March 9, 2020

Richard Vines,

Chief Executive

Rare Cancers Australia

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Cc: amanda@rarecancers.org.au

Dear Richard,

THE NATIONAL CANCER PLAN FOUNDATION PROJECT: DISCUSSION PAPER FOR STAKEHOLDER CONSULTATION

Medicines Australia appreciates the opportunity to provide input to the above project and congratulates Rare Cancers Australia on this important initiative to create a 2030 Vision for Cancer.

As you would know, MA has a dedicated group, the Oncology Industry Taskforce, comprising representatives from AbbVie, Amgen, AstraZeneca, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Janssen, Merck Sharp and Dohme, Novartis, Pfizer, Roche, Sanofi and Takeda.

The OIT was formed in 2012 to catalyse an informed public debate about accessing new medicines generally, and new cancer medicines in particular, and to work collaboratively with Government, clinicians, and patients to address the challenge of access to cancer medicines

The OIT has provided the input for MA's submission. We have chosen to provide comment generally rather than answer the specific questions posed, and will focus on the following narrative themes:

- Part 1: Emerging therapies and technologies
- Part 3: Diagnostics
- Part 5: Collaboration of stakeholders and integration
- Part 6: Equitable and timely access to the best treatment and technologies
- Part 8: Healthy lives generate a healthier economy

Should you require clarification of any information contained in this response, feel free to contact Petrina Keogh, MA's Stakeholder Relations Manager on 0422-115779.

