Getting Australia to the front of the queue

A pathway to faster access to innovative medicines and medical technologies for Australia

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Executive summary

If COVID-19 has taught us anything, it's the value of the healthcare system to our economic and social security.

It has also exposed the fragility and interconnectedness of the healthcare system and the need for the healthcare industry and Government to work seamlessly together to deliver the diagnostics, treatments and medical equipment necessary to not only respond to a global pandemic, but also deliver the medical care that Australians need and deserve.

There is an urgent need to ensure Australia's health system remains resilient no matter what challenges come down the pipeline. While Governments may be fixated on the COVID-19 response, it will be a missed opportunity if they are not also using this moment to re-evaluate and change the way Australia develops, evaluates and funds medical technologies such as pharmaceuticals, vaccines, medical devices and diagnostics.

To get to the front of the queue for world-class treatments and innovations, Australia's medical technology policy must evolve to respond to changes in technology, developing global trends and the changing health and economic needs of Australians.

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The case for change

While Australia's health system has broadly served Australia well, there have been many tensions in the system, mirroring international trends, that are now growing due to seismic shifts in the global healthcare landscape.

Personalised medicine, individualised sensor driven technologies, robotics, Artificial Intelligence, 3D printing and the interconnected global manufacture and supply chain for many medical technologies have exposed the outdated nature of the assessment and reimbursement frameworks in Australia.

The speed at which COVID-19 vaccines have been brought to market has demonstrated that there can be a faster, simpler way to deliver innovation to the Australian community safely. This has not been because of any short-cuts in the science or the process, but because the collective will has been there from regulators, policymakers and industry.

Practical solutions and support have been forthcoming from all parties and it's this collaboration that has delivered results for Australia in terms of access to a wide range of safe and efficacious vaccines and treatments.

This is in stark contrast to the usual pathway to market for a medicine or medical device. The hallmarks of the Australian system for drug and device approvals have been excessive administrative costs and inefficiencies in evaluation processes, a focus on short-term cost-saving over long-term investment in strategic capability, and Australians having one of the longest waiting times in the world for access to new medical technologies that make their lives better.

These tensions will only get worse without sensible policy reform.

The reality hits home for Australians when they see newspaper headlines about delayed new treatments or medical devices; experience limited treatment options for their condition: coupled with the growing realisation that Australia is rarely at the front of the queue in accessing life changing new scientific breakthroughs and medical technologies.

At the same time, while Australia has an admirable reputation for medical science and a track-record for developing new medical technologies, it could do much better. Australia can, and should, expand and develop its own capability to research, discover, develop, commercialise and manufacture medical technologies for Australians and the world.

COVID-19 has delivered us the momentum to change, it's important that we get this right.

What needs to change

Australia should be among the first in the world to have access to new medical technologies. Australia is a wealthy, high-income country. Australians not only contribute to healthcare expenditure through taxation and private health insurance premiums, but also by paying one of the highest levels of out-of-pocket costs compared to other wealthy countries in the OECD. Australians should expect that for this investment, we are at the forefront of developing and accessing new medical technologies in the decades to come.

However, Australia's system of evaluating and funding medical technologies needs to be brought up to international best practice, to get better value out of every healthcare dollar spent and to ensure Australia really is at the front of the queue in terms of access to new technologies.
For this to happen, we need to re-set the conversation in Australia in respect to medical technology and build greater partnerships between governments, healthcare providers, clinical and patient groups and industry, based on problem solving. We need to make the social and economic value proposition for funding healthcare and invest in building Australia's industrial capability in innovative research in medical technology.

"Getting to the Front of the Queue" proposes critical policy actions needed in the key areas of pharmaceuticals and medical devices to ensure that Australians will have first access to these medical technologies as new breakthroughs are made, and to ensure Australia does not fall even further behind.

There are five key actions that need to be implemented in relation to pharmaceuticals to ensure Australians have timely access to new medicines.

