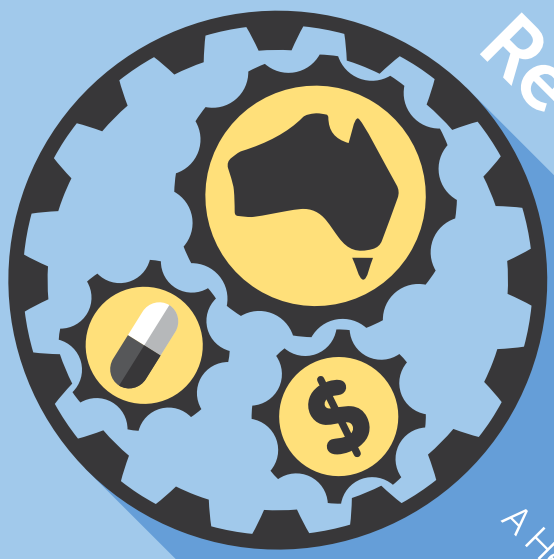

Re-imagining the funding wheel:

Sustainable access to medicines

A roundtable discussion convened by
The George Institute for Global Health
A Health Policy Report – April 2017

A George Institute Roundtable Paper

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About this report

Advances in targeted pharmaceutical therapies have led to significant improvements in health and life expectancy. However, these improvements come at a cost. Innovative medicines increasingly have high price tags which provide challenges for health systems in ensuring sustainable, universal and equitable access to medicines for those who require them.

There is a need for balance between access to new and effective medicines, and budget management. To achieve such balance, it is timely to consider how models of medicines financing in Australia can be structured differently to ensure support for equitable access to necessary medicines in the longer term.

On 10 February 2017, The George Institute for Global Health convened a special policy roundtable to examine models for the funding of medicines in Australia. The aim of this roundtable was to evaluate the potential structural and financial reforms required to support sustainable access to medicines for consumers within the Australian health system in this era of targeted medicines, and to formulate avenues for further exploration in this area.

Three broad questions were addressed during discussions:

1) What are the limitations of the current funding model for medicines?
2) What are the benefits and disadvantages of alternative funding models?
3) What are the next steps for policymakers, researchers and other stakeholders in developing sustainable pathways for funding medicines?

It was noted during the discussion on the day that one area that was not brought into the agenda was pricing policies of pharmaceutical manufacturers. Program organisers focused the topics of roundtable discussion on consumer, private health insurance and government perspectives.

The roundtable took place in Sydney where over 35 stakeholders from across the health sector, government, community, academia and industry gathered to exchange experiences, expertise and ideas. This report, authored by The George Institute, provides a reflection of the discussions undertaken on the day and sets out a summary of key avenues for further exploration identified at the event.

The George Institute for Global Health acknowledges that this topic could not be easily addressed in a one day forum. The aim of this report is to accurately reflect the discussions of roundtable participants on the day, and in doing so highlight the complexity of issues associated with medicines access and outline areas for further exploration.

Acknowledgements

The George Institute for Global Health would like to thank all those who participated in the roundtable and the organisations they represented, for their contribution to this report. We would also like to acknowledge the valuable contribution of Colman Taylor from Optum Australia, and Research Fellow in the Critical Care and Trauma Division at The George Institute, Australia, and Professor John Zalcberg OAM from Cancer Drugs Alliance for their contribution to program development and the participant list. Optum Australia provided an unrestricted grant to contribute to the running costs of the roundtable event. We would also like to thank Andrew Hollo from Workwell Consulting for facilitating the roundtable. As the meeting was held under Chatham House rules, the views and recommendations in this report represent the outcome of the group discussion and do not necessary reflect the specific views of the individuals at the roundtable or the organisations they represented (some of whom may have official positions that differ from those represented in this report).

Proudly supported* by

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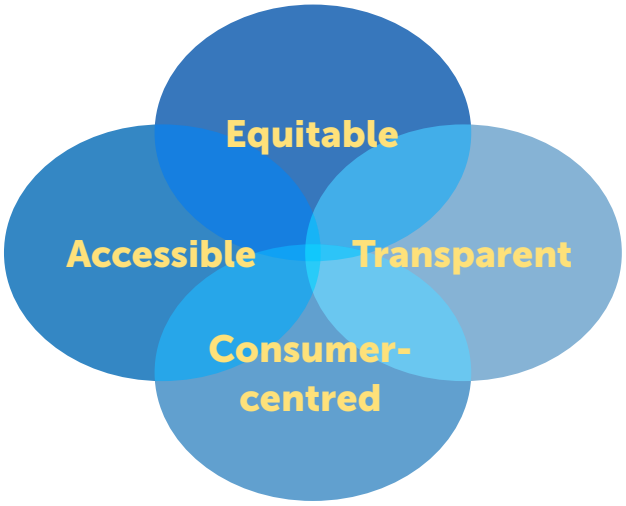
The George Institute would like to acknowledge the contributions of its staff to this event and report: Professor Stephen Jan, Head of Health Economics; Anna Palagyi, Report Writer and Research Fellow; Chelsea Hunnisett, Roundtable and Report Project Coordinator; Maya Kay, Head of Stakeholder Engagement and Communications and Alexander Baldock, Design Manager.

