incentive (see Figure 10).

This relatively high level of pessimism parallels Australia’s low participation rate in high-value pharmaceutical R&D.

We expect that clinical trials will continue to be the main focus in Australia with these trials most likely to be focused on Phases 1 and 2, owing to the patient numbers needed for further phases.

Respondents told us that while research in Australia was not cheap, Australia had well-staffed, high-quality research centres, scientists and expert doctors. Some survey respondents suggested the need to reduce costs and increase the speed of research. Respondents also said that the industry and government should “think big”, saying that the Australian industry should aim to become the fastest in the world at conducting clinical trials.

Figure 10: Do you see the proposed R&D reforms as providing an increased or decreased incentive to pharmaceutical companies to undertake innovative R&D in Australia?



17. Source: ABS, Catalogue 8104, Research and Experimental Development, Businesses, Australia, 2008-09.

In *Pharma 2020*, PwC proposed that pharmaceutical companies would have to learn much more about the molecular functions of the human body and the changes that cause disease.¹⁸ PwC foresaw the rise of virtual R&D and more accurate diagnosis and treatment of patients. Such refinements should eventually allow reduction in the number and size of the clinical trials needed to prove the safety and efficacy of new drugs. In *Issues and Challenges*, PwC reported that the average new capital expenditure by Medicines Australia members had declined from about \$335 million in the 1990s to \$165 million by 2006.¹⁹ Investment growth in drug manufacturing was only about one-third of that in the broader manufacturing sector. Survey respondents suggested

that, in the absence of more government incentives, this trend is unlikely to be reversed.

Data exclusivity

Data exclusivity was a major concern for innovator companies. In Europe the data exclusivity period is 6-10 years whilst the Obama Administration has recently extended the period to 12 years for more expensive, higher-value biologics. Most originators believe that the industry should be seeking to extend the current 5 year data exclusivity period for conventional drugs, to similar periods as overseas. As expected, respondents representing generic companies contested the need to extend data exclusivity periods.

R&D is of paramount importance to the Australian pharmaceutical industry. As noted by respondents, the Federal Government could assist substantially by creating incentives to risk capital. This could include moving R&D credits 'above the line'. This would improve Australia's ability to compete in the world pharmaceutical sector for investment here.

The proposed R&D tax credit will assist some companies, but is unlikely to sustain the industry over the long term. Unfortunately, despite strong lobbying from the industry, the 2010 Federal Budget did not contain any new pharmaceutical industry incentive programs.



18. PwC - *Pharma 2020: Virtual R&D* (June 2008) p 3.

19. PwC - *Issues and Challenges: The Australian Pharmaceutical Industry* (2008) p 8.

Collaboration

Collaboration will continue to play a key role in the continuing evolution of the modern pharmaceutical company.

Most survey respondents told us that collaborative networks will be a vital part of future business models in the industry. These results were in line with forecasts in Pharma 2020, where PwC predicted that companies would collaborate more with payers, providers and patients.

However, within the industry, increasing collaboration is also taking place between researchers, governments, healthcare payers and providers.

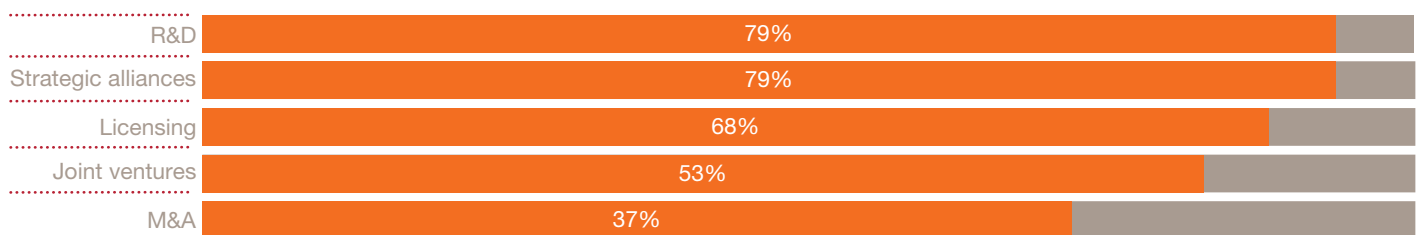
Pharmaceutical companies are being forced to develop innovative compounds more quickly and economically. With the growth in personalised medicine and the passing of the blockbuster molecules era:

- collaboration in R&D;
- faster clinical trials without loss of efficiency or safety;

- improved lifecycle management of products;
- better relations with key stakeholders such as doctors and consumers; and
- working more closely with regulatory authorities, will be critical for the future success of pharmaceutical companies.