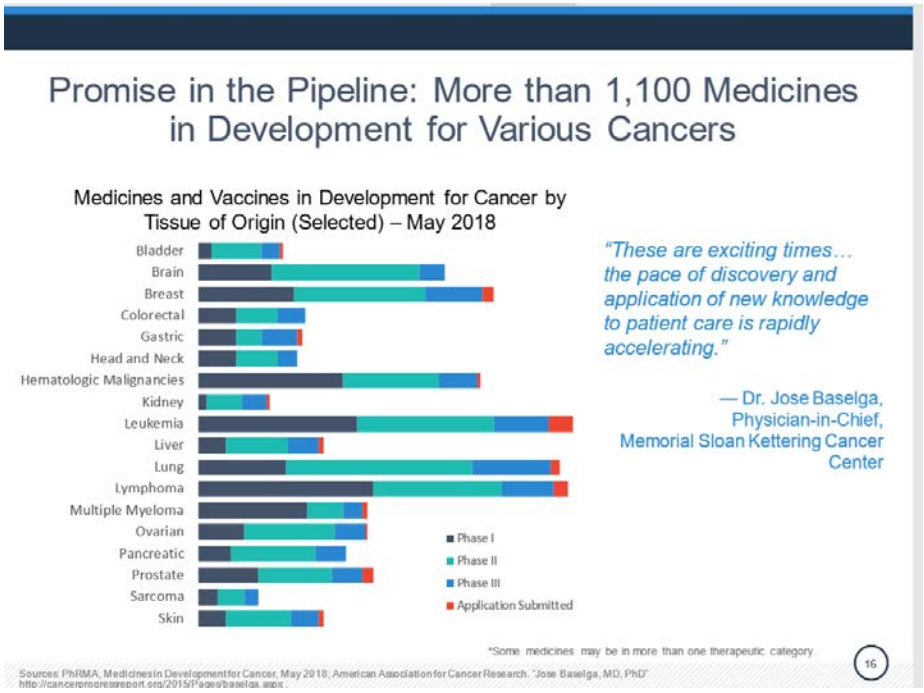
Yours sincerely

Elizabeth de Somer

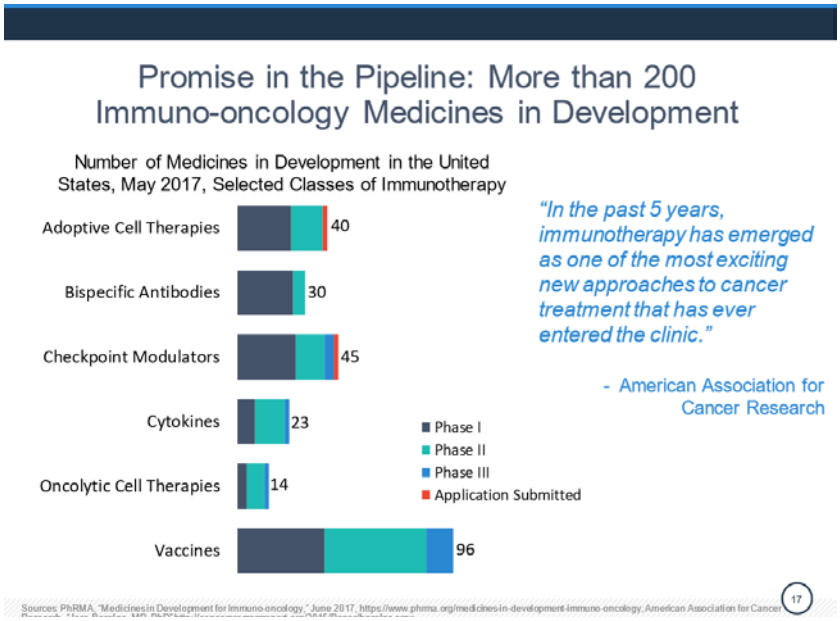
CEO, Medicines Australia

Part 1: emerging therapies and technologies

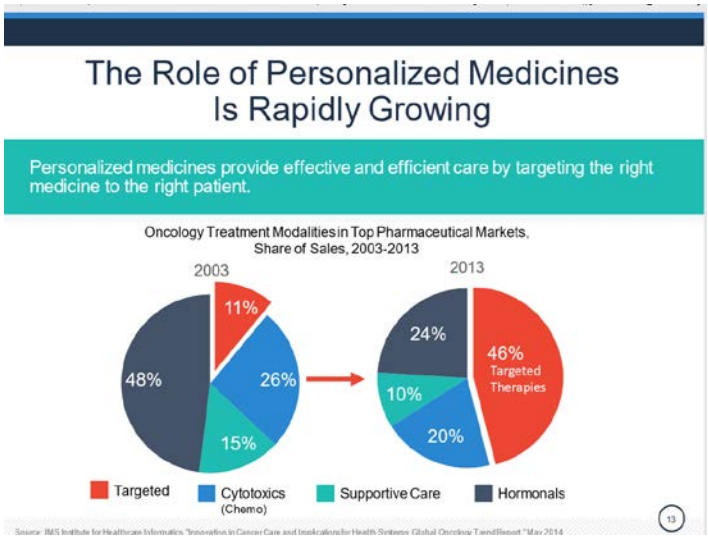
As your narrative indicates, we have made remarkable progress in the fight against the more than 200 diseases we call cancer and current research holds enormous promise to address the great unmet need. Our global industry association, PhRMA, estimates that there are more than 1100 medicines in development for various cancers.



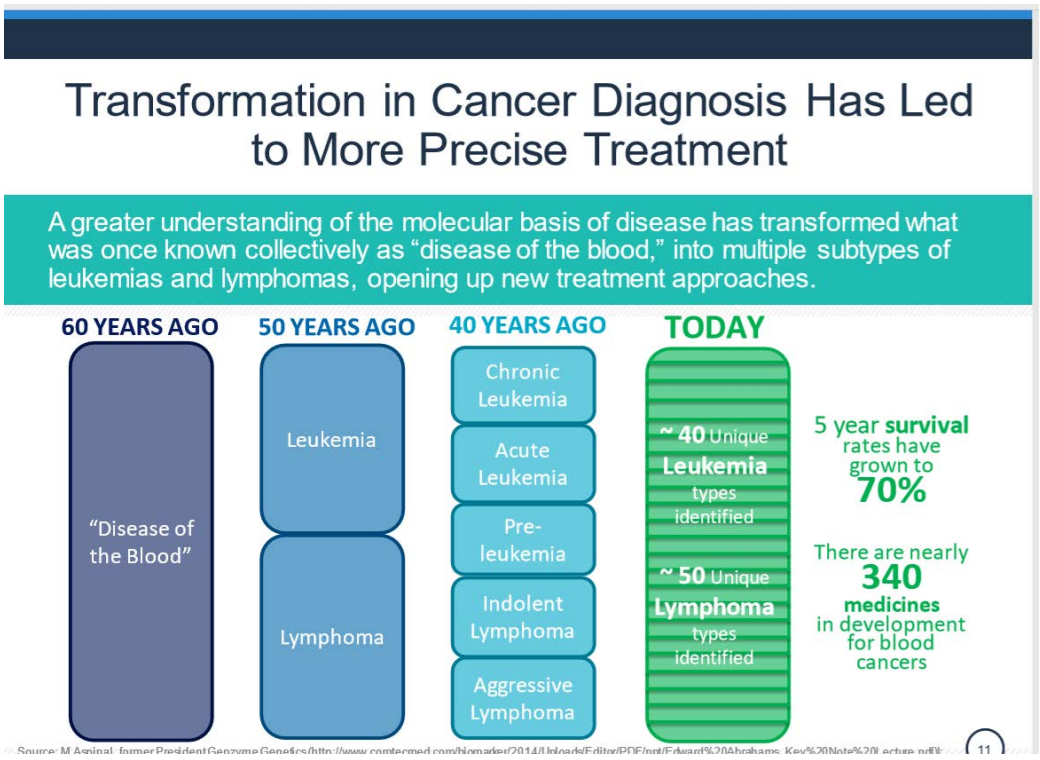
Your report has identified immuno-oncology as one of the disruptive technologies in the cancer space, and the industry estimates that more than 200 immuno-oncology medicines are in development