The current medicines assessment policy slows access for patients and therefore the Government should:

1. Limit the Pharmaceutical Benefit Advisory Committee's (PBAC) remit to health technology assessment and cost-effectiveness.
2. Undertake a review of the Quality Adjusted Life Years (QALY) range considered acceptable for cost-effectiveness to ensure it is aligned with international best practice.
3. Adopt a discount rate that appropriately reflects the long-term value of the intervention to the Australian community.
4. Require PBAC to apply as a comparator the alternative therapy which the treatment is most likely to replace in clinical practice.
5. Ensure PBAC appropriately considers social and economic value impacts of a medicine or intervention and builds early patient involvement into the PBAC process.

Similarly, for medical devices there are five key actions that must be implemented if Australia is to have a strong and medical technology sector that values innovation and timely access to new medical devices:

1. Establish a Strategic Agreement guided by a holistic and evidence-based evaluation approach for medical technologies.
2. Adopt a broad assessment of the value of innovative med-tech based on clinical benefits and health outcomes, recognising that value can be delivered to patients, surgeons, hospitals, and healthcare systems as a whole.
3. Maintain a stable reimbursement policy environment which ensures surgeons can choose the best available medical devices for privately insured patients through the Prostheses List.
4. State Governments begin an open dialogue with the medical technology industry on implementing value-based procurement to assist public hospitals to drive safety and quality improvements.
5. Create the environment to transform Australia's research and commercialisation capabilities to tackle our most difficult and complex health challenges.

As international experience has shown, key to Australia's success in achieving these reforms will be building collaboration between Government, industry, patients, healthcare professionals and other health stakeholders, and more priority given to encouraging and incentivising investment, research, innovation and collaboration in Australian medical science and technology.

As the COVID-19 pandemic has shown us, close collaboration and cooperation between public, private and community sectors in health care is critical to finding solutions to emerging issues and building a health system that provides for Australians now and in the future.

Australia can be a world leader in providing medical technologies to its population, should we choose to take that path.

Australia's place in the queue

Australia ranks 17th out of 20 OECD countries for access to new medicines.

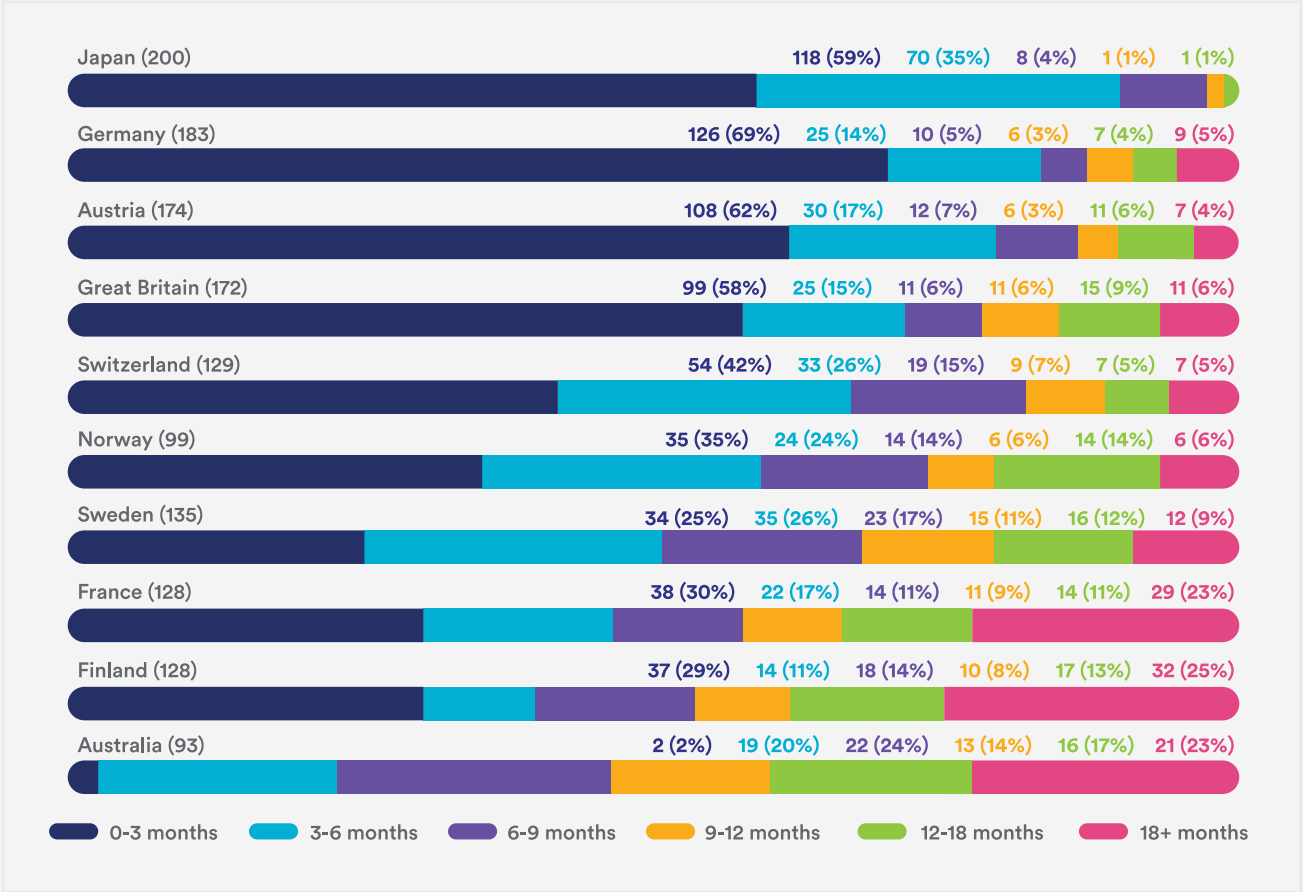
https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/MA-Compare-Edition-3-October-2017.pdf

