MEDICINES Australia

Better Health through Research and Innovation

Submission to the National Commission of Audit

November 2013

Contents

EXECUTIVE SUMMARY

The Pharmaceutical Benefits Scheme (PBS) is central to the universal health care programme provided through the Australian Commonwealth, States and Territories. Despite the implementation of numerous policies that have delivered convincing sustainability of the PBS and an enduring system to generate savings from the commoditisation of off-patent medicines, the ability for Australian patients to gain equitable and universal access to new medicines has diminished.

The purpose of this submission is to identify areas within the PBS, the pharmaceutical industry portfolio and the broader health portfolio that have potential to provide efficiency gains to government. This submission will also demonstrate the need to continue activities where there remains a strong case for continued direct involvement of government, such that they are pivotal to the delivery on the National Medicines Policy.

Medicines Australia is the peak body representing the innovative pharmaceutical industry in Australia. Medicines Australia member companies are responsible for the discovery, research, development and commercialisation of up to 86% of medicines available on the pharmaceutical benefits scheme.

For very good social policy reasons the Australian Government introduced and have sustained a publicly funded health insurance system providing universal health care in Australia. This includes provision of medical services as well as a publicly subsidised medicines scheme.

Successive intergenerational reports (IGR) have highlighted the likely impacts of an ageing population; diminishing workforce participation and the perceived spiralling costs of accessing new medicines and technologies.

In this context the pharmaceutical industry has worked successfully with consecutive governments to create a policy environment that has delivered an affordable PBS in a stable and predictable business operating environment, in-line with the National Medicines Policy[1]

The Minister for Health in the current Coalition Government has said repeatedly that the PBS is on a sustainable path. It is time for the Government and its agencies to accept that the PBS is under control. This provides governments with confidence to look elsewhere for fiscal safeguards or else risk the principles of the National Medicines Policy.

[1] Commonwealth of Australia, Department of Health. '*National Medicines Policy'*, 2000 has four central pillars that aim to:

- provide timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- ensure medicines meet appropriate standards of quality, safety and efficacy;
- ensure the quality use of medicines; and
- maintain a responsible and viable medicines industry in Australia

KEY RECOMMENDATIONS

Medicines Australia calls on the National Commission of Auditors and the Government to:

1. Acknowledge that structural reforms have delivered a sustainable model for funding pharmaceuticals through the PBS, with enduring mechanisms to generate ongoing PBS savings, such that no further savings measures are warranted.
2. Review the Pharmaceutical Benefits processes, including the administration of the programme and its associated statutory structures (e.g. PBAC) to remove red tape and make them *fit for purpose f*or the future
3. Remove unnecessary processes which are now redundant in light of PBS reforms
4. Commit to working with the pharmaceutical industry and relevant stakeholders to ensure a stable and predictable business operating environment in Australia
5. Commit to working with the pharmaceutical industry and relevant stakeholders provide a stable industry and regulatory policy setting and encourage favourable investment strategies

PHARMACEUTICAL BENEFITS SCHEME

The Pharmaceutical Benefits Scheme (PBS) has served the Government and the Australian public well since its foundation in 1948. The evolution of the public provision of medicines to veterans in the post-war era to the PBS of which we are so proud today has taken at times considerable courage to reform.

In 2007 the then Coalition Government introduced transformational changes to the PBS formulary system to acknowledge the importance of investing in innovative new therapies and the need to capitalise on competition between older molecules.

History informs us that the PBS and broader access to medicines policy settings rely on collaboration amongst many stakeholders, including patients, prescribers, pharmacy, supply chain operators, manufacturers, and the Government. Collaboration particularly between industry and the Australian Government is the best way to ensure the long term viability of the PBS

Recent achievements in ensuring the sustainability of the PBS include the 2007 PBS Reforms and the further reforms introduced in 2010.

PBS red tape unnecessary - Long term PBS sustainability assured

PBS reform 2007 and the introduction of Price Disclosure (PD) was built upon by PBS reform 2010 with Expanded Accelerated Price Disclosure (EAPD). This has been further accelerated by Simplified Price Disclosure (SPD) in 2013. Each successive reform process has provided more savings but increased red tape. The recent SPD change alone has added an additional $835m to Government savings. This last change, despite having a major impact on the PBS and the medicines industry, was announced in the 2 August Economic Statement with no prior consultation with industry.

The industry has remained a strong supporter and partner in these reforms, which came at a substantial financial impost to companies. The purpose of these reforms was to create a sustainable PBS and also to secure capacity for reinvestment in new medicines and improved health outcomes.

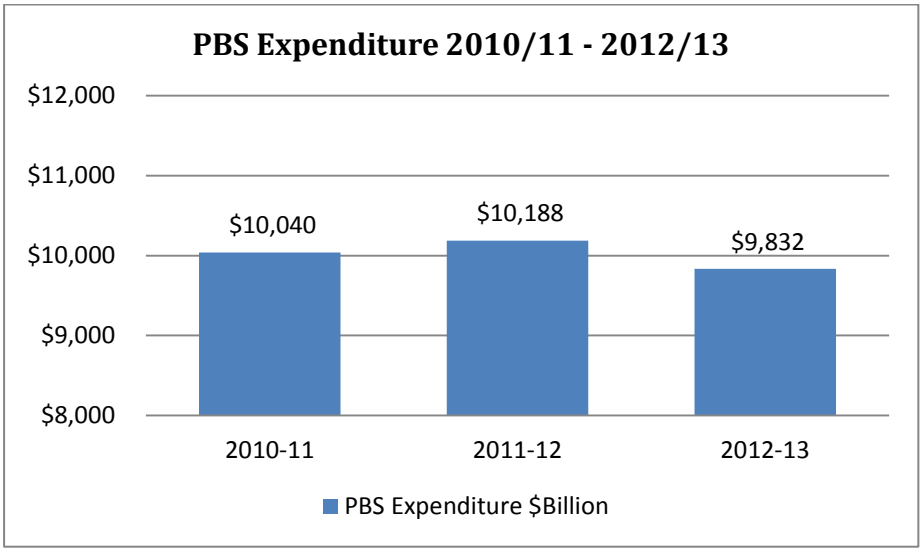
Extensive and reliable modelling conducted by the Centre for Strategic Economic Studies at Victoria University clearly demonstrates the magnitude of savings that will accrue to Government over the next five years (fig 5). It is evident that the mechanism for deriving efficiencies through commoditising the multi brand market provides enduring savings into the future.

The Department of Health and Medicines Australia's joint report '*Monitoring the Trends in and Drivers of PBS Expenditure',* released in 2013 sheds additional light on issues driving growth and factors contributing to expenditure[2].

Budget figures and repeated downward revisions clearly demonstrate the impact of the PBS savings measures. Federal budget figures show although PBS expenditure increased moderately in the 2011-12 period, expenditure took a downturn in 2012-13. Ongoing revisions to PBS expenditure indicate that this trend is likely to continue.