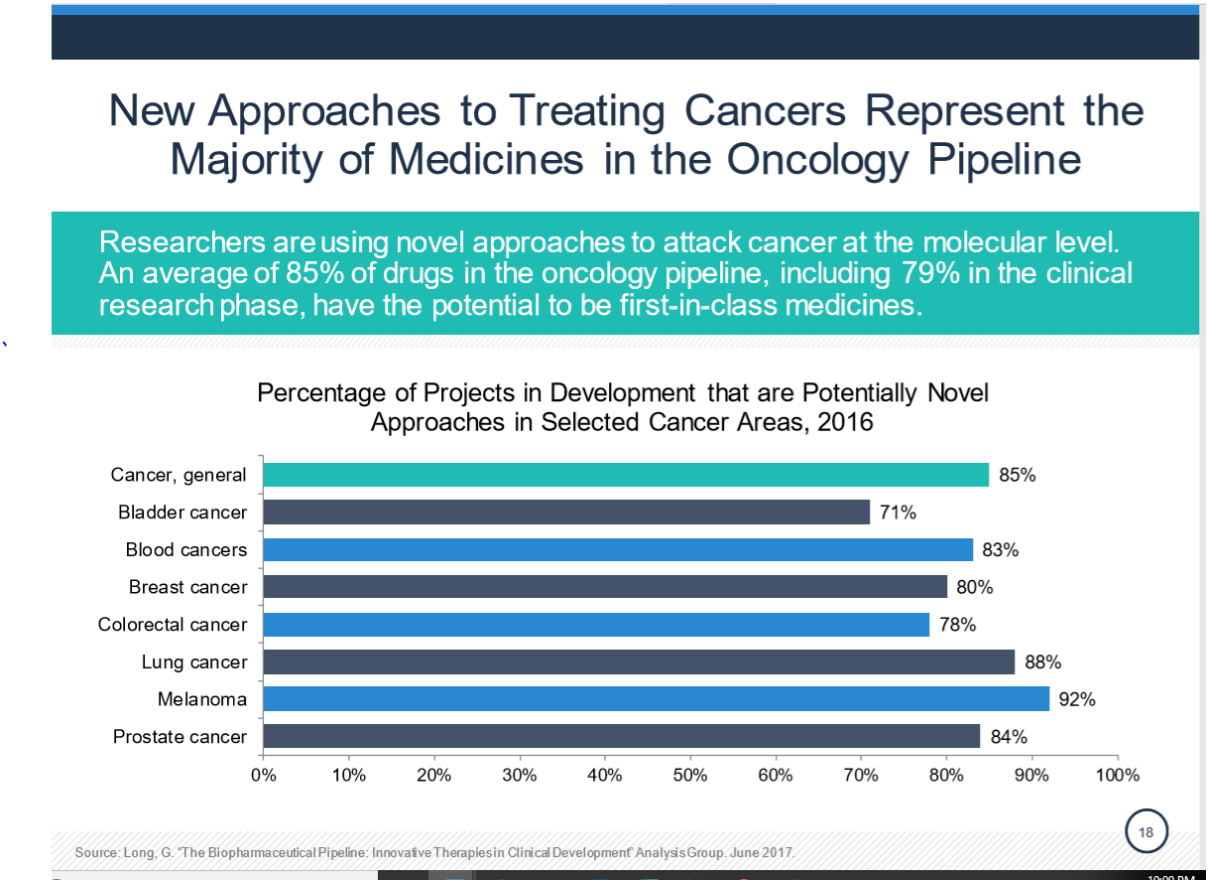
Your prediction (at p.9) that by 2030 the landscape will be dominated by personalized approaches to cancer care is seen in the growth of targeted therapies since 2003.