More than 7000 medicines are currently in development globally; approximately 70% of these are innovative, first-in-class biologics.

Introduction

Overarching principles for sustainable medicines financing arising from the roundtable.



The funding of medicines in a sustainable manner is an enduring health policy debate in many countries globally. In Australia, where the Government operates as a single payer of medicines subsidies, a careful balance must be achieved between access to medicines and budget management.

The Commonwealth Government's Pharmaceutical Benefits Scheme (PBS) is a key component of Australia's health system that has enabled access to subsidised medicines for many decades. The aim of the PBS is to provide equitable access to safe, effective medicines at a cost that individuals and the community can afford. The introduction of new, more effective medicines, together with an increased rate of prescribing and an ageing population, has seen Government spending on pharmaceuticals rise substantially.[1] The present annual level of spending on the PBS sits at approximately AU$10.8 billion, and has almost doubled in the past decade.[2]

Advancements in medicines manufacturing techniques have led to a shift from traditional 'small molecule' medicines for large patient populations, to targeted biologics (comprising more complex molecules) indicated for smaller patient sub-groups. These targeted medicines have higher price tags, often linked to greater research and development costs.

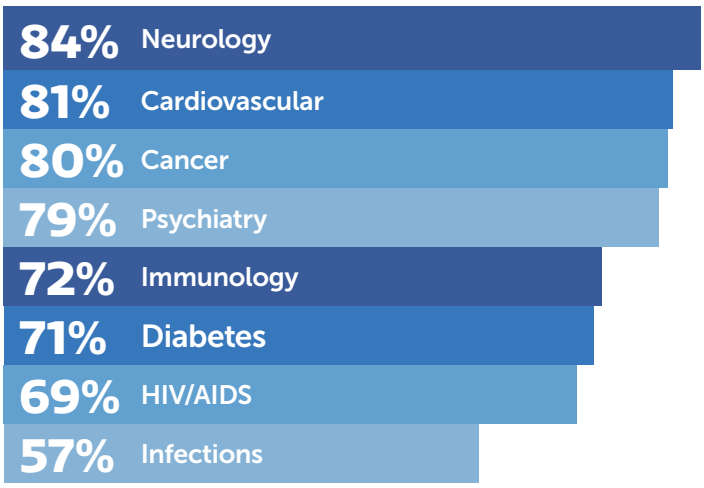
To fund new medicines, the Government has, since the 2007 PBS reforms, extracted savings from older and generic medicines.[3] However, the annual rate of savings from generic medicines is slowing, creating increasing uncertainty as to whether this model can continue to sufficiently financially accommodate necessary new medicines.

The health system now finds itself in a period with uncertain savings from generic medicines, and a large pipeline of new medicines on the way. It is the right time to closely examine the possible limitations of current funding models for medicines and assess alternative solutions that might meet the emerging issues associated with this age of medicines development and cost inflation.

The roundtable and this report arise from the growing realisation that providing equitable access to medicines is becoming increasingly challenging for Australia's health system. This problem was documented in the recent Senate report, *'Availability of new, innovative and specialist cancer drugs in Australia'*.[4] The report highlighted the challenges to health system sustainability associated with the underlying shift from high volume generic medicines to targeted biologics for cancer medicines – and their associated high price tags.

Potential innovative biologic medicines in the pipeline*

Percentage of projects in development that are potentially first-in-class medicines in selected therapeutic areas, 2011



*Pharmaceutical Research and Manufacturers of America (2016)

Fundamentals, opportunities & challenges: a multi-stakeholder perspective

Improving access to medicines in Australia is a multi-stakeholder issue requiring partnership and collaboration. A number of essential concepts must be considered when attempting to look beyond the current funding structures for sustainable and equitable medicines access.

As part of the roundtable, a series of presentations were provided by key stakeholders to set the scene for a robust informed discussion around current and future funding challenges. These presentations reflected on the essential concepts of current Government systems and processes for medicines access; the role of private health insurance; the industry perspective; and the contribution of health consumers. The following material constitutes a summary of key aspects of presentations delivered on the day. This should not be considered a thorough, binding reflection of the final views of the presentation, presenter or the organisation they represent.

Although the price setting mechanisms employed by medicines manufacturers are a key determinant of medicines affordability and access, these were considered beyond the scope of the roundtable discussion. No doubt a great deal can be done to influence industry pricing behaviour (such as through consumer and community activism), the focus of this roundtable was on policy and regulatory responses.