[2] Commonwealth of Australia, Department of Health and Ageing and Medicines Australia, Joint monitoring report, 'Trends in and drivers of PBS expenditure', Report for the AMWG, May 2013

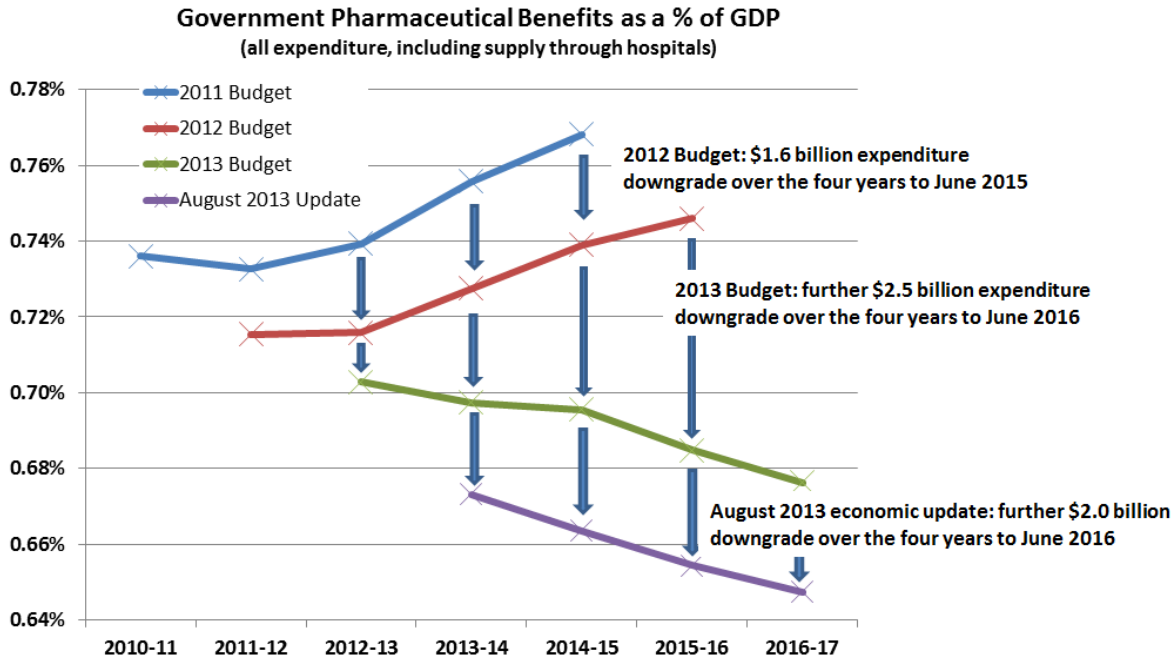
Figure 1: PBS expenditure is falling



Source: Final Budget Outcomes Appendix A: Expenses by Function and Sub-function 2013/14, 2012/13, 2011/12

The PBS will continue to attract scrutiny, especially as Governments are pressured to demonstrate their fiscal responsibility.

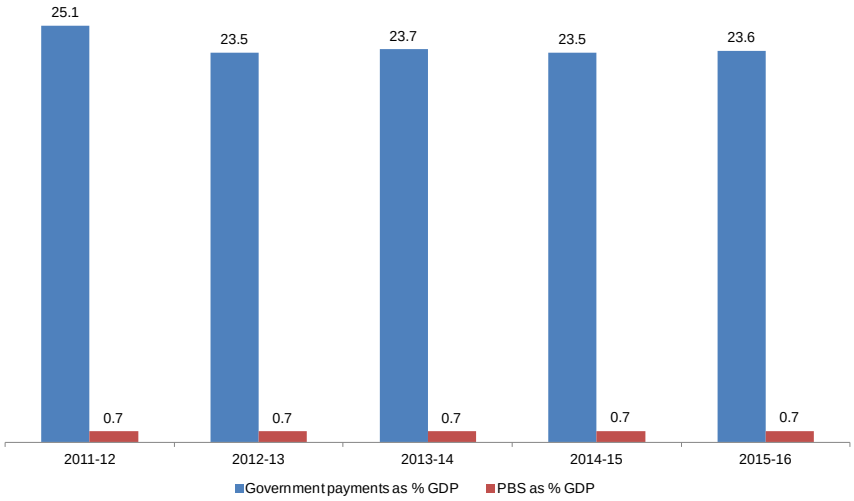
Figure 2: PBS expenditure revisions



Source: Medicines Partnership of Australia.

The existing savings mechanisms, such as price disclosure, pricing negotiations, post market reviews, and interpretation of Sections 99ACB and 99ACD of the National Health Act, will continue to inform revisions to expenditure

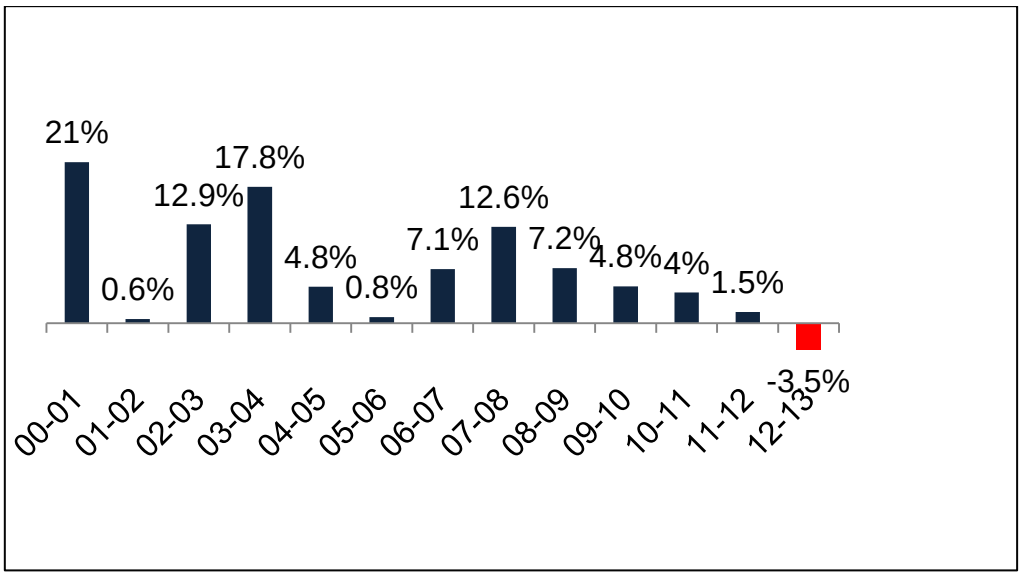
Figure 3: PBS expenditure as % GDP



Source: Treasury 2012, Budget Paper No 1, 2012-13

The Department of Health and Treasury Department have been unable to accurately anticipate in the budget the savings that will be derived from PD. As experience grows and successive budget outcomes reveal the trends in price cuts with actual figures, confidence in making forecasts may improve. It would be valuable to determine a model that Treasury can use to accurately forecast savings and make appropriate budget assessments on expenditure.