The trend towards more personalised and precise treatment is evident in the transformation that has occurred in diagnosing cancer. An example can be seen from a historical look at blood cancer.



It is interesting to note that the majority of medicines in the oncology pipeline use novel approaches to attack cancer.



Part 3: Diagnostics

As your narrative notes, there has been increased interest in precision diagnostics for cancer patients, based on the premise that early detection benefits patients as it increases the efficacy of treatment, likelihood of positive patient outcomes and rate of overall survival.

This is well illustrated by looking at the diagnosis and treatment of lung cancer.

Access to innovative diagnostics that have the ability to screen a broad range of the population and a range of tumour types can allow lung cancer to be identified earlier and patient outcomes to be improved.

Diagnosing and treating lung cancer early also has economic benefits. For example, as cancer progression increases, so does the cost of treatment, on average costing $15,500 more to treat Stage IV lung cancer than Stage I2. Treatment options for lung cancer can vary and depend on the type and stage of the cancer, as well as the size and position of the tumour, the presence of metastases, and the overall health of the patient. Diagnostics play a role in ensuring the most optimal treatment is selected with consideration of these factors.

Innovative diagnostics also allow for faster and less invasive identification of clinically relevant biomarkers in patients to guide treatment decisions. For example, in non-small cell lung cancer (NSCLC), epidermal growth factor receptor (EGFR) testing is not performed in approximately 20% of eligible patients due to unavailable or insufficient tissue.

This is where liquid biopsy can help overcome complications of a traditional lung biopsy. Liquid biopsy is an alternative to surgical biopsies and involves a blood sample that detects EGFR gene mutations, which enable clinicians to choose the right treatment for the right patient. In addition, most cancers have multiple genetic mutations and they may not have the same mutations in all parts of the cancer.

The tissue samples removed for biopsy may not show all mutations whereas liquid biopsies offer an improved chance of detecting the various genetic changes.

In a similar respect, liquid biopsies can detect disease progression or treatment resistance long before it would normally trigger clinical symptoms or appear on imaging scans. Innovative diagnostics such as liquid biopsies therefore have the potential to improve progression and survival rates.

Part 5: collaboration of stakeholders and integration

As noted in the narrative for Part 5, to remain at the forefront of cancer research, discovery and translation, the Australian health sector must continued to be recognized internationally for its contribution as a research partner and attractive clinical trial hub.

According to MTPConnect's report, Clinical Trials in Australia, the most recent data from 2015 showed that 1,360 clinical trials were started that year (including 473 industry sponsored trials) supporting approximately 7,000 jobs - a $1.1 billion in investment.

Australia needs to maintain a top position as a preferred destination for clinical trial investment due to the positive spillover effects on Australian patients and the broader economy.

The benefits for trial participants include early access to promising new treatments in Australia, concentrated specialist care and greater self-involvement in their own care. Other flow-on benefits include the exposure, education and experience of Australian clinicians and health professionals to new and cutting edge technology, which also allows the introduction of new treatments and care regimes that may increase the health and productivity of all Australians.