The Pharmaceutical Benefits Scheme: current processes and challenges for alternative funding models for innovative medicines

The PBS acts as the main (but not sole) Commonwealth Government subsidy program for medicines. It is an iconic and continually evolving program in the Australian health system, achieving successful and equitable outcomes of medicines access. In 2015-16, the PBS provided Australian consumers access to over 209 million prescriptions, at a cost to Government of AU$10.8 billion.[5]

In an exciting time of medicines innovation, a range of new, more effective therapies are rapidly coming to market. First-in-class medicines now provide pharmaceutical options for treatment areas where there were previously none. As a result of these innovations, the PBS is funding an increasing number of new medicines, at higher cost.

Consumer expectations regarding access to new medicines are rising. Decision makers are faced with progressively more difficult choices when assessing the suitability of new medicines for the Australian health system. Uncertainties surround the cost-effectiveness of many new medicines, where data from trials of effectiveness remain immature and benefits need to be extrapolated. The incremental cost of a medicine relative to the benefits gained requires careful consideration, as do target patient populations, duration of therapy, and potential sustainability risks in an era of rapidly changing clinical practice.

Medicines pricing is a consequence of market expectations and global price setting. Decision makers are required to make a judgement of benefit versus cost, relying on clear parameters established by legislation and policy. When looking at alternative mechanisms for funding medicines, there are several key issues to consider:

- What gap would alternative funding mechanisms fill?
- Is the alternative mechanism fair? Does it prioritise one patient group over another?
- Is it realistic is terms of costs to individual or others; e.g. co-payment?
- Is it practical to administer (administration burden)?
- When and how long would it apply?
- What happens if the value proposition doesn't stack up?
- What constitutes an 'innovative' medicine?
- What are the risks of undermining the mainstream process; e.g the PBS?
- Are alternative models of funding consistent with broader government policy; e.g. private health insurance?
- What is the risk of higher than predicted expenditure managed in that environment?

The annual level of spending on the PBS is approximately AU$10.8 billion, almost doubling in the past decade.

Government perspective: trends on PBS expenditure and funding medicines into the future

The Commonwealth Government Department of Health has responsibility for an AU$40 billion annual health budget, incorporating the Medicare Benefits Schedule, the PBS, aged care, and private health insurance subsidies. To manage the sustainability of the health system, it is necessary for the Government to strike a balance between safeguarding its fiscal interests and promoting health.

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent expert body appointed by the Government with the primary role of recommending new medicines for listing on the PBS. The PBAC takes new medicines through an evidence-based assessment of safety, with the aim of broadly and equitably distributing funding for medicines which are clinically safe and cost-effective. As a result, the PBS in its current form remains evidence-based and equitable; any changes to this model would need to be made with great care.

Medicines listed on the PBS are categorised into two groups – F1 and F2[6]

- *F1 is a place for innovative new medicines that the PBAC finds cost-effective. F1 medicines are a smaller proportion of script volume and a growing proportion of costs. Biologics currently comprise 25% of the PBS expenditure.*
- *F2 contains medicines that have multiple brands, or are in a therapeutic group with other medicines with multiple brands. Drugs on F2 are subject to price reductions, price disclosure and guarantee of supply.*

The PBAC is receiving an increasing number of submissions for smaller targeted F1 medicines asking for increasingly higher prices.

A number of strategies are implemented by the PBAC to enhance the quality and strength of evidence provided to decision-makers in reimbursement applications. Through a Managed Access Programme, the PBAC is working together with Medicines Australia to enable PBS listing of a small number medicines of otherwise unacceptable clinical or economic uncertainty, but where unmet clinical need is high. The PBAC also works with consumers; a cross-committee consumer group sits across the PBAC and other committees.

FOOD FOR THOUGHT: Is there a problem with the robustness of the PBAC system that will render it unable to cope with new challenges presented by new high cost drugs?

Industry perspective: pipeline, biologics and expenditure

Medicines continue to transform the treatment of many diseases and contribute to increases in life expectancy and quality of life. Treatment advances for HIV/AIDS over the past 20 years have produced an almost 87% decline in death rates[7]; the focus of rheumatoid arthritis treatment has shifted from symptom management to slowing disease progression; and therapies for cystic fibrosis are now able to target genetic mutations.

More than 7000 new medicines are currently in development globally.[8] The largest number of new medicines are in the therapeutic areas of cancer, neurology, infectious diseases and immunology. Approximately 70% of these new developments are new, innovative biologics.[8] A single medicine may take 10-15 years in research and development prior to registration, at an average cost of AU$2.6 billion; just one in ten medicines will recoup their costs.[9]

A key consideration in exploring new funding models is the total expenditure associated with a medicine. This should be considered in the context of the complete medicines supply chain: manufacturer, wholesaler and pharmacy. As a proportion of PBS expenditure in 2015-16, the manufacturer component is estimated to comprise just over 70%.[5]

Private health insurance and highly specialised medicines

Private health insurance in Australia is not a luxury market. More than 13 million people have some form of private health cover and half of those have an annual income of less than AU$50,000.[10] A strong health insurance sector benefits health service efficiency

by easing pressure on public hospital waiting lists: approximately two-thirds of elective surgeries take place in the private sector.[10] Dental and mental health services are heavily subsidised by private health funds. More than one half of extras cover payouts go to dental care and 90% of short-stay mental health services occur through private coverage. Health funds also invest heavily in chemotherapy services, with between 60-80% of PBS-funded chemotherapy now being conducted in the private sector.[10]