In 2020 there were 33 medicines that were not reimbursed in Australia but reimbursed in at least one other OECD country and, in many cases, these medicines were reimbursed in many other OECD countries but not Australia.

While countries like Japan, Germany, Austria and Great Britain get around 60% of their new medicines reimbursed within three months of registration, Australia only manages to get 2% reimbursed within three months.

There are examples of medicines for cancer, cardiovascular disease and diabetes that have taken over 1,000 days to be reimbursed in Australia.

Figure 1: The time from Registration to listing in other OECD nations.



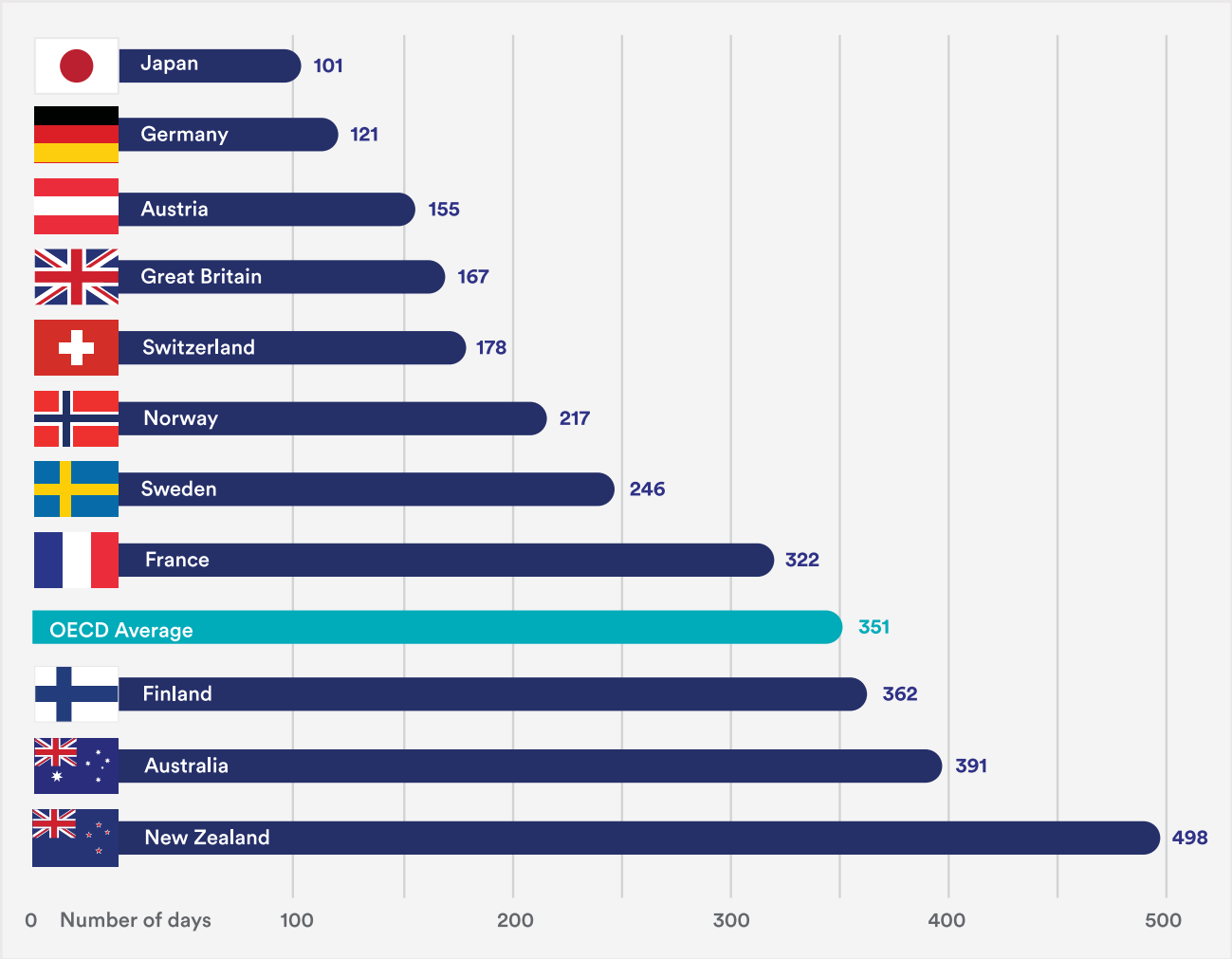
Source: Medicines Australia. 2020. Medicines Matter: Australia's Access to Medicines 2014 - 2019, Canberra, http://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Medicines-Matter-Access-Report.pdf, accessed 20/9/2021.

