Federal Budget Submission 2018





ABOUT MEDICINES AUSTRALIA

Medicines Australia is the industry association for the innovative pharmaceutical sector. Our members invent, research, manufacture and supply innovative and breakthrough medicines and vaccines that help people to live longer, healthier lives. These medicines and vaccines keep Australians out of hospital, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our membership consists of nearly 50 companies, all of whom are committed to advancing the health outcomes of all Australians.

OUR VISION

A longer and healthier life for Australians through availability and choice of world leading innovative medicines.

OUR MISSION

In partnership with key stakeholders, drive the creation and development of a predictable environment for the continued, sustainable growth of the innovative and research-based prescription medicines industry so Australians continue to lead longer and healthier lives.

LEADERSHIP

Lead and maintain industry consensus and unity to contribute to medicines policy development for the benefit of all Australians.

OUR STRATEGIC PRIORITIES

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

WHO WE WORK WITH

We aim to achieve our strategic priorities by forming effective alliances, including engaging with the Parliament, Government and government departments, other peak bodies in the medicines industry, consumer groups, health professionals and academic institutes to develop health and industry policy.



INTRODUCTION

Investing in the supply of innovative and breakthrough medicines to provide universal, subsidised access for the Australian community is a fundamental undertaking of the Australian Government.

Since its inception in the 1950s, the Pharmaceutical Benefits Scheme (PBS) has become one of the most cherished and critical components of the Australian healthcare system.

Its intent is to subsidise the cost of medicines to ensure that the latest innovations and breakthroughs in treatments can be made affordable and accessible to all Australians regardless of their geographic location or their financial situation.

For this reason, the PBS was designed as an uncapped programme to ensure that there were no barriers to the introduction of new therapies in Australia.

Investing in new, innovative medicines has been shown to provide incredible value and benefits to the community. One study found that \$7 billion was saved in hospital expenditure in 2011 alone due to the ongoing investment in, and listing of, innovative medicines on the PBS. The same study found that the listing of innovative medicines on the PBS was the major factor in the 33% decline in premature deaths in Australia between 1997 and 20121.

Other studies have shown the role that innovation in medicines has played in boosting productivity in Australia by helping people to either stay at work or return to work sooner².

Despite the clear value and benefits of keeping a strong PBS, investment in the scheme has been flat or in decline (in real terms) since 2011. This has been the result of a decade of reforms to pricing policies which had the support of the industry. However, the lack of additional funding into the PBS during this time now presents a growing challenge for government if it is to meet the community's expectation that the latest medicines will be available on the PBS.

The Strategic Agreement signed between Medicines Australia and the Government in April 2017 has given some stability and focus for the next five years but big challenges lie ahead. The challenge for government, community and industry is to ensure that the PBS can fully fund the needs and demands of patients not just for today's breakthroughs in medicines but tomorrow's advancements in innovative therapies.

Continuing to address this challenge with policies that apply statutory price cuts to medicines will on its own fail to meet the demands of an ageing and growing population.

Medicines Australia believes that only through additional funding, that results in a real increase in PBS expenditure, will the Australia of tomorrow continue to enjoy the current rate of access to the latest innovations in medicines. This will be a challenge that must be met by

² Schofield, D. et al. 'Measuring Labour Productivity and the Benefits of Interventions for Osteoarthritis', project report for Medicines Australia, http://corporate.medaus.com.au/wpcontent/uploads/sites/52/2010/01/20160905-rpt-FINAL-Schofield-OA productivity-final-report.pdf



¹ Lichtenberg, Frank R. (2017), 'The Impact of Pharmaceutical Innovation on Premature Mortality, Hospital Separations, and Cancer Survival in Australia', Economic Record, 93, 302, p.353-378, http://onlinelibrary.wiley.com/doi/10.1111/1475-4932.12332/full.

the Parliament, not just a single government, as well as industry over the near to medium term.

In this submission, we aim to address some of the issues that will help to facilitate this important discussion.

The innovative pharmaceutical sector is becoming an increasingly critical sector for Australia's ongoing prosperity as the mining boom period draws to its close.

According to a recent analysis by PWC³, our members contributed \$9 billion to the Australian economy in 2016-17, which supported the employment of 23 thousand Australians (direct and indirect). The medicines industry continues to be one of the largest exporters of manufactured goods with some of our members expanding their advanced manufacturing facilities and capabilities in Australia. Our members continue to be significant investors in Australian R&D, including one thousand clinical trials initiated in 2016-17 that helped 33 thousand Australians get early access to emerging therapies.

To support this ongoing contribution to the Australian community and economy, government needs to maintain not just a well-funded PBS, but also continue to support industry-focussed policy settings, such as the R&D tax incentive. These are important enablers to encourage investment by our members into Australia's medical technology and pharmaceutical (MTP) sector.

³ Figures from a yet to be published PWC survey of Medicines Australia member companies, "The economic contribution of the innovative pharmaceutical industry to Australia".



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EXECUTIVE SUMMARY

The priorities for the 2018-2019 Budget for the innovative medicines industry are:

Improvements for patient access to medicines

Australians should have availability of the latest medicines they need when they need them. A five year strategic agreement between Medicines Australia and the Australian Government will support ongoing access to the latest innovative medicines for patients. This Agreement acknowledges the need for growth in the Pharmaceutical Benefits Scheme (PBS) to accommodate a growing and ageing population, the increasing burdens of disease and the advent of extraordinary advances in technology to deliver innovative medicines and therapeutics. The Agreement contains specific deliverables and targets that relate to the importance of the innovative medicines sector and continuous improvement of assessment processes. Alignment of expedited Therapeutics Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) processes has a significant role to play in the delivery of rapid access to the latest technologies in medicines.

Action 1: The Australian Government, through the Department of Health, works with Medicines Australia to ensure full implementation of the Strategic Agreement. This includes the pricing measures (Clause 5); the reserving of savings for future listings (Clause 6); modernisation of e-prescribing and data capacity (Clause 7); and listing process improvements to accelerate PBS availability of world leading medicines for patients (Clause 10).

Action 2: The Australian Government, through the Department of Health, provides regular reports on the progress made against the deliverables specified in the Strategic Agreement. These include:

- development of revised pathways for approval by the Minister by July 2018
- doubling access to early advice on submissions for new medicines
- reducing the time taken for medicines to be available through listing on the PBS by at least two months
- 50% reduction in resubmissions;
- streamlining of costs for complex submissions;
- on-line submissions process for applications; and
- alignment of PBAC process in parallel to changes made to TGA processes.