36	13.5	$19.2
Competing health insurance funds	Million Australians (55.8%) rely on Private Health Insurance for treatment when they need it	Billion in annual benefits paid to members

New high cost medicines present funding challenges for private health insurance funds, for which there are no easy solutions. Risk management is the core business of health funds, yet the clinical and financial uncertainty of the patient need for highly specialised F1 targeted biologics provides great risk. Early stages of treatment are potentially hazardous for funding pools in the absence of accurate knowledge of the length and quality of life these medicines will provide the patient. Current legislation and regulations restrict the ability of health funds to reimburse out-of-hospital care as a substitute for hospitalisation.

Data from Private Healthcare Australia (PHA) shows that, despite more than 80% of people with private health insurance believing it is currently good value for money, there are concerns about holding onto memberships in the long term due to rising premiums and out-of-pocket expenses.

Upwards pressure on insurance premiums is a consequence of rising input costs not within the control of health funds. In recent years, hospital costs, medical device costs, medical specialist gap cover and allied health reimbursement have risen at rates above inflation (between 6 and 9% annually).[11] The current challenge is to bring this cost curve back in line with the Consumer Price Index.

FOOD FOR THOUGHT: Should private health funds consider reimbursement based on outcomes?

International experience with private health insurance funding medicines

As a private health insurance fund, Bupa Australia provides outpatient pharmacy benefits, for primarily non-PBS items, with the amount of reimbursement dependent on a person's policy level. In-hospital treatment is different, with PBS listed medicines covered by the health fund within the cost of hospital admissions. For medicines not listed on the PBS, the degree of health fund coverage will vary depending on the specific contract between Bupa and the hospital – in some cases, a high cost drug may be completely covered by this contract.

This present funding model relies heavily on the PBS, and is susceptible to disputes in cases where the health fund-hospital contract does not cover a certain medicine, where a medicine is not TGA approved, or where it remains part of a clinical trial or is being used off label.

The following key opportunities could be considered by private health insurance funds in further developing strategies for patient access to high cost medicines:

- Build relationships with local market access and selected medicines manufacturers
- Ask pharmaceutical companies for a contribution to all medicines approved out of licence or off label
- Ask pharmaceutical companies to contribute to specific combination medicines
- Set and publish prices for drugs chargeable outside of inpatient room rates
- Demand data from providers billing drugs outside of inpatient rooms, and use this to monitor unwarranted variation in prescribing behaviours
- Work closely with government procurement and price setting to leverage existing discount and pricing

In 2015-16, the PBS provided Australian consumers access to over 209 million prescriptions

New models of medicines funding for hospital services have been initiated by Bupa in the UK. The Cromwell Hospital provides an example. Here, the health fund negotiates with medicines manufacturers to develop models of procurement and pricing agreements, based on therapeutic standardisation, clinical rationale and prescribing trends. For new, high cost drugs, these negotiations include a risk sharing arrangement. For example, pay-for-performance contracts have been established for off label medicines; the pharmaceutical company will reimburse the full cost of medical expenses to the health fund if patients do not respond to the treatment within an agreed trial period. Additional arrangements include agreed full treatment payment by the manufacturer for the prescribed use of new medicines combinations, and fully funded treatment programs involving the use of new medicines. The use of high cost medicines while off label in all of these arrangements follow strict criteria.

***CASE STUDY:** Barriers to access and reimbursement – the cancer perspective*

The rising cost of targeted cancer therapies presents a number of challenges for Government and other payers. These challenges include the clinical uncertainty that accompanies early promising data from trials of new medications; decisions around optimal dose and duration of treatment; and assessing the downstream impact of access to these therapies on both patients and their families.

New medicines bring significant improvement to rates of survival and enhance patient quality of life - people now live for many years with cancer. Estimating the impact of potential long term therapy on cost to the payer is a difficult, yet important, consideration. With the rising number and complexity of new cancer medicines, the average time between TGA approval and PBS listing has increased from 15 months to 31 months over the past 10 years.[12]

The Australian Cancer Drugs Alliance aims to improve timely and affordable access to cancer medicines for all Australian cancer patients. The Alliance recognises that, given its complexity, this problem can only be solved if all stakeholders work together. Multi-stakeholder engagement is applied with the aim of improving understanding of new medicines and cancers during the submission process, and throughout the decision-making process.