Survey respondents have not yet fully used opportunities for collaboration. Of respondents, 76 per cent said that their levels of collaboration were limited. This may reflect the reality that most collaborative decisions are made at the overseas head office, with minimal input from local managers.

Figure 11: Drugs are increasingly coming off patent – how are you looking to fill your development pipeline?





Among respondents, the major barriers to collaboration were:

- finding the right opportunities;
- the search for compatibility between collaborating organisations; and
- the need for such decisions to receive head office approval.

Nevertheless, respondents said that collaboration on R&D, strategic alliances and licensing were on the rise as pharmaceutical companies looked at ways to fill their development pipelines (see Figure 11).

In order to maximise collaborative opportunities, the modern pharmaceutical company needs to

collaborate both locally and globally (see Figure 12).

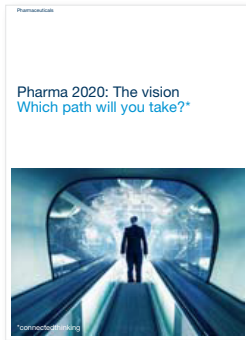
Collaboration needs to be at both the global and local levels as opportunities will become harder to find and execute in local territories.

Figure 12: What is your level of collaboration with local or global Pharma companies?

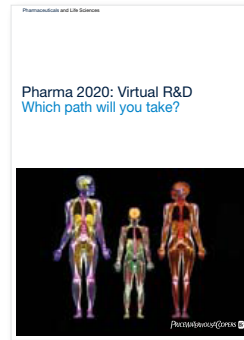


Recent PwC publications include:

Pharma 2020 Series (“Pharma 2020”):



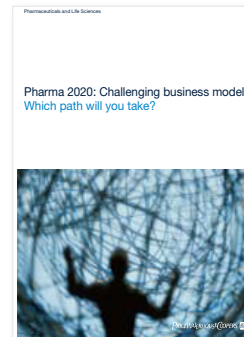
Published in June 2007, this paper highlights a number of issues that will have a major bearing on the industry by 2020. The publication outlines the changes we believe will best help pharmaceutical companies realise the potential the future holds to enhance the value they provide to shareholders and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



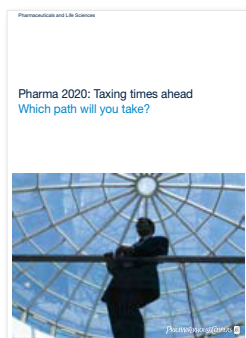
This report, published in June 2008, explores opportunities to improve the R&D process. It proposes that new technologies will enable the adoption of virtual R&D; and by operating in a more connected world the industry, in collaboration with researchers, governments, healthcare payers and providers, can address the changing needs of society more effectively.



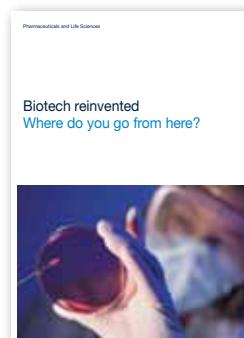
Published in February 2009, this paper discusses the key forces reshaping the pharmaceutical marketplace, including the growing power of healthcare payers, providers and patients, and the changes required to create a marketing and sales model that is fit for the 21st century.



Fourth in the Pharma 2020 series and published in April 2009, this report highlights how Pharma’s fully integrated business models may not be the best option for the pharma industry in 2020; more creative collaboration models may be more attractive.

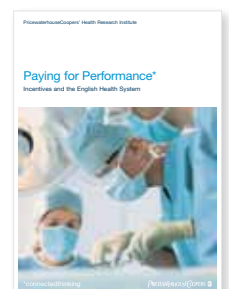
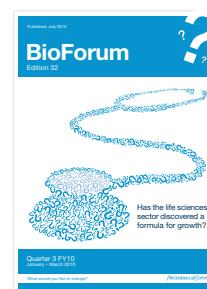
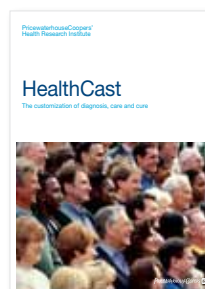


The fifth report in our series, published in December 2009, focuses on the opportunities and challenges from a tax perspective. It discusses how the political, economic, scientific and commercial environment will put pressure on effective tax rates in the industry.



This report published in 2010 looks at the changing Biotech business model and the main trends dictating the need for a new way of conducting R&D, and organisational concepts that will make biopharmaceutical companies more efficient.

Other publications



These publications can be found on PwC’s website at www.pwc.com.au/pharma-publications

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