Reporting on PBS expenditure for different areas of the supply chain

Reporting on PBS expenditure and the total cost of the associated supply chain would help explain the cost of medicines and the cost to government of providing them to patients no matter where they live or when they need them. It would make information of overall PBS expenditure more transparent over time. The best outcomes in public policy emerge when the budget process is open, accountable, and transparent.

Action 3: Update the presentation of PBS budget expenditure to acknowledge the aggregated revenue paid to the Australian Government in rebate(s).

Action 4: Report on PBS expenditure and the total cost of the associated supply chain to help explain the cost of medicines and the cost to government



Development of a National Therapeutics Policy: addendum to the National Medicines Policy

In this very exciting time of rapid advancements in modern medicine, a range of new technologies will become available to patients over the next decade and beyond. While the National Medicines Policy (NMP) has served Australia well for a very long time, it needs modernisation to ensure it remains fit for purpose into the 21st Century. An addendum that explicitly articulates the role of innovative therapeutics in areas where once previously none existed would help to refresh the policy to ensure Australia's regulatory and PBS approval pathways don't hinder access to emerging medicine technologies.

Action 5: The Australian Government, through the Department of Health works with Medicines Australia and targeted stakeholders on the development and inclusion of a National Therapeutics Policy addendum. This will ensure the NMP remains fit for purpose and keeps pace with emerging therapeutic technologies and evolving health, medicines and therapeutics delivery systems. It would also guide future reforms to evaluation processes for therapeutics through the PBAC and PBS to accommodate emerging therapeutic technologies and ensure that all Australians who would benefit from a particular innovative treatment get access to it.

Improved policy coordination – whole of medicines sector

Medicines Australia advocates for the establishment of a government-industry forum as a priority. Coordination, consistency and collaboration between Central Agencies, the Department of Health and the Department of Industry, Innovation and Science assists with the development of sound policies that lead to social, health and economic benefits for Australia through a vibrant pharmaceutical sector

Action 6: Ministers of Health, Industry, Finance and Treasury to lead a government industry forum. This forum would develop policies that lead to greater social, health and economic benefits for Australia from investment in the PBS and the pharmaceutical sector.

Digital health and e-prescriptions: transforming healthcare

Digital health can drive efficiencies across the health care system as a whole and improve patient outcomes, adherence and monitoring of medicines as they are used. Significant savings will accrue which can be reinvested in better healthcare interventions, such as innovative medicines on the PBS.

Action 7: Health Ministers continue to drive this necessary digital reform agenda by bringing forward the timeline for development of the *National Digital Medicines Management Blueprint*. This blueprint should ensure the inclusion of notification of dispensing actions back to prescribers to better track patients health outcomes, medication adherence and post market safety and efficacy monitoring of medicines (and biosimilars) **Action 8:** The Australian Government should support Australian Digital Health Agency (ADHA) to ensure the completion of the blueprint by 2018-2019.



Research & Development (R & D) tax incentive

The most recent review of the R&D tax incentive contained some recommendations that, if implemented, would have significant, disproportionate and negative impacts on the Medical Technologies and Pharmaceutical (MTP) sector.

Action 9: Commit to maintaining the existing R&D incentives for the MTP sector, including the overall level of support for business research and development.

Action 10: If the Australian Government control growth in the costs of the R&D Tax Incentive by putting in place a cap and/or intensity threshold, implement exemption arrangements the MTP sector.

Action 11: Work closely with the pharmaceuticals industry to design a 20% collaboration premium, as recommended by the Finkel, Ferris, Fraser review of the R&D tax incentive, or alternatively consider a new grants programme to incentivise the innovative pharmaceuticals sector

Champions programme

Better marketing by Australia of our world-class capabilities in research & development, such as clinical trials, is needed to promote Australia's brand to key markets and potential investors. Support for a coherent nationwide plan, coupled with high profile political delegations at key forums, will increase our reputation as a go-to destination for medical research.

Action 12: Develop a long-term marketing strategy for the medical technologies and pharmaceuticals sector (MTP). This needs to involve collaboration with the states and territories to position Australia as a preferred country to invest in. This could include coordinated delegations of high profile Federal and State politicians

Action 13: Commit \$5 million over the forward estimates to facilitate this coordinated, high-profile approach to marketing Australia's MTP sector overseas.



BUDGET SUBMISSION IN DETAIL

IMPROVEMENTS FOR PATIENT ACCESS TO MEDICINES

Australians should have access to the latest medicines they need when they need them. This is an ongoing funding challenge that must be met by government, the community and industry. A five year Strategic Agreement between Medicines Australia and the Australian Government will support ongoing availability of the latest innovative medicines for patients.

This Agreement acknowledges the need for growth in the Pharmaceutical Benefits Scheme (PBS) to accommodate a growing and ageing population, the increasing burdens of disease and the advent of extraordinary advances in technology to deliver innovative medicines and therapeutics.

The Agreement contains specific deliverables and targets that relate to the importance of the innovative medicines sector and continuous improvement of assessment processes. Alignment of expedited Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) processes has a significant role to play in the delivery of rapid access to the latest technologies in medicines.

The Strategic Agreement is the latest significant reform supported by industry to deliver changes to the PBS that make innovative medicines even more affordable than ever before.

It provides the government with \$1.8 Billion in savings through new statutory pricing measures for patented medicines that, as part of the Agreement, are nominally accrued in a "contingency reserve" to offset expenditure of future medicine listings on the PBS. It also highlights the opportunity to continuously add to the contingency reserve during the term of the Agreement.

Medicines Australia and its members have now supported a decade of pricing reform that has delivered significant reductions in forecast and actual PBS expenditure and significantly lowered the prices paid by government for both off-patent and on-patent medicines.

These reforms have reduced predicted expenditure by more than \$20 billion and will continue to deliver further savings over the five year Strategic Agreement.

The use of price reduction measures alone will not be able to meet the needs of the Australian public into the future. There remains a fundamental community expectation that government investment in the PBS must be able to afford the medicines of today but also the breakthroughs of tomorrow.

According to Budget Papers and Health Department annual reports, the PBS has seen no real growth in expenditure for almost a decade and that will become increasingly unsustainable in the future.



On average, Australia pays some of the lowest prices in the developed world for medicines. Industry will continue to deliver globally competitive prices as well as ongoing industry-government agreements to ensure Australia is getting absolute value for money.

However, it is imperative that government also increases its investment, in real terms, in the PBS to reflect both an ageing and growing population, as well as the increasing value to government and society from pharmaceutical innovation and breakthroughs in treatment.