Figure 2 shows a comparison of Australia's reimbursement timeframe outlined in Figure 1, against other comparable OECD countries timeframes for the equivalent process to achieve similar government reimbursement after registration.

Across the OECD countries assessed, on average, more than 60 per cent of medicines are reimbursed within 6 months in comparison to Australia's 22 per cent.

As seen on previous page, some countries achieve an aspirational reimbursement rate of 60 per cent within the first three months (accounting for differences in process).

Figure 2: It takes longer to achieve reimbursement in Australia than comparable OECD countries.



Source: Medicines Australia. 2020. Medicines Matter: Australia's Access to Medicines 2014 - 2019, Canberra, http://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Medicines-Matter-Access-Report.pdf, accessed 20/9/2021.

Introduction

When the COVID-19 pandemic hit in 2020, Australia's system of managing and funding medical technology was already facing a range of pressures.

Australia's health system coped well with the initial outbreak, and we have stood out as one of the leading countries in minimising the impact of COVID-19. Moreover, the loss of life that affected so many other countries because of COVID-19 was largely avoided in Australia through a combination of good management, timely evidence-based decision making and policy, unprecedented collaboration within and between the public and private sectors and the down-to-earth pragmatism, community spirit and resilience of the Australian people.

The COVID-19 pandemic also exposed some issues with Australia's system of supplying medical technology to Australians and accelerated domestic and international trends that have been pressing on this system for some time. Most Australians have become aware of Australia's place in the queue through the significant supply issues which has resulted in delayed access to the imported doses of COVID-19 vaccines, scarcity of ventilators and Personal Protective Equipment (PPE) at the start of the pandemic and sky-rocketing freight costs because of closed borders and challenged freight routes.

Global shifts are affecting – or should be affecting – Australia's system of providing medical technology to its population. Whether it is international pressures from the rise of universal health coverage, debates about 'value of a life' and 'value for money', transparency, pricing competitiveness, globalisation, rapidly developing technologies, changing population demographics, changes in global value chains, the rise of emerging and developing countries or sustainability issues like climate change, there are a multitude of forces putting pressure on Australia's health and innovation system.