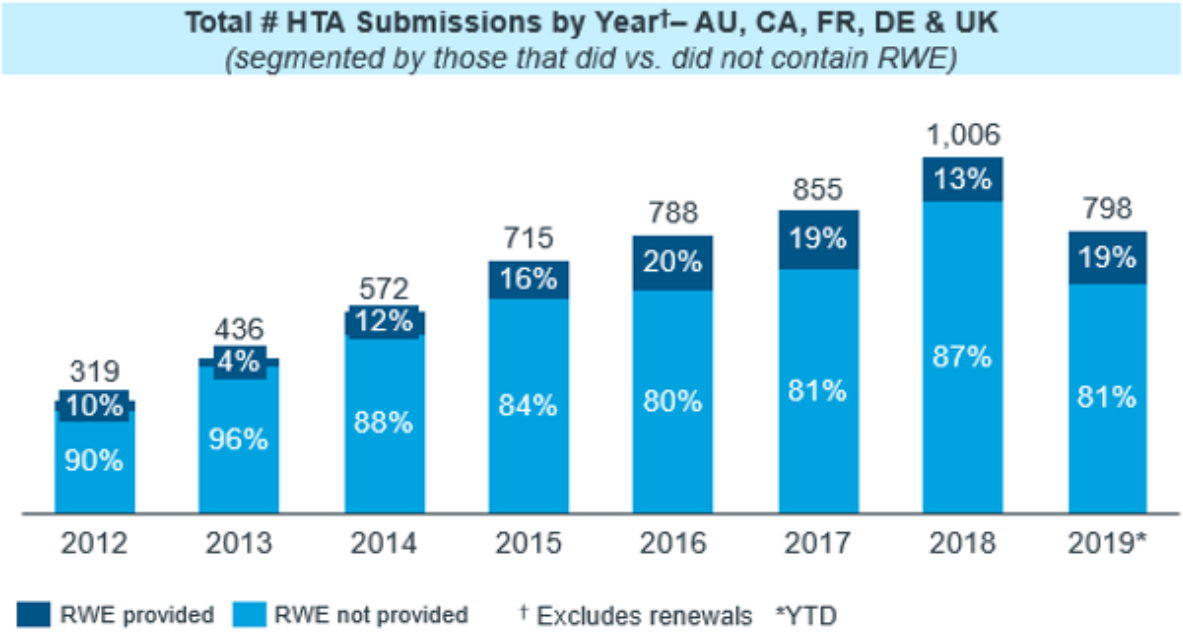
However, Australia's attractiveness as a clinical trial destination is threatened by slow initiation times for clinical trial sites, often due to fragmented governance across the States and Territories. Additionally, patient recruitment can be poor due to lack of community and clinician awareness, and costs frequently vary across sites. In some instances, costs are significantly higher than comparable sites and competing countries. These issues present increasing challenges, compared to other rapidly advancing regional jurisdictions who are competing for clinical trials.

More detail on the challenges and opportunities for Australia can be found in Medicines Australia's Issues brief, *Investment in clinical trials advances innovation,* available at https://medicinesaustralia.com.au/policy/publications/issues-brief/

Part 6: Understand and measure outcomes for future investment

The narrative for Part 6 notes that real world outcomes may be central to funding and access decisions.

The OIT has recently commissioned IQVIA to report on the evolving role of real world evidence (RWE) in Australia. While the report is still in draft form, it has produced some interesting analysis which shows that the proportion of health technology assessment submissions leveraging RWE has doubled from 2012 -2019



Source: HTA Accelerator analysis of n=5,489 HTA submissions from 2012 to 2019 (YTD); includes all single drug assessments in HTAA from PBAC, HAS, NICE, CADTH, pCODR and G-BA in this timeframe

The report notes that when it is generated using fit-for-purpose data, appropriate methodologies and transparent processes, RWE has the potential to reduce uncertainty and enable more informed, evidence-based decision-making across the healthcare ecosystem.

The report contends that there are two main of challenges associated with generation and provision of RWE as part of the HTA process:

- **Methodological challenges** – where the lack of a specific framework and language for provision of RWE leads to under-generation and under-acceptance;
- **Procedural challenges** – where the pre-reimbursement process is not conducive to the generation of RWE for inclusion in HTA submissions. An extension of this may also consider what post-reimbursement processes could be established to ensure greater alignment between value and price as more evidence becomes available.

The OIT would be happy to provide a copy of the report's findings once it is finalized.

Another important source of real world evidence is My Health Record (MHR) data. Medicines Australia generally supports the use of MHR data where it may help to provide better insights to government decision makers and policy makers, about the value of medicines and their place in the overall health care and health care delivery environment in Australia.