Figure 4: Longer term growth trend confirms decline

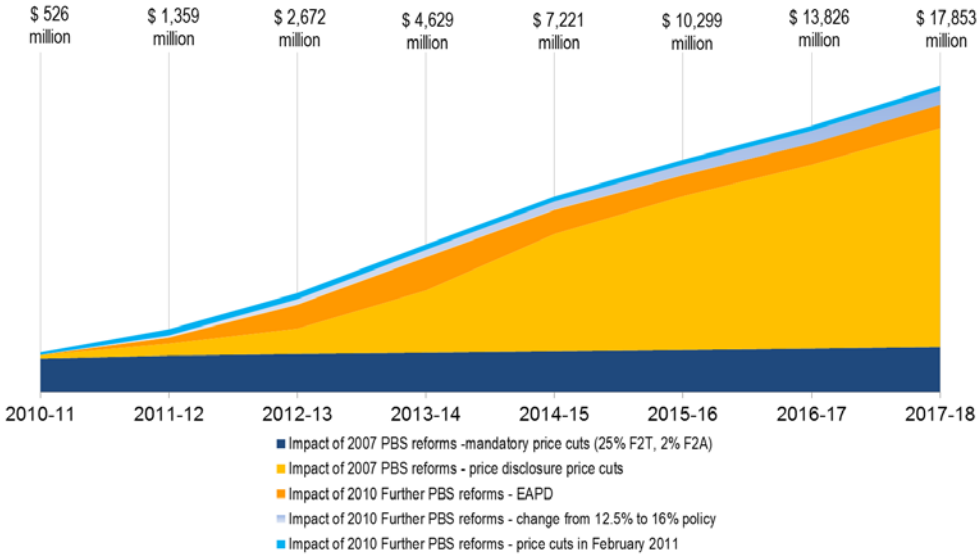


Source: Paul Cross, PharmaDispatch 2013, with permission

Growth in current PBS expenditure is declining in actual terms and as a percentage (%) of GDP (Figure 4 & 6). When reviewing the rate of growth in the Government's spending on pharmaceuticals over the longer term, budget papers show a sharp decline since price disclosure was introduced as part of 2007 reforms

Moreover, modelling in 2013 confirms that the existing reforms will contribute to a further decline in overall Government expenditure on the PBS.[3]

Figure 5: Savings from PBS reforms

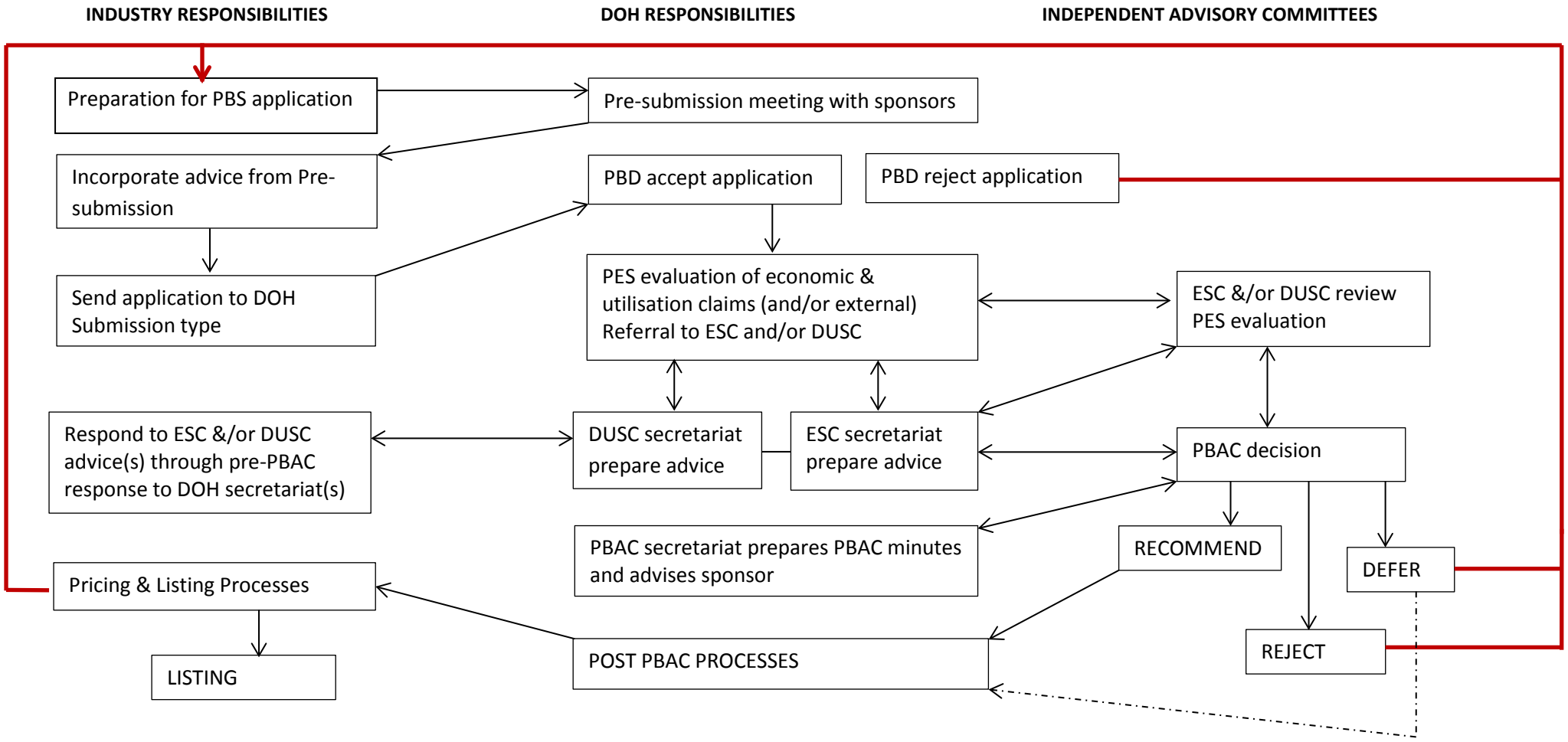


Source: Impact of Further PBS Reforms, CSES, May 2013

It is worth noting however, that the reform measures have in fact provided the Government with sufficient confidence to increase the Cabinet threshold; a measure which will support timely access to cost-effective medicines and demonstrates a pragmatic approach to creating efficiencies in the PBS.

[3] 'Impact of further PBS reform, CSES, 2013

Figure 6: PBS Reimbursement Process



Remove red tape for PBS to be more efficient and *'Fit for Purpose'*.

The listing of medicines on the PBS is underpinned by a system of health technology assessment (HTA) (figure 6) which requires companies to demonstrate their medicines deliver value for money through a robust and evidence based process. The HTA process relies on independent expert advice from a number of statutory and non-statutory committees.

These include the Pharmaceutical Benefits Advisory Committee (PBAC), the Economic Sub Committee (ESC), the Drug Utilisation Sub Committee (DUSC) and the Pharmaceutical Benefits Pricing Authority (PBPA), amongst others. These Committees have been pivotal to the current system and the administration of the PBS.

This HTA system in Australia has served Australian governments, patients and industry well since its inception in 1993. However, in an environment of increasing complexity in medicines design and increasing costs; the system which underpins the PBS also needs to evolve in order to remain *fit for purpose.* The advancements in medicine technology include targeted therapies which not only improve the selection of patients who will benefit from treatment but also reduces the unnecessary harm to patients who do not have the therapy target.

Therefore, whether the current administration of the PBS; PBAC and implementation of PBAC outcomes is most efficient for government also needs review.

Medicines Australia wishes to highlight a number of areas in this process where efficiencies could be gained that support the call for a review.