There have been reforms implemented in various healthcare policy areas such as the Pharmaceutical Benefits Scheme for medicines, the National Immunisation Program for vaccines, the Prostheses List for medical devices and reforms to private health insurance. The question is whether these reforms have been enough to deliver a truly world-class health system?

While Australia broadly enjoys access to medical technologies, there is more that should be done to ensure that Australia's health system is fit for purpose, can easily adapt for future technologies and is resilient enough to withstand the next major challenge. Moreover, there are both opportunities and challenges for Australia's medicine, vaccine, device and diagnostic industries in a changing world that, managed and leveraged appropriately, can position Australia as a much larger player in the global health and innovation space than it currently is today.

These issues warrant further detailed discussion, reflection and creative thinking than is currently occurring. Without it, Australia and Australians risk getting left behind as the world of healthcare and medical technology moves forward at pace.

This report contemplates five key aspects of the Australian medical technology policy landscape:

International trends in global health - reviewing developments in global health and in health policy.

Impact of the COVID-19 pandemic - discussing how the pandemic has up-ended existing thinking about healthcare and technology.

Australia's system of medicines funding – examining schemes such as the Pharmaceutical Benefits Scheme, the National Immunisation Program and the role of Australia's medicines industry.

Australia's system of medical device funding - reviewing the operation of initiatives such as the Prostheses List and Medical Benefits Scheme as they relate to medical devices and diagnostics and reviewing Australia's medical device sector.

Taking the debate forward - recommendations for further work on how to improve Australia's medical technology system and industrial sectors.

To get to the front of the queue there must be genuine partnerships between governments, healthcare providers, clinical and patient groups and industry based on ensuring timely and affordable access to transform patients' lives. We need to make the social and economic value proposition for funding healthcare to shape an access environment that is less focused on cost-containment and more geared towards addressing patient needs in a timely manner. To achieve this goal, this report contains recommendations for further action for both pharmaceuticals and medical devices which are discussed in more detail at Appendix 1.

The international environment for medical technology policy and funding

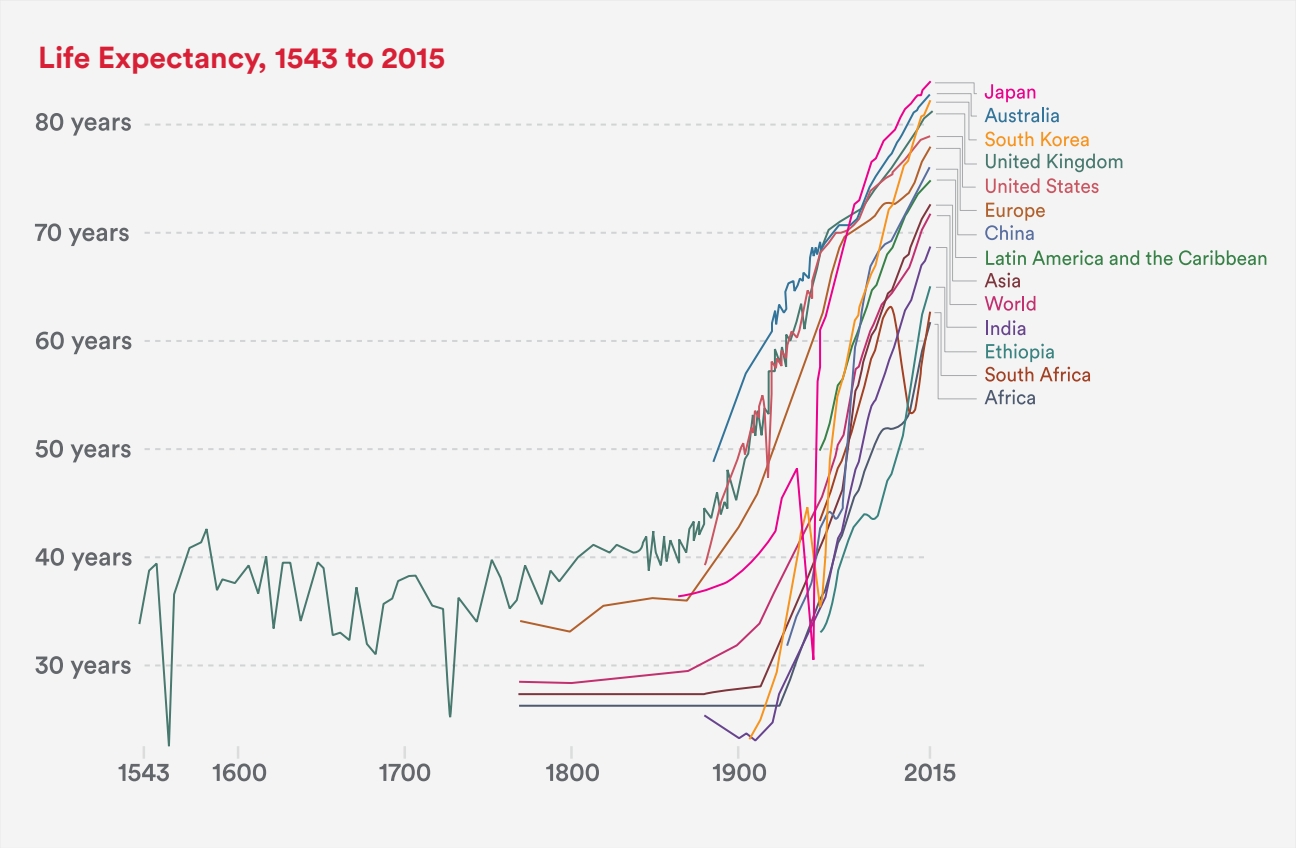
The world has changed dramatically since the first pharmaceutical and medical device technologies became available to the community. Whether it is vaccines that have dramatically reduced childhood mortality, medicines to treat infection and non-communicable diseases, devices to keep someone's heart beating or monitor blood glucose, or reliable diagnostic tests and imaging systems for cancer and respiratory diseases, medical technology has played a defining role in improving the lives of people worldwide.