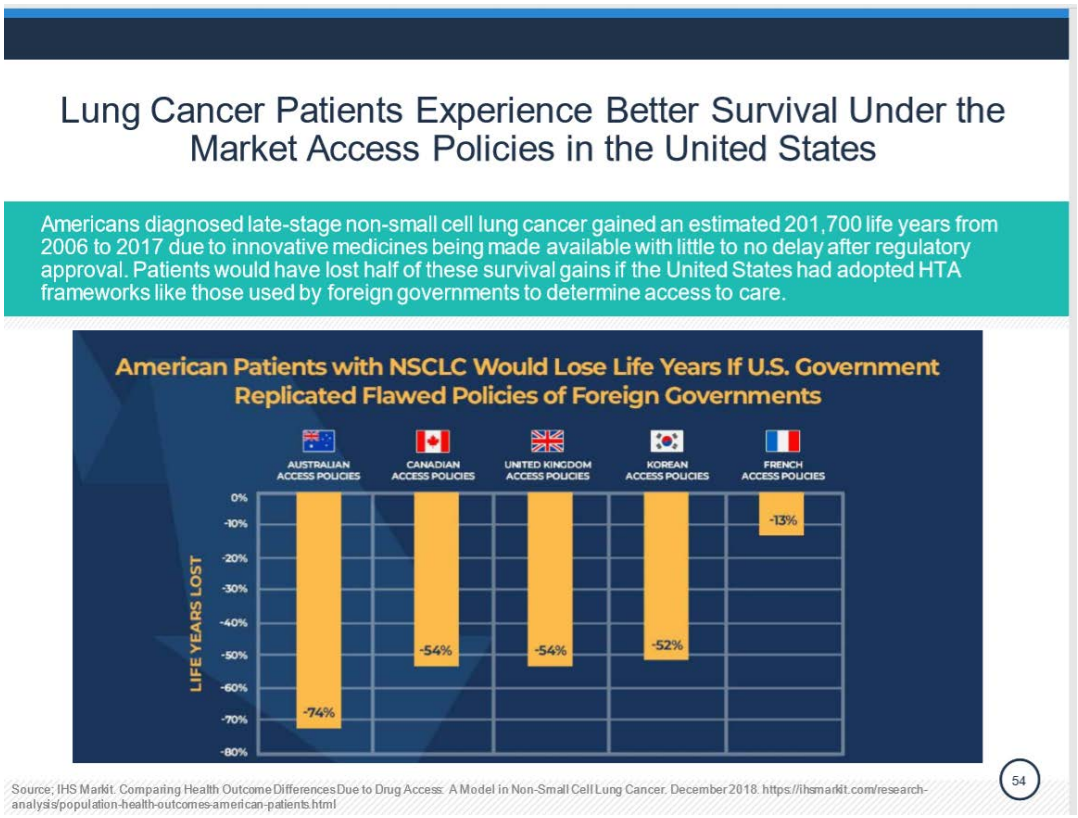
Whilst the intent of the My Health Record is not to determine remuneration or appropriate rebate claiming practices, there is an opportunity presented by the MHR to better understand the experience of patients, particularly those with certain medical conditions. In doing so, this may better inform public policy and ensure the appropriate use and uptake of new technologies. This use of real world evidence of patients' interactions with the health system and use of medicines, may require a shift in perspective regarding how secondary data is provided by the government, and how relevant bodies view this data in reimbursement submissions.

Development of real world evidence need not be complex or expensive. By linking important datasets, government and researchers could have much easier access to the kind of evidence that would support the full value of medicines. Secondary access to My Health Record data will assist in supporting the accurate measurement of this value, for example, through data that demonstrated the number of hospitalisations avoided, the reductions in demand/need for other medical services, the number of patients remaining in employment and/or carers returning to paid employment.

Part 7: equitable and timely access to the best treatment and technologies

Your narrative notes that Australia is lagging behind other countries in access to the newest cancer therapies and technologies.

Research done by PhRMA illustrates the access challenge for Australia in terms of the HTA framework.



In 2017, MA's OIT worked with Deloitte Access Economics to investigate *Access to Cancer Medicines* in Australia.

This report has found Australia has broadly kept pace with its international peers, who are also grappling with the challenge of how patients can best access specialised, high cost cancer medicines- however opportunities for further improvements still exist.