The Alliance proposes the following potential solutions to reduce barriers to access:

- Creating a National Cancer Registry to enhance the evidence base
- Expedited pathways for new medicines already approved by accredited partner agencies
- Early access models
- Alternative funding strategies

1 in 2
Australians will develop cancer in their lifetime

1 in 5
will die from cancer before the age of 85 years.*

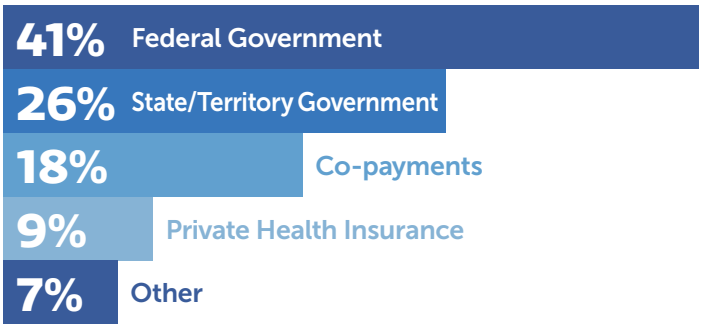
*Australian Institute of Health and Welfare (2017). Cancer in Australia: in brief 2017. Cancer series no. 102. Cat. no. CAN 101. Canberra: AIHW.

The patient and consumer contribution

Rethinking co-payments in Australia

Australian health consumers provide a sizeable contribution to health system financing: 18% of health funding arises from co-payments.[14] This consumer contribution is higher than many countries on an international level, including those with less equitable health systems. However, despite their significant contribution to health funding, there are no regulatory systems for health consumers, and no single point of contact for people who are required to make decisions about paying for their health care.

Sources of health funding in Australia



*Australian Institute of Health and Welfare (2016). Health expenditure Australia 2014–15. Health and welfare expenditure series no. 57. Cat. no. HWE 67. Canberra: AIHW.

Co-payments are currently applied unevenly across the spectrum of the health system. Co-payments comprise 58% of total expenditure on dental services, 15% of total expenditure on medicines listed on the PBS, and just 3% of expenditure on private hospital services.[15] But discussion about co-payments by individual health sector fails to acknowledge the holistic, multi-sectorial nature of accessing health care.

Consumers with chronic health conditions use a variety of different health services on a regular basis. These people are the 'daily commuters' of the health system and the system of co-payments needs to work for them.

FOOD FOR THOUGHT: We need to exercise caution with the term 'co-payment' to define the consumer contribution to health care – out-of-pocket expenses may better describe the total consumer contribution.

Strategies for re-thinking health care co-payments that take a more consumer-centred approach may include:

- Restructure and reallocate current private health insurance rebates across the health system, giving the consumer a choice as to how they use their health cover
- Consider predictable vs unpredictable costs: predictable health expenses are frequently insured. It may be time to structure insurance to focus on the unpredictable
- Make co-payments more convenient: current co-payments occur in an inconvenient manner, with expenses often unpredictable and with short payment timelines. A system where co-payments are consolidated (for example billed by the Government each month) and paid off over time may make co-payments easier to manage.

FOOD FOR THOUGHT: Do the policy justifications for medicines co-payments, (i.e. to discourage unnecessary use by consumers, and to contribute to some of the costs), apply to high cost medicines?

FOOD FOR THOUGHT: Would reduction of inequity be a motivator to change the system? If the co-payment system is seen as a way of achieving equity then this may improve potential of structural change.

Consumer perspective on paying more for innovative medicines

For many consumers on fixed and lower incomes with ongoing medicines needs, co-payments can account for a large portion of their budget. There are an increasing number of reports of people choosing not to fill prescriptions, or making a choice between one medicine and another, because they are unable to afford it.

Consumer expectations of their health care are rising, particularly around access to new approved medicines. Some consumers undertake individual fundraising efforts to finance their medicine needs, yet the uncertainly of treatment duration of many high cost innovative medicines poses potentially significant funding issues in the long term. Fast-tracked access to innovative medicines also presents concern, with the possibility of the medicine later being proven ineffective.

FOOD FOR THOUGHT: Determining equity should be based on community values and this as well as cost-effectiveness should be considered in decisions about the funding of new medicines.

Equity provides an overarching principle from the consumer perspective when considering the funding options for innovative medicines. The involvement of private health insurance funds in the payment of innovative medicines, for example, may be a step towards a two-tiered health system: those with private health insurance will be accessing drugs in a different way to those who cannot afford private health insurance.

Potential consumer-centred strategies to consider for the pricing of innovative medicines may include:

- Differential pricing: different consumer payment for different drugs, e.g. at a percentage of their cost, or a tiered pricing structure. However, the risk of inequity in this approach should be considered.
- Encourage uptake of generics and biosimilars through a lower co-payment. This may free up funds to be spent on other drugs.
- 'Dollar discount' program at the pharmacy level.

FOOD FOR THOUGHT: The fundamental issue is to agree as a community on the role of co-payment. Government and policy makers require a good understanding of community priorities.

Experience from the National Disability Insurance Scheme

The National Disability Insurance Scheme (NDIS) arose as a solution to the previously inequitable provision of disability services across Australia. Despite state-based financial investment in disability services prior to the NDIS, consumers and their families had been unable to access the services they required. Through the NDIS, state Governments now invest all funding for disability services into a central pool, and the Commonwealth bears the risk if NDIS expenditure goes beyond agreed funding.