Going forward, several international trends will set the stage for how medical technologies are developed, what opportunities they bring for the community and how they deliver better health outcomes.

Improved health, longer life expectancy and an ageing population

One of humanity's greatest achievements is the substantial improvement in human life expectancy over the last two centuries. Prior to the Industrial Revolution, the average human being lived about 30 years on average, whereas by 2019, world life expectancy was around 72.6 years[1]. Not only has life expectancy increased, but the quality of that life has increased due to a reduction in the global burden of disease[2]. Today people are living longer, healthier lives than previous generations, acknowledging that there are major differences across the world and continue to be major disparities. One of the implications of longer life expectancy is that the world is witnessing an ageing population. Today 9.3% of the world's population is aged 65 and over, up from 5.1% in 1950, and 0.8% of the population is aged 85 and over, up from 0.2% in 1950[3]. The United Nations' projections are that by 2100, 22% of the world's population will be aged 65 and over while 8% of the population will be aged 85 and over.

Figure 3



Note: Shown is period life expectancy at birth, the average number of years a newborn would live if the pattern of mortality in the given year were to stay the same throughout its life.

Source: Roser, M., Ortiz-Ospina, E. & Ritchie, H. 2019 "Life Expectancy", Our World in Data, Global Change Data Lab, Oxford Martin School, University of Oxford, October, https://ourworldindata.org/life-expectancy, accessed 12/10/2020.

Ageing populations will trigger a greater reliance on healthcare and an expectation of better healthcare in the future. With an increase in older people requiring healthcare as they age, this will provide opportunities for industry and payers, but also challenges if preparatory policy development work, analysis and debate are not done now.

