

Better budgeting for a healthy Australia

ROCHE PRE-BUDGET SUBMISSION 2017-18
DECEMBER 2016



About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in-vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in research and development, including almost AUD 36 million in pharmaceuticals in Australia. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

Roche's pharmaceutical division in Australia employs approximately 350 people who are dedicated to the clinical development, registration, reimbursement, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to about 40 Roche medicines, and the company is the leading provider of cancer medicines in Australia by sales. For more information, please visit www.roche-australia.com.

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Executive Summary

Roche welcomes the opportunity to contribute to the formulation of the 2017-18 Federal Budget.

The ageing population and the persistent fiscal deficit have created a strong temptation to implement sweeping savings measures, focused on large expenditure items such as healthcare. Yet savings or funding constraints frequently have flow-on effects to other areas of spending, which can counteract the benefit to the taxpayer and even lead to higher costs in the long term.

If the Federal Budget is to be truly sustainable, it is important that these indirect benefits and consequences of policy decisions are fully understood. Fortunately the emergence of Big Data allows governments to see and understand linkages and interdependencies throughout complex systems such as health. For example, the impact of innovative pharmaceuticals may extend well beyond improved health and longevity - by keeping people out of hospital or allowing patients and their families to self-care, work, save, invest and contribute to society. Linkage of public and private datasets can provide a picture of how medicines impact on a range of other policy outcomes and funding streams.

Innovation and research also have flow-on benefits to the Australian economy through jobs and investment. Medical research, particularly using genomics, is an opportunity for Australians to lead the way to more efficient care and better patient outcomes. Australia's expertise in conducting high quality clinical trials allows patients to access treatments early and for researchers to be linked in to global networks. With the right policy settings, Australia can continue to grow in this field.

This is an opportunity to understand value beyond cost: not just theoretically but quantifiably, allowing for other savings and offsets to be identified and "banked". In this Pre-Budget Submission, Roche has identified opportunities for Government policies to support the creation, improved understanding and demonstration of value in the healthcare sector. These include refocusing R&D tax incentives towards quality and collaboration, rather than reducing the level of benefit; implementing red-tape reform to support clinical trials; investing in data linkage to quantify the value of health investments; and streamlining medicines funding systems to support early access, with strong safeguards that ensure value for money.

Similar opportunities will exist in other areas of Government spending. A 21st century approach to assessing and prioritising high value investments is essential to allow Australia to optimise the community benefits from limited Budgets, both now and into the future.

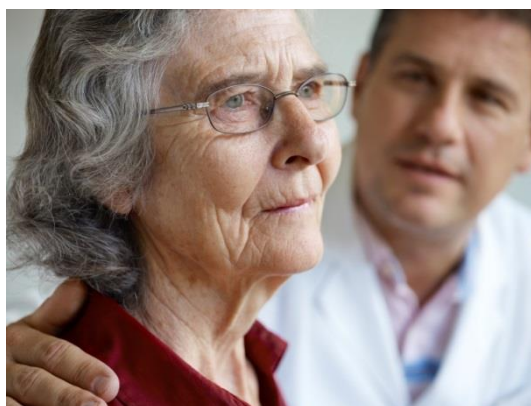
Recommendations

1. Implement the 2016 Federal Election commitment on clinical trials competitiveness
2. Reform reimbursement systems to allow timely funding of diagnostics that support targeted use of medicines
3. Ensure reforms to the R&D Tax Incentive target improving research quality, collaborations and partnerships, instead of reducing the value of the incentive
4. Explore cross-portfolio costing for health interventions with benefits to other portfolios
5. Support greater patient and community involvement in policy and Pharmaceutical Benefits Scheme (PBS) decisions through dedicated liaison staff and targeted advertising
6. Align medicines funding with the updated registration system to maximise efficiency
7. Partner with industry to develop fit-for-purpose PBS managed access programs that can provide timely access for patients through data collection
8. Invest in data linkage projects to support value demonstration in health

An ageing Budget?

The impact of the ageing population on the Federal Budget has been well-documented¹. In addition to lower tax receipts as baby boomers retire, increased demand for medical services and technologies is expected to drive expenditure growth.

Yet medicines and medical technology do not only fall on the “expense” side of the ledger. Medicines are essential to keeping older Australians healthy, which helps maintain their contribution to the workforce² and society more generally. An eighth of Australians over 65 are still in the labour force³ and grandparents regularly provide childcare, enabling parents to work⁴.