Its 3 key recommendations- which are still valid today - are:

1. A need for greater investment in real-world evidence, to be supported by revised evidence requirements for the valuation of cancer medicines
2. The implementation of provisional a drug listing scheme; and
3. Further enhancements to consumer, clinician, and community involvement

1. **Make real-world evidence a reality –**

The collection of real-world data to enable the development of real-world evidence is seen as essential in the context of increased uncertainty of medicines valuation. Real-world evidence represents enabling infrastructure, which could potentially support the development of a system for provisional listing, as well as the more systematic and evidence-based valuation of patient outcomes. Over the long-term and if properly implemented, this has the potential to substantially improve the quality use of medicines, and deliver broader health service efficiencies.

• Agree evidence requirements for cancer medicines – A review of the PBAC Guidelines has now been completed and has provided industry, government, and other stakeholders with the opportunity to update aspects of the submission process. Given the potential 'long tail' of benefits associated with cancer medicines, and opportunities for more systematic evaluation of patient-important outcomes, which may not be valued by current measures, it is imperative to start considering additional evidence requirements for cancer medicines. This could inform the development of provisional listing arrangements and opportunities for more systematic data collection of patient outcomes through a system for RWE.

2. **Implement provisional listing to match provisional registration** – Stakeholders saw an opportunity to match reforms for provisional registration with a policy for provisional listing based on a common set of agreed criteria. Provisional listing would support access to medicines even as evidence was in development, and the use of robust contractual measures based on real-world outcomes would ensure public monies continue to fund medicines, which are cost effective.
3. **Make patient, carer, clinician, and community engagement meaningful** – The review also made recommendations, building on stakeholder feedback, for substantially enhanced consumer, clinician, and community engagement. The major opportunities for improvement, included increased engagement with patients and clinicians through a Consumer Engagement Group, the use of a Citizens Jury to inform government policy regarding community priorities for medicines, and additional consumer and clinician representation on the PBAC with formal roles for these members. In addition, there may be scope for a specialised expert cancer panel to support evaluation processes and enhance transparency of the value of patient and clinician evidence in PBAC deliberations.

These policy ideas enjoyed strong stakeholder consensus as major priorities for change.

Part 8: Healthy lives generate a healthier economy

Your narrative recognizes that restoring people to full health generates costs savings to the health system and stimulates the economy.

MA strongly agrees with this. Medicines are an essential component of healthcare and help Australians live longer and healthier lives; remain in the workplace, out of hospitals and positively contributing to the community and the economy. Every innovative medicine made available in Australia generates a significant return on investment to the patient, the community, the economy and the Government.

Adopting medical advancements is a vital step for Australia; innovation has a substantial role to play in the evolution and sustainability of our health system. There are monumental shifts taking place in the way diseases will be treated and their consequential positive impacts. We must ensure we have the right systems in place to provide the best healthcare outcomes in this rapidly changing environment. Our members have brought many innovative advances to Australia.

Lost wages now account for just one third of the total economic burden, compared to half seven years ago, thanks to advances in medical treatment.

Broader economic benefits from the listing of innovative medicines also offset costs across the wider government budget. The cost of early retirements on GDP was estimated to be $45.3 billion in 2017 and expected to increase to $53.4 billion in 2025. Effective health programs, such as listing of new medicines, can reduce these costs by up to 20%.[1]

Similarly, Australians lose $20.8 billion in superannuation each year from early retirement due to ill health – but health strategies that include new classes of medicines to treat chronic disease could recover as much as $1.9 billion in superannuation and return $3.9 billion to the economy.[2]

Finally, new medicines help reduce the days of hospital care for Australians, helping to reduce hospital expenditure. It is estimated that hospital expenditure in 2015 was reduced by $3.47 billion because of planned investment in medicines in the decade prior.[3] These examples demonstrate why investment in medicines has a significant positive influence on the economy.

[1] 2018, The McKell Institute, '*Our Health Our Wealth, The Impact of Ill Health on Retirement Savings in Australia',* Accessed 5 December 2019: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/09/Our-Health-Our-Wealth-full-report.pdf, sponsored by Medicines Australia, 2018.
[2] Ibid.
[3] 2019, Lichtenberg F. *The Impact of Pharmaceutical Innovation on Premature Mortality & Hospitalization in Australia 1998-2018.*