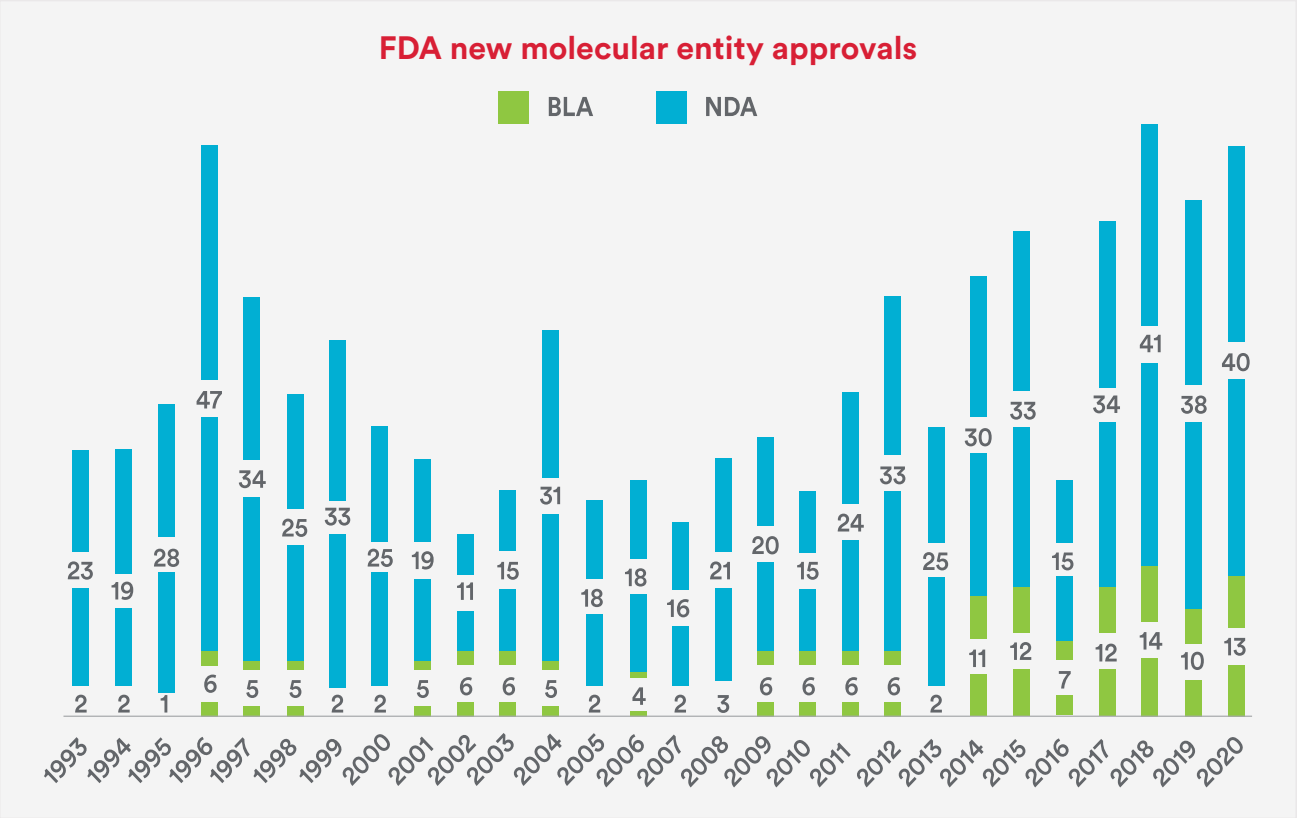
This ageing of the population, combined with longer life expectancy, has led to a rise in the incidence of non-communicable diseases (NCDs) in the population as communicable diseases have increasingly been treated and managed. While eradicating communicable diseases around the world is still a major issue, addressing NCDs has become a more important goal in health systems and health policy around the world.

Developments in medical technology

Medical technology has evolved at varying pace over time. The range and speed of medical technology development is accelerating with progress in underlying technological platforms such as cell and gene-based therapies in medicine, big data, robotics, implantable sensors and artificial intelligence more generally.

To give an example of the pace of technological development, with already thousands of medicines in existence today – one study[4] from 2014 found that there had been 1,453 new medicines developed between