Ensuring that the PBS is fully-funded is critical to Australia having first-world access to innovative medicines into the future. The speed at which these medicines are made available on the PBS must also be addressed through ongoing improvements to registration and listing processes.

The Strategic Agreement incorporates significant improvements that will modernise the PBS submission processes for evaluation by the PBAC that will help to accelerate access to the latest medicines for Australian patients.

The measures include a commitment from government to halve PBAC submission churn over the life of the Agreement, which would reduce delays to the listing of new medicines on the PBS.

It's imperative that these commitments are honoured by government and the Department of Health.

Action 1: The Australian Government, through the Department of Health, works with Medicines Australia to ensure full implementation of the Strategic Agreement. This includes the pricing measures (Clause 5); the reserving of savings for future listings (Clause 6); modernisation of e-prescribing and data capacity (Clause 7); and listing process improvements to accelerate PBS availability of world leading medicines for patients (Clause 10).

Action 2: The Australian Government, through the Department of Health, provides regular reports on the progress made against the deliverables specified in the Strategic Agreement. These include:

- development of revised pathways for approval by the Minister by July 2018
- doubling access to early advice on submissions for new medicines
- reducing the time taken for medicines to be available through listing on the PBS by at least two months
- 50% reduction in resubmissions;
- streamlining of costs for complex submissions;
- on-line submissions process for applications; and
- alignment of PBAC process in parallel to changes made to TGA processes.



REPORTING ON PBS EXPENDITURE FOR DIFFERENT AREAS OF THE SUPPLY CHAIN

Reporting on Pharmaceutical Benefits Scheme (PBS) expenditure and the total cost of the associated supply chain would help explain the cost of medicines and the cost to government of providing them to patients no matter where they live or when they need them. It would make information about overall PBS expenditure more transparent over time. The best outcomes in public policy emerge when the budget process is open, accountable, and transparent.

The operation and administration of the PBS is complex, involving multiple government agencies, manufacturers, wholesalers, prescribers, pharmacies and patients.

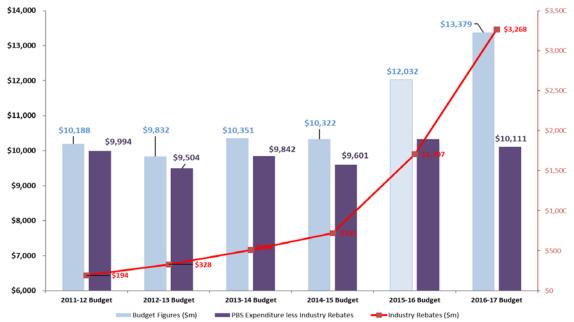
Currently, the PBS figure reported in the Federal Budget handed down in May only provides the headline expenditure. It does not include the aggregated rebates paid back to the Australian Government by pharmaceutical companies. It also doesn't separate the cost of the medicines supply chain that includes wholesalers and pharmacists.

This can create confusion amongst policymakers, the media and the general public about the true cost of the medicines on the PBS.

REBATES

Rebates have become an increasing but hidden percentage of the headline cost of the PBS reported in the Federal Budget. In 2011-12 the value of rebates was \$194 million. In contrast by 2016-17 the aggregated rebates paid back to government by pharmaceutical companies was over \$3.2 billion.





⁴ Graph derived from Federal Budget figures and incorporating concepts previously reported in Pharma Dispatch



Confidential rebate agreements with pharmaceutical companies have become an increasingly common tool for governments to get the medicines they need at a price significantly lower than would otherwise be the case.

However, current budget accounting practices do not identify the aggregated rebate amount received by government within a financial year and do not attribute the revenue to the health portfolio figures. The perverse effect makes the PBS look like it is growing when in actual fact the PBS is not.

Rebate agreements come in a variety of forms, but often involve the repayment of the difference between a higher published price of a medicine and a confidential price agreed between the manufacturer and the government. Other common rebate agreements involve confidential risk-sharing arrangements, whereby companies agree to pay all or part of any additional expenditure on a medicine above a pre-agreed amount.

Commentary on increases in PBS expenditure frequently does not take into account consideration of risk-sharing and confidential pricing agreements between manufacturers and the Australian Government.



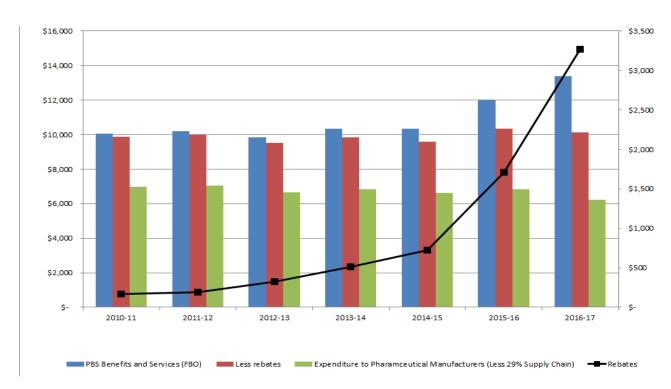


FIGURE 3 – Expenditure on PBS and related services growth compared to industry rebates (\$m)

*The figure above shows headline PBS expenditure in budget papers (Blue) which appears to grow significantly over recent years. Net expenditure, once rebates are accounted for (Red), shows that true PBS expenditure has stayed flat since 2011. The figure also reveals the proportion of the cost of the medicines against the associated supply chain. PBS payments to pharmaceutical manufacturers for medicines is shown in Green. The difference between the Red and Green values represents the supply chain cost which currently accounts for one third of total PBS expenditure.

Action 3: Update the presentation of PBS budget expenditure to acknowledge the aggregated revenue paid to the Australian Government in rebate(s).

SUPPLY CHAIN

The whole supply chain is a critical function of the delivery of all medicines to Australians who need them, when they need them. A significant element of the supply chain includes the cost of wholesalers who transport medicines from the manufacturer to the pharmacy and provide the storage and handling in between. It also includes the cost to government for a pharmacy to hold and dispense the medicine to a patient.

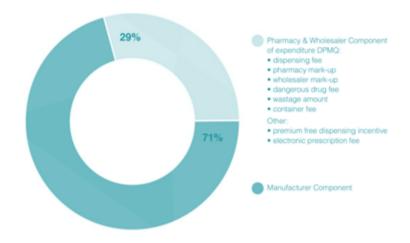
The Australian Government subsidises the cost of wholesaler's distribution to community pharmacies through the Community Service Obligation (CSO) which mandates certain minimum delivery standards. Wholesalers reach agreements with individual and groups of pharmacies regarding the supply of medicines. Pharmacies often choose to manage small inventories of medicines and still maintain the ability to dispense a prescription medicine to a patient with minimal delay because of the government subsidy that enables frequent re-supply through the CSO.