Declining PBAC recommendation rates:

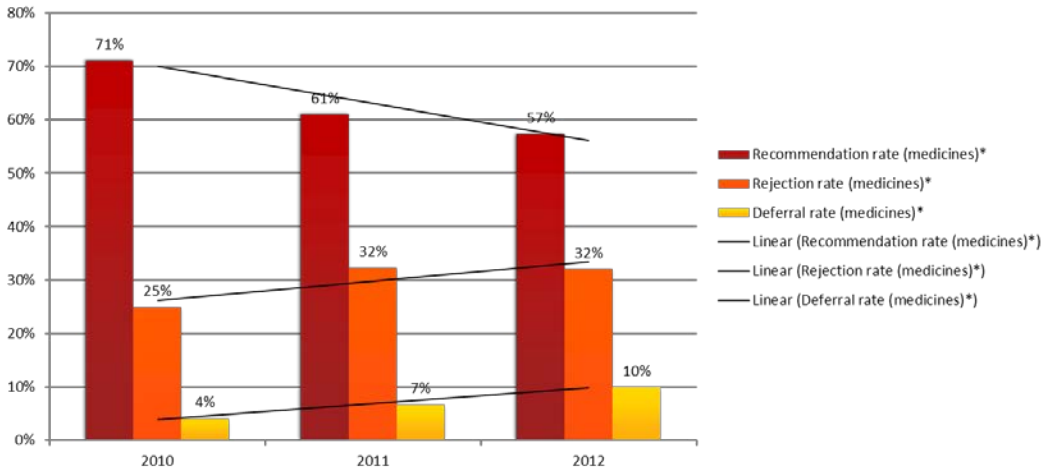
PBAC recommendation rates are declining, (Fig 7). This supports the request to assess whether the PBAC process remains fit for the intended purpose.

Declining recommendation rates reduce access to new and innovative treatments for Australian patients in a number of ways and have ongoing impacts on the Australian medicines environment;

1. Delays in availability of new treatments
2. Increased re-submission-churn, increasing regulatory burden and unnecessary costs; creating waste for Government and threatening the commercial viability of manufacturers pursuing PBS listing.
3. Diminishing the attractiveness of Australia as a destination country for investment.[4]

[4] A recent report by PwC has shown that 75% of manufacturers surveyed have medicines which are not available to Australian patients due to the current operating environment.

Figure 7: Declining PBAC recommendations



Source: Michael Wonder, Key Performance Indicators for the PBAC, unpublished

Reasons for the increasing number of deferrals and rejections are shown from PBAC Public Summary Documents to be attributed to clinical uncertainty, inadequate clinical evidence, clinical complexity and issues around the selection of main comparator.

This further highlights the inadequacy of current technical guidance, ineffective pre-submission processes held with the Department of Health and the need for a better understanding of the PBAC's decision-making. The increasing number of resubmissions required to navigate the process places a significant resource and cost burden on PBAC, departmental and industry resources. Issues around cost-effectiveness, which may have been addressed through discussion with the PBAC at the point of decision-making, rely on multiple re-submissions to progress the discussion as no other reliable mechanisms to resolve these issues exist outside the process.

Biosimilars Reimbursement

Biosimilars are off-patent biologic medicines which reach the market by referencing the data of an originator (reference) product, in a similar fashion to generic chemical medicines. However, registration of biosimilars requires more detailed clinical comparisons than simple molecular bioequivalence studies referenced for registration of generic molecules.

Heterogeneity of biologic medicines means that to ensure ongoing safety and efficacy, higher regulatory standards must be applied.5 This is reflected in the Therapeutic Goods Administration guidance for the evaluation of biosimilars, which details the requirements for specific clinical trial data. Additionally the TGA state categorically that automatic substitution (i.e. substitution by the pharmacist) is not

[5] http://www.tga.gov.au/industry/pm-argpm-biosimilars-01.htm

appropriate for biosimilars. For this and other reasons the TGA have determined that each biosimilar must be recognised by a distinct name.

As a result of the TGA's naming policy the Government does not have a consistent or effective mechanism for capturing savings from these medicines. Reforms would deliver savings to Government while also ensuring the consistency of medicines pricing policy which differentiates between newer, single-brand medicines and off-patent, multi-brand medicines.

An efficiency which is therefore warranted is to redress the uncertainty surrounding the treatment of biosimilars in the reimbursement system to ensure biosimilars contribute to the enduring system of generating savings in the off-patent market.

Streamlined pathway for submissions

Medicines Australia contends that there are a number of submission types which could be processed more efficiently thereby allowing more efficient management of relevant PBAC processes and freeing up resources to allow greater focus on the complex PBAC submissions going through the system.

PBAC meetings have been extended from 3 to 4 days and there has been a significant increase in the number of decision items on the agenda. However, a review of the PBAC agenda would indicate that many of the items for consideration are less complex and perhaps do not require full consideration by the PBAC.

For example, minor submissions require a complex financial implication assessment which in view of the revised Cabinet threshold would seem of less relevance.

Conversely, minor submissions are not allowed for co-dependent technologies which could be implemented to further improve the system and encourage timely access. Due to ongoing deficiencies in navigating the co-dependent assessment system, this would need to be implemented with caution and collaboration

Co-dependent technologies

Medicines Australia has been working with the Department to establish a timely, predictable and transparent Medical Services Advisory Committee (MSAC) process for the assessment and reimbursement of targeted therapies (co-dependent technologies). Typically these types of medicines are increasingly requiring a genetic diagnostic test to determine whether the medicine will be effective in a particular patient. Both the medicine and the test are subsidised by the government, but approved under different processes: PBAC for medicines and MSAC for diagnostic tests. Despite previous government reviews highlighting the issue, there is still much room to better coordinate these processes. The number of co-dependent technology applications is predicted to increase yet the time to access is at least twice as long in comparison to a medicine that does not have, for example, a genetic target.

A wide range of stakeholders, including the innovative pharmaceutical industry, have previously highlighted concerns about the current listing process. These concerns range from a lack of flexibility in the evidentiary requirements for reimbursement, differences in value perception of medicines among stakeholders and delays due to Federal Government fiscal measures.

There is a clear demand for an informed public debate about sustainable access to innovative medicines and therapies. Medicines Australia commits to working with

Government to ensure the timely listing of value for money medicines through streamlined administration of the PBS.

Medicines Australia still holds concerns about the complexity and duration of the draft process for assessment of co-dependent technologies. The former Government's HTA review in 2009 identified the need for reform to MSAC and there has been significant progress in this regard[6]. However, the scope of responsibility for MSAC is very broad and co-dependent technologies for pharmaceuticals are only one part of this. It is not logical that improved therapies, with clear biomarkers to identify suitable patients, are taking longer to be provided to Australian patients.

The urgency to ensure Australia has a world class, fit-for-purpose process to ensure access to targeted therapies is clear.

Cost Recovery

The Government listing process for medicines on the PBS is designed to determine the efficient allocation of taxpayer funded resources using health economics. The goal is to provide Australians with timely, reliable and affordable access to medicines. The listing process is not intended to provide a service to the industry but rather to deliver a service to the Government in determining which medicines to list on the PBS.

Despite possible inconsistency with the Australian Government's Cost Recovery Guidelines, the industry has conceded PBAC cost recovery as a business expense and built the lodgement fees into their assessment of whether (and when) to bring a new medicine to market in Australia.