The NDIS operates on insurance principles. Individuals in the scheme receive a plan which outlines what they are going to achieve and what the NDIS will fund. The NDIS will not fund anything that falls under the responsibility of another system (e.g. medicines). Decisions about service funding are based on the benefit to the person and a review of available evidence. The Administrative Appeals Tribunal may provide additional review of NDIS service decisions.

The payment of services by the NDIS is controlled by the use of 'benchmark' prices, i.e. a published list of maximum prices the scheme is willing to pay for certain services. For services where some payment flexibility is required, these benchmarks send a price signal to the patients and suppliers, while still allowing for variation. The use of a consumer co-payment was first considered in the NDIS development phase, at which time it was thought that this may have the effect of driving up service prices to an unsustainable level.

Consumer-centred strategies are built into the NDIS to ensure the scheme's sustainability. These components include:

- The option for participants able to manage their own funds, to make decisions about the services they receive under the NDIS, and to negotiate service prices. In this way the NDIS encourages a consumer-driven market.
- The availability of a Plan Manager who will negotiate prices and services with providers, working on behalf of the consumer to enhance cost-benefit.

Assessing options with the Pharmaceutical Benefits Scheme

Can we drive better value from the PBS?

Reform is needed in the way Australia negotiates prices for its medicines. An example where improved leadership is needed is in generic drugs, where we have historically paid substantially more than New Zealand, Canada and the UK. It is estimated that there are over AU$1.3 billion in unrealised savings over four years based if prices were altered to reflect international benchmarks.[16]

'Therapeutic group premiums' is a policy which commits the PBS to only cover the price of the lowest cost medicine in a class of equally safe and effective medicines. This is based on the principle that the PBS should only be subsidising medicines if they are cost-effective. However, according to the Grattan Institute, the policy has not been widely used, resulting in the PBS paying the full price of medicines in which a cheaper alternative exists.[11]

In Germany, there are a greater number (18) of therapeutic groups. In an example of how we could extract more value from medicines, by extending the number of therapeutic groups in Australia to 18, and enabling more medicines to be linked in price to the lowest cost alternative, the health system could potentially save AU$205 million per year.[16]

Pay-for-performance to drive better value from the PBS

The current system of medicines approval in Australia is underpinned by a value proposition. The extent of emphasis placed on a medicine's incremental benefit and cost-effectiveness, and the subsequent direct relationship with the listed price, is unique to the Australian system.

The PBAC approval process for a new medicine is multifaceted with many stages of review. New medicines with appropriate safety, efficacy and price tags face a relatively simple process through to PBS listing: regulatory approval > PBAC submission > positive recommendation > decision to list by Minister or Delegate. However, medicines may also face complexities during their PBAC review process following initial regulatory approval. Initial PBAC submissions may be rejected, or may be deferred subject to proposed specific pricing arrangements and negotiations, indicative analysis, agreement in principle, or operational considerations. Special pricing arrangements for high cost medicines may include performance-based continuation rules or pay-for-performance pricing schemes.

Industry considerations in the special pricing arrangement approval process could include:

1. **Impact upon annual revenue (and extent of uncertainty)**
   Prior projections; Scenario analysis re uncertainties; Revenue recognition requirements
2. **Setting a precedent**
   Same product globally, especially HTA countries; Pipeline products
3. **Perceptions / C-suite 'rules'**
   Return on investment expectations; Acceptability of sub-groups, stopping rules
4. **Deal vs No-deal decision**
   Market landscape, Patient; clinical, political pressure; Cutting Australia loose (1.7% market*)

*OECD (2015), Health at a Glance 2015: OECD Indicators, OECD Publishing, Paris. http://dx.doi.org/10.1787/health_glance-2015-en

PBAC and Government considerations in the special pricing arrangement approval process could include:

1. **Impact upon various budgets (and extent of uncertainty)**
   (Extent of budget impact reduction; Scenario analysis re uncertainties; Predictability; Affordability)
2. **Setting a precedent**
   ICER after applying effective price; Rigour of PBAC decision-making (same sponsor and generally)
3. **Perceptions / Practicalities / Transparency (or not)**
   Equity; Clinical palatability, Administrative burden; Implications of confidential SPA downstream
4. **List vs No-list decision**
   Market landscape; Patient, clinical, political pressure; Implications of not listing

*ICER, incremental cost-effectiveness ratio; SPA, special pricing arrangement

Pay-for-performance may best be integrated in the current PBS structures during the time period after PBS listing, i.e. to appropriately reward the actual performance of a medicine once listed, rather than pricing being based on clinical trial data that may be immature or otherwise uncertain. To successfully achieve a pay-for-performance model, there is a need to consider the practicalities of the current system, the level of willingness from all stakeholders, and capacity and available resources. The important question also is whether pay-for-performance models are in themselves cost effective.

A single medicine may take 10-15 years in research and development prior to registration, at an average cost of AU$2.6 billion; just one in ten medicines will recoup their costs.