While the costs of medicines have reduced significantly over the past ten years, the distribution and dispensing costs have not.

This has seen the cost of the supply chain reach 29% of PBS expenditure today and is expected to increase as a proportion of medicines costs in the coming years.

FIGURE 4 – ⁵Supply chain proportions of PBS and RPBS expenditure



^{*} Claimed by Community Pharmacies and Friendly Societies 2014-15 (Government and Patient Contribution) **Source:** Review of Pharmacy Remuneration and Regulation, Discussion Paper, July 2016

Reporting these costs as part of a more transparent PBS in the Budget papers will help to inform policymakers, taxpayers and the community about the value for money of medicines but also the complexity and cost of ensuring Australia maintains the universal PBS that provides the same standard of access for any Australian regardless of where they live.

Medicines Australia strongly supports this approach to help inform governments and community about the value of a well-funded PBS that can accommodate future medicines listings and the supply chain system that supports it.

Action 4: Report on PBS expenditure and the total cost of the associated supply chain to help explain the cost of medicines and the cost to government.

⁵Review of Pharmacy Remuneration and Regulation, Discussion Paper, July 2016, pg 20. Accessed December 2017 see: http://www.health.gov.au/pharmacyreview;



DEVELOPMENT OF A NATIONAL THERAPEUTICS POLICY: ADDENDUM TO THE NATIONAL MEDICINES POLICY

In this very exciting time of rapid advancements in modern medicine, a range of new technologies will become available to patients over the next decade and beyond.

While the National Medicines Policy (NMP) has served Australia well for a very long time, it needs modernisation to ensure it remains fit for purpose well into the 21st Century.

An addendum that explicitly articulates the role of innovative therapeutics in areas where previously none existed would help to refresh the policy to ensure Australia's regulatory and PBS approval pathways don't hinder access for Australians to emerging medicine technologies.

Australia was one of the first advanced economies to formulate a national medicines policy in the late-1990s.

The NMP is the overarching framework on how medicines are handled. It does not provide technical direction, but broad conceptual goals that help to guide developments in policy and regulation.

The Australian health care system now faces significant challenges. There are a number of important drivers of health care expenditure: increasing burden of chronic disease, rising community expectations, new technologies and an ageing population.

The World Health Organisation (WHO) notes that internationally, the majority of NMPs have been updated within the last ten years. A NMP typically has a future perspective of 10 years to adapt to the changing environment⁶.

Given Australia's NMP has not been substantially reviewed over the past two decades, modification is needed to modernise it for emerging and disruptive technologies.

The National Medicines Policy was launched in 1999 and includes four central aims:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Source: Department of Health, National Medicines Policy (2000) ⁷

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⁶ World Health Organization, How to develop and implement national drug policy see: http://apps.w ho.int/iris/bitstream/10665/42423/1/924154547X.pdf

Medicines Australia

NEW TECHNOLOGIES

Recent discussions between manufacturers, consumer health organisations, and those involved in the development, testing, regulation, and funding of medicines have identified some challenges likely to impact upon the ongoing evolution and implementation of the NMP8.

While, in part, rising health expenditure is due to Australia's relative wealth and ageing populations, it also reflects the introduction of new technologies. Advancements in manufacturing techniques have led to a shift from traditional 'small molecule' medicines for large patient populations, to targeted biologics (comprising more complex molecules) for smaller populations⁹.

These targeted medicines are more expensive to research, develop and manufacture. New treatment methods such as immuno-oncology (IO) and the use of genomics to identify likely patient response, has raised community expectations such that patients expect to have access to these new technologies as soon as they are available 10.

Under the NMP, the PBS forms one of the main vehicles for implementing and managing this policy process. After, or in parallel to, the medicine's assessment for quality, safety and efficacy by the TGA, the PBAC receives applications for the listing of medicines on the PBS. These are considered according to relative safety and effectiveness in comparison to existing medicines already available for the treatment of the same conditions. It has been noted that this is a lengthy and complex process which has been acknowledged and addressed to some degree in the Strategic Agreement.

The evolution of new medicines and therapeutic approaches has resulted in treatments that don't fit neatly into the PBAC process and therefore don't easily fit into the PBS. New treatments may inadvertently fall outside traditional categories and hinder equitable access.

Medicines Australia acknowledges the challenge of working on new definitions, and acknowledges the role the TGA and PBAC play in this process.

A recent report¹¹ finds that around 7,500 Australians with cancer could benefit from checkpoint inhibitor immunotherapy, where "benefit" is defined as a greater than 30% reduction in tumour size.

However, immunotherapies are currently only available for a small number of cancers through the PBS.

Australians, October 2017 see: https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-aueconomics-new-wave-immunotherapy-cancer-medicines-121017.pdf



⁸Medicines Australia, PharmAus2017 report, September 2017 see: https://medicinesaustralia.com.au/wp-

content/uploads/sites/52/2011/03/MEA_PharmAus-2017-Report.pdf

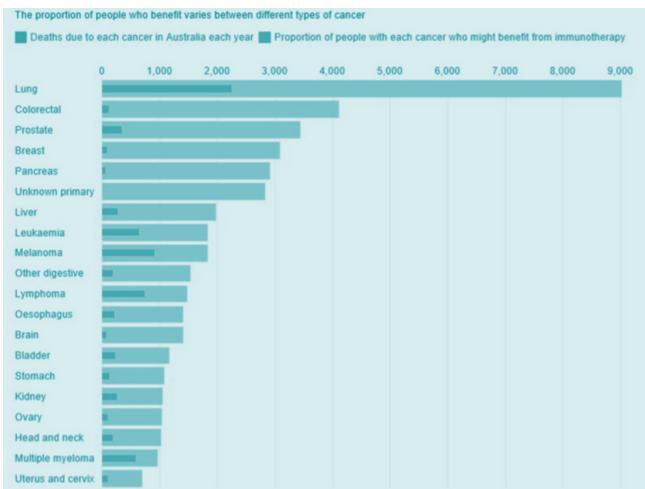
St George Institute for Global Health, Re-imagining the funding wheel: Sustainable access to medicines April 2017 see: https://www.georgeinstitute.org.au/sites/default/files/funding-innovative-medicines-april-2017.pdf

10 Deloitte's Access Economics, The New Wave of Immunotherapy Cancer Medicines – The Untapped Potential for

Australians, October 2017 see: https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-aueconomics-new-wave-immunotherapy-cancer-medicines-121017.pdf

11 Deloitte's Access Economics, The New Wave of Immunotherapy Cancer Medicines – The Untapped Potential for





* **Source:** Craig Gedye, University of New castle. This figure w as calculated using Australian Institute of Health and Welfare cancer mortality forecasts and the percentage of people experiencing a greater than 30% reduction in tumour size as estimated using a collation of the available evidence from a variety of manuscripts and conference abstracts.