However, lodgement fees may be prohibitive where a business case for bringing a medicine to market in Australia is not strong. In a 2011 member survey, Medicines Australia members reported five submissions that had been delayed or not lodged due to cost recovery. This occurred despite the introduction of fee waivers for submissions considered to be in the public interest and demonstrated to be financially unviable.

Cost recovery is one of many bureaucratic costs to industry; others include submission processes for post market reviews and requirements for post market surveillance. It is recommended that the Government consider the efficiency of the bureaucratic hurdles and costs to industry in order to minimise unintended consequences which may result in sponsor's declining to bring new medicines to market in Australia.

Secure the supply chain

Around the world there have been increasing reports of medicine shortages. Emerging research is showing that a key factor in medicine shortages in a range of markets was radical price reductions imposed on medicines.

While there may be shortages arising from a number of other issues, including product or manufacturing matters, a significant underlying cause of many of the increasingly frequent medicine shortages has been large price reductions which

[6] Department of Health and Ageing, 2009, Review of Health Technology Assessment in Australia, December, http://www.health.gov.au/internet/main/publishing.nsf/Content/AF68234CE9EB8A78CA257BF00018CBEB/$File/hta-review-report.pdf (accessed 28/11/2013).

reduce the commercial viability of supplying medicines. In an environment of radical and substantial reductions in the prices of medicines, companies have cut investment in their facilities or withdrawn from the market altogether, leaving a smaller number of suppliers.

Closer to home, aggressive government pricing policies in New Zealand has led to multiple and repeated medicine shortages whilst generating only modest savings for its Government. This overwhelming focus on cost containment at the expense of health outcomes has drawn strong criticism from New Zealand's medical community and patient groups.

Australia's system of pricing has gone through radical reform over the last decade. We are yet to see the full impacts of this system on the viability of the Australian medicine supply chain. Rather than discussing even more options for driving prices down, it will be important to monitor the impact of policies now operating on the viability of the medicine supply chain in Australia and the region.

Remove processes which are unnecessary in light of PBS reforms

In addition to the inefficiencies surrounding the PBAC submission process, there are a range of other improvements for securing greater efficiencies and effectiveness in the PBS. These include:

Weighted Average Monthly Treatment Cost (WAMTC)

The WAMTC programme conflicts with measures implemented through PBS reforms and places unnecessary burdens on both industry and the Government.

PBS reforms have reduced the capacity to generate savings from this programme, as price disclosure achieves the best price for any given medicine over time. This is more efficient that simply equalising costs. The administrative costs to Government versus the limited savings achieved through this measure demonstrate that it is of questionable value and should be removed.

Therapeutic Groups

Therapeutic Groups are groups of PBS-listed medicines that are linked together for pricing reasons regardless of whether the medicines are included in the single brand, non-competitive F1 formulary or the multiple-brand, commoditised F2 formulary. They comprise different medicines which the Minister for Health, on the advice of the PBAC, has determined in accordance with the National Health Act to be *'interchangeable on an individual patient basis'.*

The purpose of grouping medicines into Therapeutic Groups is to impose a ceiling on the price that the Government will pay for any medicine in that group based on the lowest priced medicine in the group. The Government subsidises all drugs within a group at the same price, regardless of the cost-effective price previously negotiated and agreed between a company and the Department of Health.

Should one member of a Therapeutic Group move to F2 following the entry of a generic competitor into the market, all members of the group are moved immediately into F2 regardless of patent status or whether there is market-based brand competition for the medicine. This triggers an automatic 16% price reduction for all medicines in the group.

Decisions to form a Therapeutic Group effectively dissolve the boundary between F1 and F2 and undermine PBS Reforms which were intended to drive efficient savings while maintaining ongoing access to new medicines. The F1/F2 system, introduced under the former Howard Government, was designed to ensure that sponsors of new F1 medicines have a business rationale for supplying that medicine through the PBS in Australia.

Sponsors invest hundreds of millions of dollars and years of clinical research and development to bring a new medicine to market. The PBS system provides a means to recoup on that investment, and thus encourage ongoing, future investment in new innovations in the pipeline, but only if the sponsor can demonstrate through health technology assessment acceptable clinical and cost effectiveness, as is appropriate.

More efficient and predictable policy options to reduce PBS expenditure, namely price disclosure are now in place. The continued success of these reforms makes the application of the outdated and inconsistent Therapeutic Groups policy redundant and unnecessarily risky.

Minimise unnecessary regulation and improve processes

Some existing programmes warrant improvements in process to garner efficiencies such as:

Post Market Reviews

Over the past two years, there has been an increase in the number and frequency of post-market reviews of PBS listed medicines. These reviews were allocated funding in the 2011 Federal Budget. Whilst the industry acknowledges the governments right to review medicines value for money, the programme has been implemented inefficiently, inconsistently and with inadequate consultation with affected stakeholders. As a result, the programme undermines both the *National Medicines Policy* [7] and the existing process for listing drugs on the PBS.

Post-market reviews have had an overriding focus on reducing the price of patented medicines with a disregard for the savings already being generated by the existing PBS reform measures and compromising the business operating environment.

The resource intensity required from the Department of Health (DOH) to implement and manage the programme and costs to Government in maintaining this programme are not justified by the price reductions they achieve when balanced against the negative impact on medicines availability and the industry as a whole.

Reviews tie up a great deal of company and Government resources and are an inefficient and inappropriate way to generate Government savings. The combined burden of company resourcing and revenue impact adds a great deal of uncertainty to pharmaceutical companies doing business in Australia and undermines the viability of the Australian innovative medicines industry.

[7] Commonwealth of Australia, Department of Health. ' *National Medicines Policy'*, 2000 has four central pillars that aim to:

- provide timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- ensure medicines meet appropriate standards of quality, safety and efficacy;
- ensure the quality use of medicines; and
- maintain a responsible and viable medicines industry in Australia

Minimise market intervention

PBS policy settings for the F2 formulary are built to capture savings related to the competition and discounting amongst different companies offering their own brands of a single medicine.