Exploring a way forward:
key considerations from the roundtable

In a series of working groups, roundtable participants considered three components of the current medicines approval and funding processes (private health insurance, consumer contribution, and the role of the PBS) to identify possibilities for future reform and avenues for further exploration.

***QUESTION:** Can **private health insurance play a role in funding necessary medicines?** What are the barriers and potential solutions?*

The role of private health insurance in enabling sustainable, equitable access to new and innovative medicines in Australia was agreed by working group members to be a complex issue. While the problems to be solved were clear, contention surrounded the formulation of recommendations and their benefits. Despite agreement of health insurance being a shared risk among members, participants raised issues of serious inequity surrounding the involvement of private health insurance in facilitating access to new medicines outside of the PBS process.

Problems to be solved	Recommendations
Undermining the current medicines reimbursement system. Multiple payers may drive up prices. Managing financial risk – placing investment in premium products. New medicines have not been assessed as being cost-effective. Rise in insurance premiums. Global implications. Draws in patients at high risk. Outpatient treatment is uncertain. Long timelines to PBS listing. Equitable access. Data fragmentation.	From the perspective of insurers, a business case for extending coverage to new medicines is required, particularly whether it is feasible within the current regulatory environment of community rating. An alternative view raised was that private health insurance has no role in this space, and that opening up this option potentially reinforces inequities in access to care. If this option is to be pursued, further discussions could be held between all stakeholders in the National Medicines Policy (private health insurance funds, medicines manufacturers, government, clinicians and consumers) to explore the feasibility of private health insurance contribution and risk management.

***QUESTION:** If we were to **make consumer contribution to cost of medicines work,** what are the options available to us?*

While the above question was posed to working group members for consideration, participants agreed that the focus on co-payments was too narrow and there was a need to look at the issue of consumer involvement more broadly. *The question was therefore re-framed to: How can consumers contribute to the question of making the PBS more sustainable?*

Problems to be solved	Recommendations	Benefits
How can consumers contribute to the question of making the PBS more sustainable? Involving consumers in the PBAC health technology assessment. Accessibility of PBAC processes. Issues with the accessibility of the processes to have consumers involved in PBAC decisions. How should the PBAC evaluate the contributions from consumers in decision-making? Difficult to see how consumer experience is used in cost-effectiveness decision making. How do you quantify the consumer experience? Need to consider holistic approach to care – affordability of the whole healthcare experience. Perceived conflicts of interest with both industry and publicly funded consumer groups.	Consumers are supported to have formal inclusion in the PBAC process, from submission through to listing, by: • Capacity building • Financial support for patients to attend hearings • Individual support for health literacy. Complementary qualitative and quantitative research methods be used to incorporate consumer views into the decision making process. Increasing co-payments has no role in sustainable access to medicines. All out of pocket expenses should be included in any assessment of affordability of the whole healthcare experience. Consumer advocacy groups are provided with independent funding.	Legitimise patient and consumer views as valid forms of evidence. Increase community faith in the PBAC. Improved community understanding of how medicines are delivered in Australia. Improved transparency and equity in decisions across different areas of service. Fairer access. Reduced conflict of interest.

***QUESTION:** If we were to **make the PBS more fit-for-purpose,** what are the options available to us?*

In addressing this question, working group members agreed that the PBS is a good scheme facing challenges. New strategies may be required to address issues of access to innovative medicines. The emphasis of discussions of this working group centred on a need to identify important outcomes and measurement indicators for the assessment of expedited medicines; and engaging consumers and clinicians in the space of expedited access. The working group noted that strategies to improve access to innovative medicines through PBAC/PBS processes cannot be considered in isolation from co-dependent technologies and Medical Services Advisory Committee approval.

Problems to be solved	Recommendations	Benefits
Delays in access to medicines due to ill-defined negotiation processes: • no face to face interaction between sponsor and PBAC • time and resources wasted in the process of cycling through PBAC submission and resubmission.	More explicit PBAC negotiation processes are defined for innovative drugs, with concurrent provision of non-reimbursed access. Negotiation processes may involve: • set time frames • face to face (real time) decisions • lessons from international systems. Negotiation processes should always involve consumer and clinician input.	More rapid access to necessary medicines. Improved alignment between expedited TGA processes and PBS listing.
Inequitable access to medicines, including no access for some, due to immature/very poor trial data. This leads to significant uncertainty, especially in rare disease areas i.e. uncertainty where limited trial data is available and the value proposition is not great. Potentially stronger disincentives should be considered for unrealistic PBAC submissions.	Clear consumer- and clinician-driven indicators and outcome measures underpin early access strategies which may include: • Options for provisional registrations • More use of pay-for-performance schemes, where practical • More risk sharing, with agreed outcomes by agreed times • Transition from paper-based to electronic authorisation processes, to capture real time data • Clear structures of informed consent.	More rapid access to necessary medicines. More equitable access to necessary medicines.
The need for expenditure offsets to create headroom for new drugs. Lack of transparency surrounding how offsets work and the application of rebates. Rebates currently end up as consolidated revenue within the health portfolio.	Rapid uptake of biosimilars be encouraged once medicines go off-patent to facilitate additional savings for the system through price disclosure. Structural changes should be considered to pinpoint PBS rebates for future allocations to medicines within the health portfolio. Consideration should be given to improving operation of the therapeutic group premium policy.	A better value PBS, with financial headroom to allow timely access to new drugs. Greater opportunity for savings from within the health system.