¹²Gedye, C 2017, Cancer immunotherapy drugs like Keytruda and Opdivo hold hope for some, but there's still a w ay to go, The Conversation see: http://theconversation.com/cancer-immunotherapy-drugs-like-keytruda-and-opdivo-hold-hope-for-some-but-theres-still-a-way-to-go-81320



An addendum to the NMP is needed, with a focus on updating the policy framework to accommodate emerging technological advances and avoid delays to new treatments reaching patients from outdated policy definitions.

Action 5: The Australian Government, through the Department of Health works with Medicines Australia and targeted stakeholders on the development and inclusion of a National Therapeutics Policy addendum.

This will ensure the NMP remains fit for purpose and keeps pace with emerging therapeutic technologies and evolving health, medicines and therapeutics delivery systems. It would also guide future reforms to evaluation processes for therapeutics through the PBAC and PBS to accommodate emerging therapeutic technologies and ensure that all Australians who would benefit from a particular innovative treatment get access to it.



IMPROVED POLICY COORDINATION - WHOLE-OF-MEDICINES SECTOR

Medicines Australia advocates for the establishment of a government-industry forum as a priority. Coordination, consistency and collaboration between Central Agencies, the Department of Health and the Department of Industry, Innovation and Science assists with the development of sound policies that lead to social, health and economic benefits for Australia through a vibrant pharmaceutical sector.

Governments, across portfolios, frequently struggle to balance government policy with budget commitments. Changes to industry incentives, corporate tax rates, research and development activities, negotiations across borders for free trade agreements all have an impact on industry's operations in Australia. The ability to optimise economic growth and manage health expenditure needs cross portfolio collaboration. Development of an industry policy needs full support across the central agencies and a number of portfolio agencies.

A number of agencies and regulators are involved in programme administration or in policy matters that relate to the medicines sector (to varying degrees). Australian Government agencies have distinct and separate responsibilities cutting across health, industry, trade, immigration, employment and financial matters with limited incentives to look at the sector on a more holistic basis. Often decisions made in one policy space have broader sectoral impacts and cross-portfolio implications.

In the past, Medicines Australia has raised concerns about the degree of coordination among some government agencies and the capacity of agencies to deliver on consistent, whole-of-government approaches to policies affecting the medicines sector.

It appears the evidence base for making decisions is often fragmented, with different information used to inform decisions about different aspects of the sector. There is no obvious platform to support a whole-of-government approach to policy development and evaluation.

Establishing a government-industry forum would improve coordination, consistency and collaboration between agencies and the development of sounds cross-portfolio policy settings.

Action 6: Ministers of Health, Industry, Finance and Treasury to lead a government-industry forum. This forum would develop policies that lead to greater social, health and economic benefits for Australia from investment in the PBS and the pharmaceutical sector.



Digital health and e-prescriptions: transforming healthcare

Digital health can drive efficiencies across the health care system as a whole and improve patient outcomes, adherence and monitoring of medicines as they are used. Significant savings will accrue which can be reinvested in better healthcare interventions, such as innovative medicines on the Pharmaceutical Benefits Scheme (PBS).

The Australian Digital Health Agency (ADHA) recently published the *National Digital Health* Strategy (the Strategy)¹³. ADHA was established by governments in 2016 to implement the Strategy.

A new Medicines Safety Programme was established in 2017 to enhance medicines management and capability in the My Health Record system. It is envisaged there will be paper-free options for all medication management by 2022.

Medication management systems are integral to transforming healthcare, improving health outcomes and optimising cost-effective health care.

Under the Strategic Agreement, there is acknowledgement that the Australian Government intends to introduce enhancements to electronic systems for prescribing, dispensing and capturing data for PBS medicines and improve the consumer experience in medication management.

SIGNIFICANT GAPS IN OPTIMAL USE OF DIGITAL HEALTH & E-PRESCRIPTIONS

Australia's current prescription model still relies on a paper based system through pharmacy to collect medications ¹⁴. Just over a third of prescriptions are issued electronically.

It was recommended in the interim report of the Review of Pharmacy Remuneration and Regulation (King Review), that the current paper-based system of prescriptions be urgently replaced 15. The review panel was chaired by Professor Stephen King, an expert economist, with two other members, Jo Watson (Deputy Chair of the Consumers Health Forum) and Victorian community pharmacist Bill Scott. The panel concluded:

"Australia lacks an integrated and effective electronic health record system through which all health professionals can access comprehensive patient health information, including medicine records. The current system is lagging behind comparable overseas health systems....It is the Panel's preference that the e-prescription system.....forms part of the MyHealth Record system, which includes patients' broader medical history. If MyHealth Record is not likely to achieve universality in the near future, the Panel believes that an

¹³ The Australian Government, National Digital Health Strategy accessed November 2017 see: https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy

14 Review of Pharmacy Remuneration and Regulation, Interim Report, pg44-52. Accessed December 2017 see: http://www.health.gov.au/pharmacyreview;



lbid.

appropriate universal electronic medicine record should be introduced in the short term, which could later be linked into MyHealth Record".

Similarly, the Organisation for Economic Co-operation and Development (OECD) has characterised Australia as relatively poor in its capacity to collect and link health data. While vast amounts of data are collected on medicines, there are gaps ¹⁶.

FIGURE 5 – King review interim report - key findings & recommended options for e-prescriptions

HEALTH RECORD FOR CONSUMERS

The current paper-based system of Prescriptions used in Australia is outdated. It inhibits the creation of a Universal medication record for Australians, creates excessive administration, is less convenient for consumers and presents significant challenges in meeting the standard required for quality use of medicines.

OPTION 2-7: ELECTRONIC PRESCRIPTIONS

The government should initiate an appropriate system for integrated electronic prescriptions and medicine records as a matter of urgency. Under this system the electronic record should become the legal record. Participation in the system should be required for any prescriber of a PBS-listed medicine, any pharmacist wishing to dispense a PBS-listed medicine and any patient who is seeking to fill a PBS prescription.