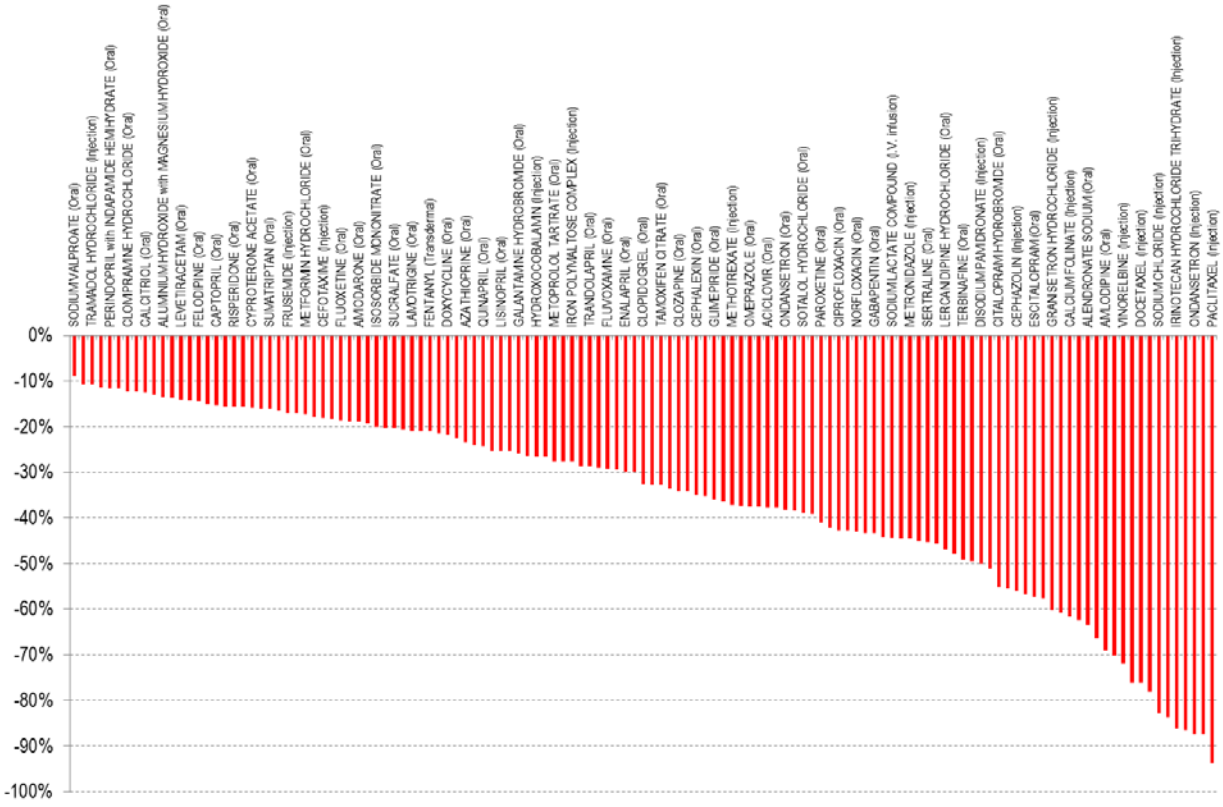
The Government adjusts the price it will reimburse for a medicine based on a weighted average price, taking into consideration the prices and market shares of each of the different brands of that medicine available in the market.

Some stakeholders have suggested that policies should be introduced to drive greater market share for generic competitors. These stakeholders suggest that generic competitors discount more deeply than the originator brand, and therefore, by stimulating a greater market share for the generics companies, the weighted average price to be paid by the Government following price disclosure will be lower.

This policy suggestion is based on flawed assumptions. The incentive for a generic company in offering deep discounts is to gain market share and to divert usage from the originator to their brand. There would be minimal or no incentive to discount a generic brand so significantly if it were able to gain market share by some other means (e.g. a Government policy setting guaranteeing market share).

There is no budgetary rationale for policy settings to grow market share for one group of companies over another group. In addition, such policies would prove detrimental for patients. Quality use of medicines is a critical component of the National Medicines Policies, and policies which interfere with patient and prescriber choice and consistency of treatment are dangerous and also, importantly, unnecessary given strong existing PBS policy settings.

Figure 8: Price disclosure - size of price cuts



Source: CSES, Victoria University, Cumulative price disclosure price reductions

CONCLUSION

The PBS provides universal prescription medicines cover for Australian patients. As medicines design and medical technologies have advanced, the system for assessing and valuing their contribution to the population health has remained static.

Expenditure on the PBS is unfortunately primarily seen as a cost rather than an investment and savings derived in alternative portfolios are not easily recognised as originating from the PBS.

Success in constraining PBS growth and expenditure has been achieved through successive collaboration and formal agreements between Government and industry. In light of these successes Medicines Australia calls on the National Commission of Auditors and the Government to:

1. Acknowledge that structural reforms have delivered a sustainable model for funding pharmaceuticals through the PBS, with enduring mechanisms to generate ongoing PBS savings, such that no further savings measures are warranted.
2. Review the Pharmaceutical Benefits processes, including the administration of the programme and its associated statutory structures (e.g. PBAC) to remove red tape and make them *fit for purpose f*or the future
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Appendix 1

PHARMACEUTICAL INDUSTRY POLICY

Intellectual Property

Patents and other forms of intellectual property rights such as data exclusivity act to mitigate the commercial risks of bringing new medicines to market, making it significantly more likely that companies will continue to invest in R&D . A stable and predictable intellectual property system is critical not just to Australia's ability to attract investment in R&D, and high-tech manufacturing, but also to Australian patients being able to receive the latest treatments as quickly as possible.

The recently concluded Strategic Review of Health and Medical Research in Australia was conducted over two years by some of this country's most respected scientists, clinicians and business leaders[8]. It came to the conclusion that certain important areas of Australia's intellectual property system are "weak" and stated that "the best way to protect valuable IP is by ensuring Australia's IP system is strong, stable, predictable and harmonised with global best practice". The Review, led by former Australian-Of-The-Year, Mr Simon McKeon, called on the Australian Government to ensure the strength and stability of Australia's IP system through such means as:

- rejecting calls to exclude biological materials from patentable subject matter;
- rejecting calls to make it easier to obtain compulsory licences; and
- extending the term of data exclusivity to harmonise an important element of the Australian IP system with global best practice.

Regulatory Reform

Medicines Australia supports the Therapeutic Goods Administration's objectives of increasing efficiencies in the regulatory system by providing:

- reliable, predictable and timely processes for the evaluation and registration of prescription medicines in Australia;
- enhanced access to prescription medicine information; and
- increased transparency of the prescription medicine regulatory process

The TGA is hampered by its position within the DOH, which constrains its ability to deregulate processes and garner efficiencies. For example, significant inefficiencies remain with regard to document management systems.

Medicines Australia further recognises that the establishment of a joint regulatory agency between Australia and New Zealand for therapeutic goods (ANZPTA) represents a significant opportunity for potential efficiency gains.

[8] Department of Health and Ageing, 2013, Strategic Review of Health and Medical Research: Final Report, (McKeon Review), February, http://www.mckeonreview.org.au/downloads/Strategic_Review_of_Health_and_Medical_Research_Feb_2013-Final_Report.pdf (accessed 28/11/2013).

However, international best practice has evolved and it is important that the most recent developments are taken into account when assessing what is and what is not efficient for a joint Australia-New Zealand regulator.

The continuous and rapid advancements in medicines and technologies require an adaptive and forward-thinking regulatory development process. In this regard, ANZTPA must be developed with the needs of the future in mind, rather than consolidating the 'familiar' based on what already exists today. In particular, ANZTPA offers important opportunities for efficiency gains such as:

- the ability to gain parallel regulatory approval for new innovative medicines in both markets offers the potential for earlier access to medicines;
- a single submission fee under ANZTPA should be less than the combined costs of both agencies thus reducing industry operating costs;
- a single application and evaluation should optimise resource utilisation for industry by eliminating the duplication currently necessary to meet individual country requirements as well as improve compliance monitoring;
- a single point for reporting of adverse events and undertaking post marketing surveillance will optimise resources and enhance compliance;
- the adoption of appropriate technology solutions to support e-submissions will further enhance efficiency and resource utilisation for both industry and the agency; and
- international harmonization will facilitate global compliance and supply chain management reducing the risk of medicines shortages due to unique requirements in ANZ

R&D Tax Incentive

Medicines Australia strongly supports the current R&D Tax Incentive system. It replaced a system which was unpredictable, overly complicated and required companies in Australia to demonstrate year-on-year growth in their R&D expenditure in order to secure a (relatively insignificant) tax benefit.