How the Australian Government sets the Federal Budget impacts on decision-making at every level. As Roche noted in its Pre-Budget Submission for 2016-17, decisions in Australia on medicines funding are generally taken from the perspective of Commonwealth health spending – and potentially the PBS alone. Impacts on state and territory governments, or productivity, lifetime savings and dependence on welfare or other transfer payments, are not generally considered. This is a classic consequence of silo budgeting⁵. As a result, medicines funding decisions that are focused on keeping spend within an annual budget are not the most efficient^{6,7}. Underinvestment in one area can lead to increased spending elsewhere, or lost opportunities for growth.

In fact, there are silos even within the PBS. Budget figures are inflated by the payment of rebates by pharmaceutical companies, due to confidential pricing agreements or companies taking on the risk of higher than expected use of a medicine. While these mean that the real cost to Government can be significantly less than the gross expenditure, these rebates are captured separately to the PBS and are not available to be reinvested in medicines. They may also suggest the PBS is growing faster than it is in reality.

The use of “second-round” effects such as impact on productivity, disability support or welfare would require some change to current Budget conventions. The Charter of Budget Honesty costing guidelines sets out that “second-round effects are generally not included...for a range of reasons, including uncertainty in estimating the magnitude and timing of the effects” and because they “are likely to be small relative to the direct financial impact of a measure”⁸. However, examples in this submission will show that for medicines spending, these effects can be both sizeable and well-quantified^{15,16,17}, yet are not reflected in the Budget.

It is relevant to ask if this is appropriate for an era of Big Data, where governments have access to large volumes of information and predictive models that can readily show flow-on effects and quantify the impact. A Budget that is able to take into account flow-on impacts of decisions and consequences for the “whole of government” would be one equipped to deal with the increasing complexity of our world and the challenges Australia faces.

Value beyond cost

Value has to be created

Budgets and data alone cannot deliver a healthier and more productive Australia. We will also need to develop and deliver innovative healthcare solutions. Australia has the opportunity to position itself at the forefront of medical innovation, capturing the potential of personalised healthcare (PHC) and a greater share of global clinical trials investment.

Clinical trials provide early access to medicines; save taxpayers around \$100 million annually in medicines costs⁹; support translation of evidence into local practice; enhance local research expertise and linkages; and help retain researchers in the public health system. The value of clinical trials to Australia is being recognised and supported by the Government through:

- The industry “growth centre” MTPConnect developing a 10-year sector competitiveness plan and providing matched funding for sectoral projects out of a \$15.6 million funding pool¹⁰; and
- The Government’s election commitment of \$7 million to improve access to clinical trials in Australia¹¹.

A particular area of opportunity is around Australia’s significant expertise in genomic research. Local clinicians are actively undertaking studies using PHC approaches. Diagnostic approaches such as genome sequencing help researchers and health professionals to understand why patients with the same diagnosis react to a treatment in different ways and how to target medicines to increase their efficacy and safety¹².

PHC is not well understood by regulators and payers in Australia, despite its potential advantages. The time to access a diagnostically-targeted therapy is currently at least twice that for a medicine that does not require a test¹³. These challenges will only be exacerbated as treatments and



diagnostics are further tailored to look at multiple genes or markers.

Health innovators are receiving very mixed signals. The continued cost-containment of the PBS, without recognition for savings elsewhere in the Budget, sends a message that the sector cannot grow year-on-year in Australia for the foreseeable future. As the Australian Government is the largest purchaser of medicines, this indicates to overseas company head offices that Australia is not a viable investment destination.

Changes to the R&D Tax Incentive also counteract the positive messages on clinical trials competitiveness. The value of the R&D Tax Incentive was reduced in 2016, and a recent review suggests further limiting eligibility¹⁴. Roche is concerned that the quality of the R&D is not being recognised as the most important factor. The focus appears to be on reducing the cost to the Government. Medical research such as clinical trials is of inherently high value, developing new products in partnership with Australian clinicians who expand their research skills and networks. Any restriction of support is likely to have a significant effect on investment.

These barriers and negative signals can discourage innovative research. Roche recommends any changes to the R&D Tax Incentive focus on targeting high quality R&D rather than arbitrary cost cutting. In addition, Roche supports regulatory and funding reform to encourage clinical trials and embed PHC into research and practice.

Recommendations

Implement the 2016 Federal Election commitment on clinical trials competitiveness

Reform reimbursement systems to allow timely funding of diagnostics that support targeted use of medicines

Ensure reforms to the R&D Tax Incentive target improving research quality, collaborations and partnerships, instead of reducing the value of the incentive

Value has to be understood

As noted above, value-for-money decisions need to understand the whole value of a product or service. Otherwise, the Government risks underinvesting in valuable treatments because they are seen as too costly, which may have medium and long term ramifications.