ELECTRONIC RECORD KEEPING

Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers.

OPTION 2-8: ELECTRONIC MEDICATIONS RECORD

The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.

The introduction of electronic medical records that can share information across the full spectrum of a patient's health care is fast approaching.

Currently the gaps in the visibility and transfer of information between doctors and pharmacists and between hospitals (tertiary care) and GPs (primary care) lead to misinformation, incomplete information, duplication and, at worst, mistakes.

There is also a lack of integration with many systems not being interoperable, even within the same hospital ¹⁷.

¹⁷ As cited in Productivity Commission, Shifting the Dial: 5 year Productivity Review, pg 67. Accessed October 2017 see: https://www.pc.gov.au/inquiries/completed/productivity-review/report#media-release;



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¹⁶ As cited in Productivity Commission, Shifting the Dial: 5 year Productivity Review, pg 67, Accessed October 2017 see: https://www.pc.gov.au/inquiries/completed/productivity-review/report#media-release;

Around 41% of Australians have stopped taking prescribed medicine before they were meant to, on at least one occasion¹⁸. Another study found that out of 11 OECD countries: Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the UK, the USA and Australia, that Australia had the second highest amount of self-reported non-adherence¹⁹.

As patients transition between their local doctor, their specialist doctor, their pharmacist, a hospital and other allied health care professionals (HCPs), such as nurse practitioners, physiotherapists etc., relevant, reliable and accurate information does not follow so easily.

Sick patients, their families or carers may be required to complete paperwork numerous times for different HCPs and government agencies, which may further lead to medication errors.

More than 40 per cent of GPs report that they are dissatisfied with the information provided for their patient upon discharge from hospital²⁰. Reliable and accurate information regarding treatments that have been prescribed or indeed ceased, to help manage their condition may not be transferred to the range of HCPs involved in the care of a patient.

BETTER USE OF MEDICINES IMPROVES HEALTH OUTCOMES AND REDUCES HEALTH EXPENDITURE

Fortunately, where there are gaps there are also tremendous opportunities to drive efficiencies across health care systems through digital health initiatives.

In fact, the Australian Government estimates that the gross economic benefit of securely implementing enabling services could be around \$2 billion over 4 years and more than \$9 billion over 10 years²¹.

The My Health Record and enhanced e-prescribing systems should bind and integrate a range of information into a central portal.

This should be accessible to relevant parties to ensure safe transitions across care settings and deliver better health outcomes. This includes:

- Accurate data on all prescriptions issued. This includes direct notification back to
 prescribers on prescriptions dispensed (and not dispensed). This will help to reliably
 track patient adherence and link to health care outcomes;
- Functionality (such as reminders and messages) to assist patients with follow-up appointments and medication management (e.g.: when repeat prescriptions are due and collected);
- Improve tracking of PBS medicines dispensed, which may assist government forecast expenditure with even greater accuracy and may assist in monitoring supply;

²¹ The Australian Government, National Digital Health Strategy, pg 24 accessed November 2017 see: https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy



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¹⁸Pharmacy Guild of Australia, accessed December 2017 see: https://www.guild.org.au/ data/assets/pdf_file/0021/5655/medication-adherence-programs.pdf;

¹⁹ Morgan, Stephen, BJM open (2017). Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5293866/; <a href="h

- Secondary use of de-identified data for government agencies, manufacturers and researchers may help to better understand the benefits of medicines and experiences of patients. Particularly those with a chronic disease or other certain medical conditions. This can help inform public policy and ensure the appropriate use and uptake of new technologies²².
- Linking electronic medicines data for community pharmacy, hospitals and all doctors may also help to verify patient claims across systems; and²³.
- Integrating all health services and treatments provided to a patient into a single portal would also help reduce duplication or unnecessary tests²⁴.

Some of these options merely scratch the surface of what is possible.

Medicines Australia estimates the benefits could be significantly higher than \$2billion over four years, depending on how aspects of the strategy are rolled out.

A large body of evidence demonstrates how better use of medicines can lead to reductions in health care spending. The most obvious objective of an e-prescription system would be to reduce avoidable adverse drug events.

An adverse drug event (ADE) can occur because of a preventable or non-preventable medical intervention related to medicines. They can occur when:

- the incorrect drug or the wrong dose of a drug is prescribed, dispensed and administered to a patient;
- a drug's effects are dangerously impacted by a patient's pre-existing condition; and
- because of an interaction of one or more drugs a patient is using.

It has been estimated that as many as 18,000 Australians die each year as a result of ADEs, with 2000 deaths directly related to medication errors²⁵.

ADEs caused by medication errors (medication misadventure) should be avoidable.

Medication errors commonly occur when there is human involvement and are reduced when systems are automated. For example, in hospitals drug requests are usually hand written and the quality of handwriting or use and misuse of abbreviations can lead to errors in selection, dispensing, dosing and administration of a medicine. Quality use of medicines would be greatly improved if all prescriptions were electronic and were linked to the My Health medical record.

²⁵ Pw C, Strategy & (2010), Optimising e-health value, Using an investment to build foundation for program success see: https://www.strategyand.pwc.com/reports/optimizing-health-value-using-investment;



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²²Medicines Australia (2017) Submission, Development of a Framew ork for Secondary Use of My Health Record Data Public Consultation Paper see: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20171117-sub-My-Health-Record-secondary-uses-of-data-consultation-Nov-2017-a.pdf

Record-secondary-uses-of-data-consultation-Nov-2017-a.pdf;

National Health Funding Body, response to the Productivity Commission Draft report on Data use and Availability see: https://www.pc.gov.au/ data/assets/pdf file/0005/211289/subDR234-data-access.pdf

As cited in Productivity Commission, Shifting the Dial: 5 year Productivity Review, pg 68. Accessed October 2017 see: https://www.pc.gov.au/inquiries/completed/productivity-review/repor#media-release;

Studies in the United States have estimated that electronic prescriptions decrease the risk for adverse drug events and drug-allergy interactions by 30-50% and can lead to a 0.25% reduction in Emergency Room and hospital costs²⁶.

In Australia, it is estimated that ADE's could be reduced by up to 50% with a digitally enabled medicines platform. ADEs that lead to hospitalisation are understood to cost to taxpayers around \$1.2 billion annually²⁷.

NATIONAL DIGITAL MEDICINES BLUEPRINT

Should government primarily focus on PBS cost-containment policies such as price cuts for medicines, this approach risks missed opportunities.