The R&D Tax Incentive, which was implemented after nearly three years of extensive community consultations, was specifically designed to make access to tax benefits more efficient and predictable. In addition, under the new system, there is no requirement for companies to demonstrate year-on- year growth in their R&D expenditure in order to claim a tax benefit, nor is there any requirement for intellectual property from eligible R&D projects to be held in Australia.

Above all, the R&D Incentive provides a globally competitive tax incentive for conducting R&D activities in Australia.

Cutting the rate or otherwise restricting the eligibility criteria beyond what has already been done would mean that other countries, which offer more generous tax incentives, would attract an even greater share of global R&D investment than they do now, at Australia's expense.

Clinical Trial Reform

A majority of the private investment in medical research in Australia is on clinical trials, which are an indispensable and, in many cases, the most expensive component of the drug development process. Since 2007, industry has initiated around 5000 clinical trials in Australia in more than 30 therapeutic areas, such as oncology and mental health. Every year, more than 18,000 patients participate in clinical trials conducted in Australia.

Clinical trials are important not only for the massive investment they bring to Australia, but also for the role they play in improving Australia's healthcare system. Among other things, clinical trials provide early and often free access to new healthcare technologies, which, according to the Commonwealth estimates, saves Australian taxpayers around $100 million each year in hospital and PBS costs.

In recognition of the importance of maintaining private investment in clinical research, the then Australian Government established the Clinical Trials Action Group in 2009 to "help cement Australia's position as a good place to conduct clinical research".

In its final report[9], the Action Group made 11 recommendations, aimed mostly at improving patient recruitment and making the process of initiating and conducting clinical trials in Australia significantly more efficient and cost-effective.

Unfortunately, nearly three years after the report's release, most of the Action Group's recommendations have not been implemented to the extent necessary to change the "realities on the ground". There is no doubt that Australia needs to take urgent action to improve its competitiveness as a destination for global investment in clinical trials. To do this, the Clinical Trials Action Group's recommendations have to be implemented in full and as quickly as possible.

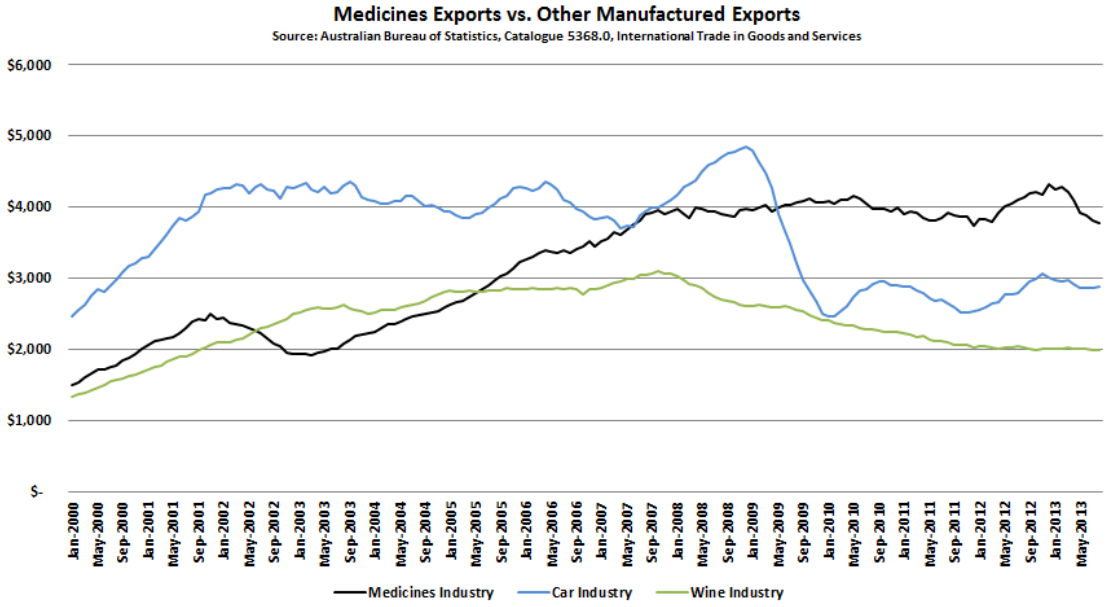
[9] Clinical Trials Action Group, 2011, Clinically Competitive: Boosting the Business of Clinical Trials in Australia, Report, Commonwealth of Australia, http://www.innovation.gov.au/industry/PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Documents/Clinical_Trials_Action_Group_Report.pdf (accessed 28/11/2013).

Appendix 2

KEY FEATURES OF THE AUSTRALIAN MEDICINES INDUSTRY

The Australian medicines industry is part of the global medicines industry which is currently worth $900 billion, and which is expected to be worth over $1 trillion by 2015.[10]

The medicines industry is one of Australia's largest exporters of manufactured goods. It exports more by value than the Australian car and wine industry. Since 1990, exports of medicines have increased by than 800%. Major markets for Australian medicinal exports include Asia (40%), southern Africa (20%) and Europe (16%). [11]

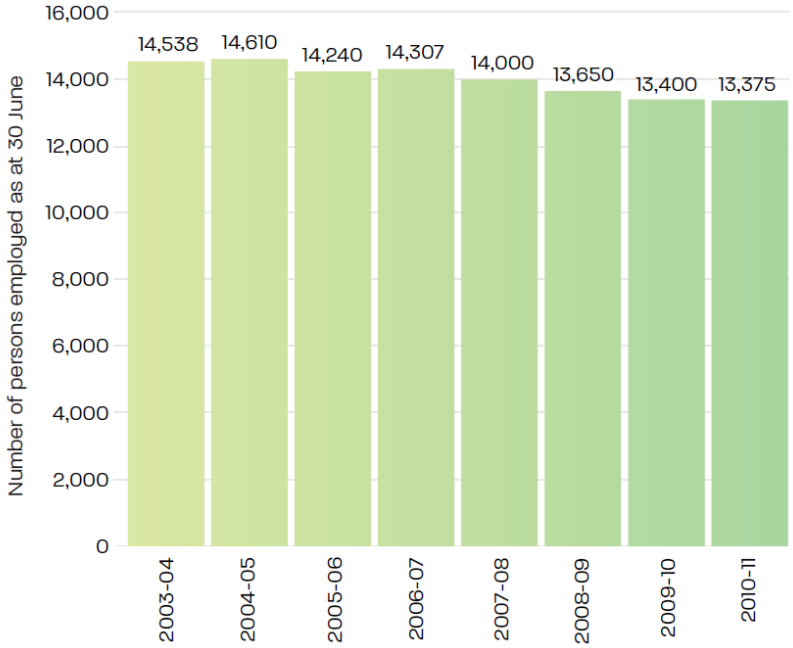


The Australian medicines industry employs over 13,000 exceptionally talented Australians (Figure 2). It is one of the largest employers of university graduates, especially science graduates, in Australia. The medicines industry creates high-quality jobs, which builds high-value skills, helps retain skilled professionals in Australia and attracts outstanding talent from overseas.