The path forward...

The outcomes from the roundtable discussions resulted in the following set of recommendations designed to guide subsequent conversations on this important topic. These span four overarching principles for sustainable medicines financing stemming from the day - equitable, accessible, transparent and consumer-centred:

- ***Increasing co-payments should have no role in policies to promote sustainable access to new medicines,*** as they are inequitable and, for new high cost medicines, would need to be set at an unfeasibly high level in order to substantively offset costs.
- ***Evidence around the consumer experience of illness and medicines needs to play a prominent role in the PBAC decision making process,*** and complementary qualitative and quantitative research methods should be used to elicit this evidence. The burden of out of pocket expenses needs to be included in any assessment of the consumer experience.
- ***Consumers need to be supported to enable more substantive input in the PBAC process, from submission through to listing.*** This should include capacity building, financial assistance and support for health literacy. In supporting this process, access to independent funding needs to be made available to consumer advocacy groups.
- ***Greater transparency involving consumer and clinician input needs to be built into the PBAC process,*** including a role for negotiation, establishment of an explicit price negotiation timeframe in the review process, and other efficiency enhancing processes such as the use of real time data.
- ***If there is to be a greater role for private health insurance*** in funding necessary high cost medicines, then ***the discussion needs to consider firstly the impact more broadly on access to care and equity.***
- ***If the role of private health insurance in funding new medicines is an option*** that is to be further developed, ***the case for providing such coverage amongst individual companies needs to be determined in light of the current regulatory constraints,*** such as community rating and regulatory options such as risk rating of premiums.
- ***A greater role for risk sharing arrangements and pay-for-performance agreements needs to be considered*** in offsetting the risk to government in the funding of necessary high cost medicines.
- ***Price reductions based on introduction and uptake of biosimilars need to be expedited*** and achieved to maximise savings to the PBS.

References

1 Australian Government National Commission of Audit (2014). Towards Responsible Government: the Report of the National Commission of Audit – Phase One

2 Australian Government Department of Health Annual Report 2015-2016: www.health.gov.au/internet/main/publishing.nsf/Content/annual-report-1516-toc Accessed 6 March 2017

3 Australian Government Department of Health (2007). The Impact of PBS reform – Report to the Parliament: www.pbs.gov.au/info/industry/useful-resources/impact-of-pbs-eform Accessed 6 March 2017

4 Availability of new, innovative and specialist cancer drugs in Australia. www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Cancer_Drugs/Report

5 Australian Government Department of Health Annual Report 2015-2016: www.health.gov.au/internet/main/publishing.nsf/Content/annual-report-1516-toc Accessed 6 March 2017. Reported cost is exclusive of high-cost drug recoveries, which comprised AU$1.6 billion in the 2015-16 financial year

6 Australian Government Department of Health (2017). The Pharmaceutical Benefits Scheme Formulary Allocations: www.pbs.gov.au/info/industry/pricing/pbs-items/formulary-allocations Accessed 6 March 2017

7 US Department of Health and Human Services, Centers for Disease Control and Prevention (August 2016). Today's HIV/AIDS Epidemic, CDC Fact Sheet: www.cdc.gov/nchhstp/newsroom/docs/factsheets/todaysepidemic-508.pdf Accessed 6 March 2017

8 Pharmaceutical Research and Manufacturers of America (2016). Profile – Biopharmaceutical Research Industry: www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf Accessed 6 March 2017

9 Medicines Australia (2015). Medicines Australia Facts Book (Fourth Edition): www.medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/11/MAFactsBook4_update2015.pdf Accessed 6 March 2017

10 Private Healthcare Australia (2016). 'Private Health, Public Benefit' Fact Sheet: www.privatehealthcareaustralia.org.au/have-you-got-private-healthcare/private-health-public-benefit Accessed 6 March 2017

11 Private Healthcare Australia (2017). Pre-budget submission 2017-18.

12 Deloitte Access Economics. Access to Cancer Medicines in Australia (July 2013).

13 Australian Institute of Health and Welfare (2016). Health expenditure Australia 2014–15. Health and welfare expenditure series no. 57. Cat. no. HWE 67. Canberra: AIHW.

14 The Senate Community Affairs References Committee. Out-of-pocket costs in Australian healthcare, August 2014.

15 Duckett SJ, with Breadon P, Ginnivan L and Venkataraman P (2013). Australia's bad drug deal: high pharmaceutical prices. Grattan Institute, Melbourne.

16 Duckett SJ and Banerjee P. (2017). Cutting a better drug deal. Grattan Institute, Melbourne.

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