There are significant opportunities to make cost savings and improve health care outcomes by making other changes to the health system (i.e increasing efforts to improve medication adherence).

Other nations and governments in implementing large-scale electronic health records systems have quantified a range of proven benefits, including savings to government, due to improved use of medicines. These have been well documented when forecasting government expenditure for public health programmes²⁸.

For example, one non-partisan legislative scoring overseas agency responsible for budget analysis has credited effective adherence to medicines to reductions in other health care spending. Based on this methodology, every 1 % increase in the number of prescriptions filled corresponds with a 0.20% decrease in spending on other medical services²⁹.

A key principle underpinning the Strategy is the judicious use of taxpayer money³⁰. This principle is defined by the Australian Government as the:

"Development of strategic activities based on sound investment of funds to eliminate waste, deliver value for taxpayers, and ensure that investments are assessed on the basis of delivering the best health and care outcomes".

While there will be investment infrastructure, software, and human resources needed to fully implement My Health, it will deliver significant value for money when the efficiencies are realised.

³⁰ The Australian Government, National Digital Health Strategy accessed November 2017 see: https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy



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National Conference of State Legislature, "Views from the Nation: An Overview of e-

Prescribing Experiences From the States see: http://www.ncsl.org/documents/telecommunications/EPrescribing.pdf

27 https://safetyandquality.gov.au/wp-content/uploads/2014/02/Literature-Review-Medication-Safety-in-Australia-2013.pdf;

²⁸ Pw C, Strategy& (2010), Optimising e-health value, Using an investment to build foundation for program success see: https://www.strategyand.pwc.com/reports/optimizing-health-value-using-investment;

https://www.strategyand.pwc.com/reports/optimizing-health-value-using-investment;

29 'Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services.

November, 2012. http://www.cbo.gov/sites/;

ADHA has been tasked by governments to develop a *National Digital Medicines Management Blueprint* (the blueprint) to support implementation of the Strategy. This blueprint is to include details on the infrastructure, specifications, policies, legislation and change, adoption and training activities needed for healthcare professionals. In keeping with the principle of judicious expenditure, quantifying the budgetary impact of digital initiatives as the Strategy is implemented would be prudent.

The Australian Government should work with key stakeholders, including the medicines sector, to quantify benefits associated with digital platforms identified in the blueprint. A number of benefits can and will be realised, depending on how the Strategy is implemented (see Figure 6).

FIGURE 6 - Evidence demonstrating the potential for quantifiable benefits

Reduction in adverse drug events (ADE's) - A digitally enabled medicines platform, linked to the My Health record will generate substantial cost savings. There are an estimated 230 000 hospital medicines-related admissions occurring per year, estimated to cost \$1.2 billion³¹. Even a 30% reduction in ADE's would generate savings of around \$360 million per year.

Enhanced adherence to health care plans and treatments- facilitated by using digital platforms will help patients, particularly those with chronic conditions, better manage their health. Estimates indicate this can create substantial savings of around \$2.3 billion per year, with the Australian Government and the States sharing a combined 68% of this benefit³². This equates to government savings of around \$1.9 billion each year.

Elimination and duplication of tests – The Productivity Commission suggests medical tests are duplicated for about 10 per cent of adults with chronic conditions, thereby adding to costs without adding value. Reducing duplication of efforts (enabled through My Health) could avoid unnecessary pathology and x-ray tests.

Conservative estimates suggest \$600 million each year could be saved by reducing duplicate tests, with the Australian Government and the States sharing a combined 68% of this benefit. This equates to government savings of around \$408 million each year³³.

Improved use of infrastructure— Australia's National Digital Health Strategy agreed to by all governments suggests duplication and operating costs will be reduced through alignment of government health gateways and infrastructure. Agreed interoperability standards, an implementation roadmap, a conformance scheme and digital maturity measures to be developed to minimise duplication of digital infrastructure services across governments. Improved use of electronic health infrastructure (costs typically borne by governments) could result in savings of around \$600 million each year³⁴.

https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy

32 Pw C, Strategy& (2010), Optimising e-health value, Using an investment to build foundation for programsuccess see: https://www.strategyand.pwc.com/reports/optimizing-health-value-using-investment



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³¹ The Australian Government, National Digital Health Strategy accessed November 2017 see: https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy

Better use of medicines, health records and e-prescriptions can reduce government expenditure, freeing up funds which can be re-invested back into the PBS. Any savings accrued should be re-allocated to other areas of unmet need. Additional resources are required to help patients access the new medicines they need.

Action 7: Health Ministers continue to drive this necessary digital reform agenda by bringing forward the timeline for development of the National Digital Medicines Management Blueprint. This blueprint should ensure the inclusion of notification of dispensing actions back to prescribers to better track patients health outcomes, medication adherence and post market safety and efficacy monitoring of medicines (and biosimilars).

Action 8: The Australian Government should support ADHA to ensure the completion of the blueprint by 2018-2019.



RESEARCH AND DEVELOPMENT (R&D) TAX INCENTIVE

The most recent review of the R&D tax incentive contained some recommendations that, if implemented, would have significant, disproportionate and negative impacts on the Medical Technologies and Pharmaceutical (MTP) sector.

At least fourteen members of Medicines Australia claimed the R&D tax incentive in 2016³⁵. It is a critical programme for attracting pharmaceutical investment in Australian medical research, such as clinical trials.

One issue for resolution in the 2018-19 Budget is the response to the Review of the R&D Tax Incentive. Mr Bill Ferris AC, Chair, Innovation Australia; Dr Alan Finkel AO, Chief Scientist; and Mr John Fraser, Secretary to the Treasury, were appointed to review the current scheme as part of the National Science and Innovation Agenda (NISA).

Unfortunately, the recommendations from the review that would specifically have a significant, disproportionate and negative impact on the MTP sector are: the introduction of a \$2 million cap and the application of an 'intensity threshold'. These unilateral measures that disregard unique aspects of the MTP sector will act as handbrakes on investment in Australian medical research.

This view is reinforced by MTPConnect, the Australian Government's industry growth centre for medical technologies and pharmaceuticals, who have also stated that the review's recommendations, if implemented, would negatively impact on the sector³⁶.

A medium term, sustainable policy that is globally competitive is needed to drive the outcome of a thriving, innovative MTP sector.

While the proposed cap may be seen as necessary to appropriately curb growth in other industries, alternative arrangements should apply for the MTP and medical research sector. Exemptions are necessary to ensure any changes to the programme do not damage the ability of Australia's highly-regarded medical research community, including small Biotechnology companies and other start-ups, to conduct valuable R&D such as clinical trials in Australia.