[10] IMS Health, 2012, IMS Market Prognosis.
[11] Department of Foreign Affairs & Trade, 2012, STARS Database, based on ABS Cat No. 5368.0.

Employment in the Medicines Industry in Australia

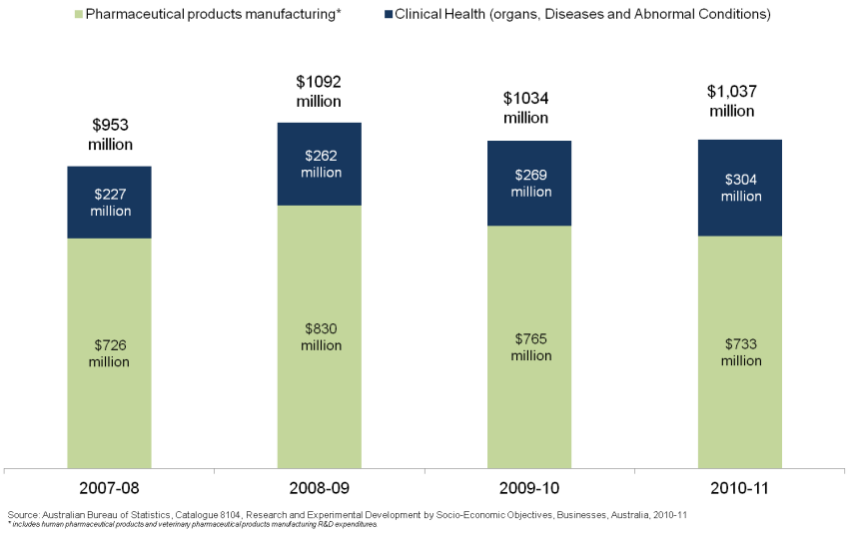
Source: Department of Industry, Australian Pharmaceuticals Industry Data Card, Key Statistics, 2012



Since 2007, the Australian medicines industry has invested over $4 billion in research and development, including on over 5000 clinical trials[12] in more than 30 therapeutic areas such as oncology and mental health.

Medicines R&D in Australia

Source: Australian Bureau of Statistics, Cat. 8104, Research and Experimental Development by Socio-Economic Objective

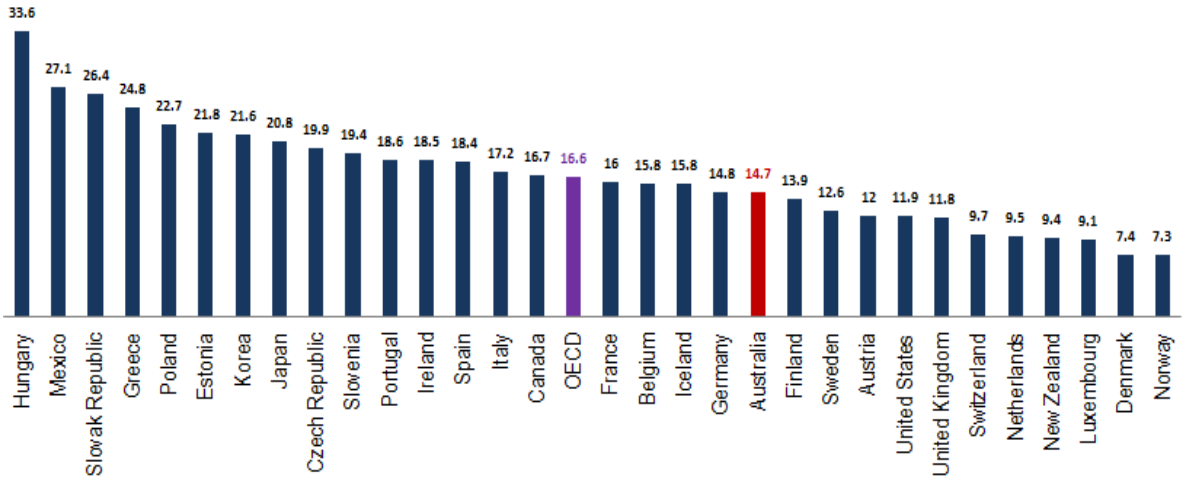


[12] Therapeutic Goods Administration, 2013, Half-Yearly Performance Report, Clinical Trials (Medicines).

Australia's expenditure on medicines as a share of total health expenditure is below the OECD average. Australia's expenditure on medicines as a share of GDP is also below the OECD average. Importantly, at around 0.6%, expenditure on medicines in Australia as a percentage of its GDP has remained virtually unchanged over the past decade.[13]

Expenditure on Pharmaceuticals as a Share of Total Expenditure on Health in OECD Countries, 2011

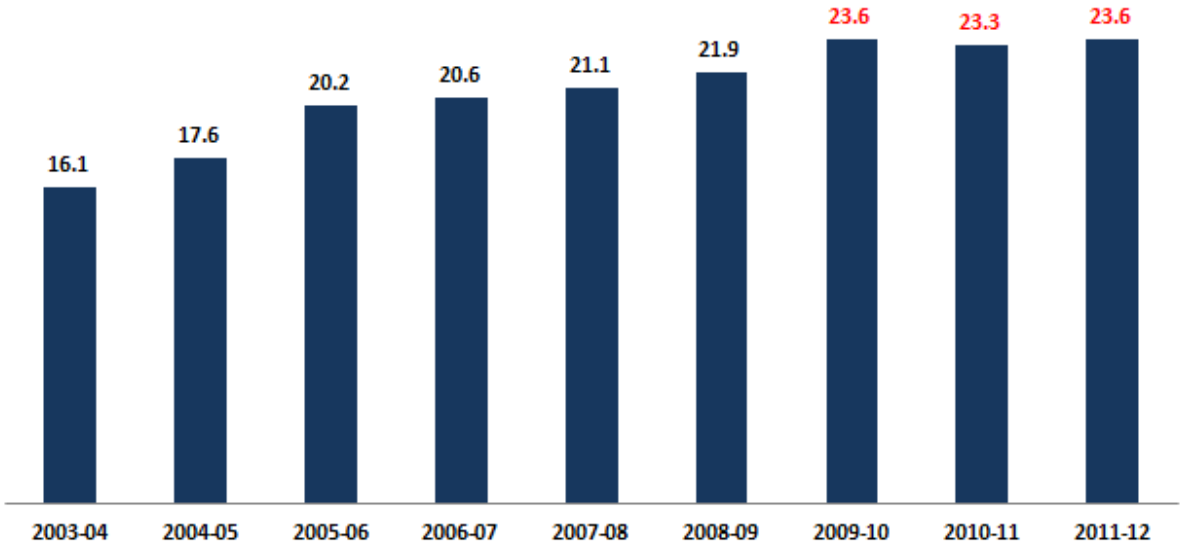
Source: OECD, Health at a Glance 2012: OECD Indicators



Whilst Australia remains an important market for the medicines industry, growth has been stagnating.

Pharmaceutical Industry Turnover in Australia, $billion

Source: Department of Industry, Australian Pharmaceuticals Industry Data Card, Key Statistics, 2013



[13] Australian Institute of Health and Welfare, 2012, Australian Health Expenditure 2011-12