A recent study found that Australia's investment in innovative medicines has "paid for itself" through savings from reduced hospital admissions¹⁵. While this value may accrue to state and territory governments directly, the Commonwealth is embedded in the hospital system through transfer payments. Sustainability across all levels of government is critical.

Spending on medicines also saves money throughout the Budget, such as in disability support, or results in additional taxes paid. With an ageing population affected by chronic diseases ranging from diabetes to arthritis, loss of lifetime earnings and increased dependence on the aged pension is a major concern^{16,17}.

Case study: medicines for multiple sclerosis (MS)

MS is a condition of the central nervous system that affects over 23,000 Australians¹⁸. Clinical studies in MS measure the extent to which medicines delay accumulation of cognitive and physical disability. As a person with MS's level of disability increases, the costs of care and support increase significantly¹⁹. This cost is partially borne by taxpayers, with over 400 people living with MS across Australia already receiving support from the Australian Government's National Disability Insurance Scheme (NDIS)²⁰. Avoiding increases in disability is critical for the quality of life and wellbeing of people with MS, but it could also potentially reduce the cost of support, whether through the NDIS or informally through family and friends. Increasing disability is also correlated with early retirement²¹ and therefore taxes paid by people with MS and their carers, retirement savings and dependence on pensions and other welfare. Where broad social benefits can be demonstrated for a medicine, Government decision-making would be improved by taking them into account.

Of course, the value of medicines to the community is more than just savings to the Government. Roche supports a more holistic approach to assessing value, through greater engagement of patients and the general public. Patients and carers can assist with understanding the aspects of diseases that are most impactful on their lives, and allow for them to be weighted appropriately in reimbursement decisions. Citizens can feed into priority setting, ensuring taxpayers' views are reflected in funding decisions. Citizens' juries have been used in the UK²² and Canada²³ to answer complex ethical questions such as how to value end-of-life treatments.

The Pharmaceutical Benefits Advisory Committee (PBAC) does consult with patients, carers and others through a web-based form linked to the agenda for their meetings. It has also increased



use of meetings with patient groups later in the process. However, public awareness of this opportunity is low and it is not advertised except through Departmental email bulletins. Countries such as Canada engage patient groups proactively at an early stage. At a small additional cost, funding for a Departmental liaison officer for patients and citizens or targeted advertising of new consultations could drive more valuable input. It would also increase community confidence in our health system due to participation and a sense of ownership of decisions.

Recommendations

Explore cross-portfolio costing for health interventions with benefits to other portfolios

Support greater patient and community involvement in policy and PBS decisions through dedicated liaison staff and targeted advertising

Value has to be demonstrated

For the Government to shape the Budget around value, it is essential that it is demonstrated and robust. Only then can taxpayers be confident that they are getting what has been promised.

Unfortunately, not all of the necessary information to assess value will be available at the time that a medicine first comes to market. The value noted above may only be quantified after a medicine has been used in Australia for some years. For that reason it is essential that Australia moves away from a “one-size-fits-all” approach to assessing medicines and considers where measuring long-term value may be important.



Without flexibility, there will be a tension between robust consideration of value and the push for timely access to medicines. The Government’s response to the Medicines and Medical Devices Review supports flexibility in the process for making medicines available, for example by considering “breakthrough” designations²⁴. The Government has also acknowledged that the same principles could be applied to reimbursement decisions²⁵. One option for balancing scrutiny and timely access is “tiering” submissions by complexity, budget impact and unmet need. This could be coupled with sensible use of “managed access schemes”, where companies commit to providing the Government with subsequent data so pricing and Budget caps can be revisited.

Development of “real world evidence” need not be complex or expensive. An upcoming report from the McKell Institute has highlighted how much health data is already routinely collected²⁶. By linking important datasets, the Government would have easy access to the kind of evidence that would support the full value of medicines: hospitalisations avoided, reduction in need for other medical services, patients remaining in employment or carers returning to work.

Recommendation

Align medicines funding with the updated registration system to maximise efficiency

Partner with industry to develop fit-for-purpose PBS managed access programs that can provide timely access for patients through data collection

Invest in data linkage projects to support value demonstration in health

Conclusion

Australia's fiscal challenges provide a compelling reason to explore innovative solutions, not just at the level of service delivery but in the very way we budget and prioritise public investment. The emergence of Big Data allows us to see and understand links between policies and outcomes that have been unclear up to this point. Yet savings and investment decisions are still considered within silos, such as pharmaceutical funding or spending on public hospitals. Only by taking a holistic approach to value – and ensuring that value claims are backed up by evidence – can we have confidence that taxpayers' money is being used in the best possible way. Roche is eager to partner with the Government to explore how value can be created, understood and demonstrated throughout the health system – leading to a sustainable, healthier and more prosperous Australia.

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Notes

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