Medicines Australia members invested in one thousand clinical trials last year at a cost of more than \$200 million dollars to the industry, making it a significant investor in the capacity of Australia's medical research community.

Clinical trials provide early access to new treatments for Australians and have a pivotal role to play in the economy. Beyond the economic benefit to Australia, R&D in the life sciences can develop therapies, cures, medical devices and diagnostics for patients around the world.

Action 9: Commit to maintaining the existing R&D incentives for the MTP sector, including the overall level of support for business research and development.

³⁶ MTPConnect, Sector Competiveness Plan, December 2016 see: https://www.mtpconnect.org.au/SCP



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³⁵ Medicines Australia, Member Survey 2016, unpublished

For our medicines exporting capacity to increase, Australia needs to ensure that barriers to attracting investment are not blocked unreasonably.

Investment capital is globally mobile, and the competition with other comparable markets is significant, as demonstrated in Figure 7 below.

FIGURE 7- International competitors' incentives for advanced manufacturing and R & D³⁷



Source: Adapted from EY, 2013-2014 Worldw ide R&D incentives reference guide, and Singapore Government, Incentives for businesses.

With Australia maintaining a comparably high corporate tax rate, middle of the pack intellectual property provisions and no incentives directly related to industry specific manufacturing investment, it is crucial that the R&D tax incentive remains useful and relevant for the MTP sector.

Medicines Australia also notes proposals to use the R&D incentive as a mechanism to encourage collaboration between industry and universities and other research institutions.

Members of Medicines Australia invested at least \$100 million in collaborative partnerships in 2016-17.

As highlighted in Figure 8 below, of members surveyed in 2016-17, 35% of collaborations involved a partner arrangement with a university, 29% with a patient group or hospital and 35% with organisations such as technology related entities or other innovators.

³⁷ EY. 2013-2014 Worldw ide R&D incentives reference guide. Available at: http://www.ey.com/GL/en/Services/Tax/Worldw ide-R-D-incentives-reference-guide---Country-list; and Singapore Government. Incentives for businesses. Available at: https://www.edb.gov.sg/content/edb/en/why-singapore/ready-to-invest/incentives-for-businesses.html;



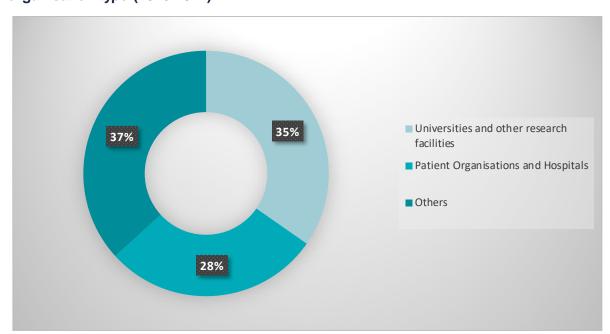


FIGURE 8 - Members of Medicines Australia collaborative partnerships by organisation type (2016-2017)

*Not all Members of Medicines Australia surveyed in 2016 participated. The figure above is based only on details provided by members that indicated the collaboration partnership arrangement by organisation type.

While the collaboration premium could be a positive initiative, it needs further consultation with industry. Any new initiative introduced would need to contain clear definitions. The design would also need to be sufficiently strong enough to act as a genuine incentive to encourage further collaboration between the pharmaceuticals sector and researchers. An untried initiative like the collaboration premium would certainly need to be refined and reviewed over time.

The Australian Government recently announced a new \$30 million medical technologies and biotech grants programme. This is to be made available for enterprises and researchers who partner and collaborate on new and innovative technologies ³⁸. Given a new fund has been established for these sectors, making grants available to the innovative pharmaceuticals sector might also warrant consideration.

Action 10: If the Government controls growth in the costs of the R&D Tax Incentive by putting in place a cap and/or intensity threshold, implement exemption arrangements for the MTP sector.

Action 11: Work closely with the pharmaceuticals industry to design a 20% collaboration premium, as recommended by the Finkel, Ferris, Fraser review of the R&D tax incentive, or alternatively consider a new grants programme to incentivise the MTP sector.

³⁸ MTAA agreement letter, Department of Health, October 2017 see: www.health.gov.au/.../Attachment%20to%20MTAA%20letter%20-%20agreement.docx;



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CHAMPIONS PROGRAMME

Better marketing by Australia of our world-class capabilities in research & development, such as clinical trials, is needed to promote Australia's brand to key markets and potential investors. Support for a coherent nationwide plan, coupled with high profile political delegations at key forums, will increase our reputation as a go-to destination for medical research.

Creating the right environment for innovation is key to the success of innovative endeavours. The way in which researchers, companies, universities and governments work together directly impacts on Australia's ability to attract investment.

Australia's presence recently at key international events has been marginal. For instance, earlier this year only two states (QLD & VIC) were involved in promoting our research capabilities at the Bio Conference in the United States.

This event, one of the largest that relates to the life sciences sector, is attended by some 17,000 people each year. Exhibitions are displayed by nations that compete for investment by the pharmaceutical industry. Visitors were unaware of the true scale of the MTP sector in Australia given the nature and focus of exhibit materials.

Medicines Australia recommends that significant effort be made to coordinate and promote "Brand Australia" at major international events such as the Bio Conference, held annually and to be held in Boston, USA in June 2018.

This could include a high-profile delegation of Federal and State Parliamentarians, led by the Prime Minister and Premiers, along with leaders of Australia's science, medical research and MTP community to act as "champions" for the sector. This would help boost Australia's reputation and send a strong signal that Australia wants this much sought after investment.

In the longer term, the Ministers for Industry, Health, Trade and Foreign Affairs could commission a more coordinated, nationwide approach to the marketing of the MTP sector.

Medicines Australia suggests that \$5 million be set aside over the forward estimates to support medical technologies and pharmaceuticals activities overseas. State Governments and industry peak bodies would be encouraged to co-invest and collaborate at key events.

Action 12: Develop a long-term marketing strategy for the medical technologies and pharmaceuticals sector (MTP). This needs to involve collaboration with the states and territories to position Australia as a preferred country to invest in. This could include coordinated delegations of high profile Federal and State politicians such as State Premiers and the Prime Minister and relevant portfolio Ministers.

Action 13: Commit \$5 million over the forward estimates to facilitate this coordinated, high-profile approach to marketing Australia's MTP sector overseas.