Figure 4



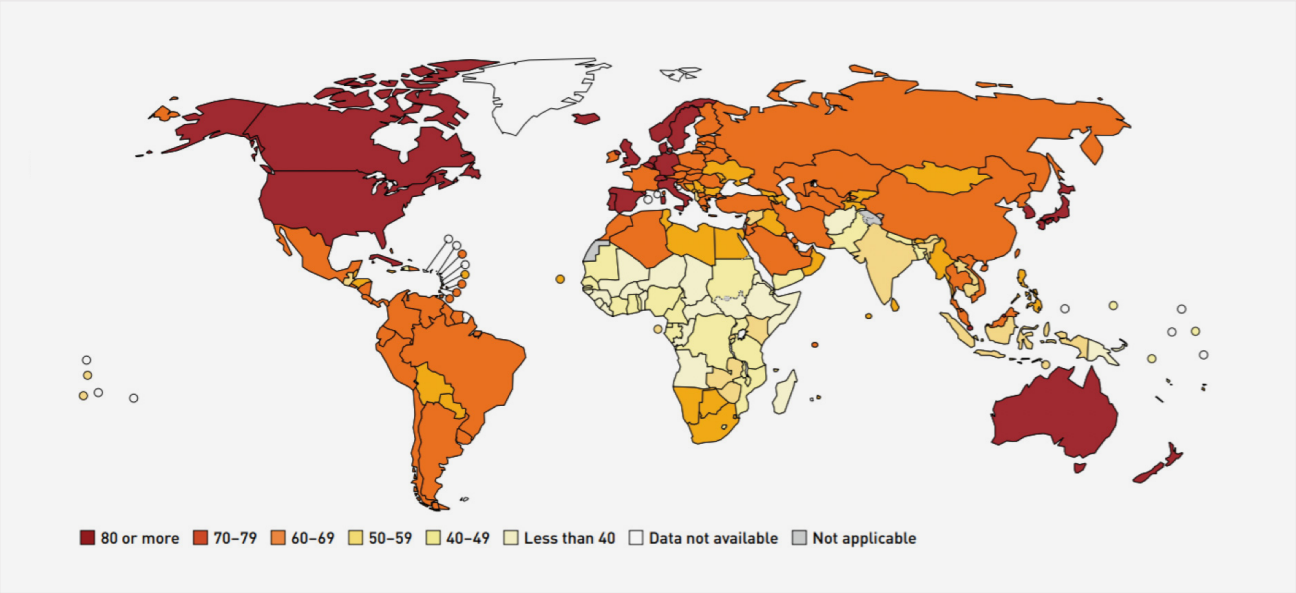
Source: Shawview Consulting chart. Data source Khushboo Sharma, Acting Chief of Staff, Office of New Drugs, FDA, https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM628150.pdf, slide 7, 11 Dec 2018, accessed 3/1/2019; FDA. 2020. "Compilation of CDER NME and New Biologic Approvals 1985 - 2019', https://www.fda.gov/media/135307/download, accessed 5/3/2020.; Van Arnum, P. & Greenberg, M. 2021. "New Drug Approvals in 2020: Which Drugs Made the Mark?", Value Chain Insights, 20 January, https://dcatvci.org/6945-new-drugs-approvals-in-2020-which-drugs-made-the-mark, accessed 6/3/2021. BLA = new Biologic License Application (excluding BLAs not including new active ingredient). NDA = New Drug Application; Data current as at 6/3/2021.

1827 and 2013. However, there are over 7,000 new medicines and vaccines in development for the future[5]. Moreover, there has been a resurgence of new medicines and therapies becoming available on the market, with the pharmaceutical industry achieving more and more approvals for new therapies in recent years (Figure 4).

Universal health coverage and the funding of healthcare

Another major issue in global health policy has been the drive to implement universal health coverage (UHC) in countries around the world. A key health goal of the UN Sustainable Development Goals (SDG), Goal 3.8[6] has as its objective to secure a basic package of health coverage for every person on the planet. This objective dominates much of the global discussion about healthcare and is being implemented by a range of countries around the world. The WHO's measure of the extent to which people have basic healthcare coverage around the world shows that today between one-third and one-half of the world's population is covered by essential health services[7].

Figure 5: UHC Service Coverage Index, 2017



Note: This map has been produced by the World Health Organization (WHO). The boundaries, colours or other designations or denominations used in this map and the publication do not imply, on the part of the World Bank or WHO, any opinion or judgement on the legal status of any counry, territory, city or area or of its authorities, or any endorsement or acceptance of such boundaries or frontiers.

Source: WHO. 2019. Primary Healthcare on the Road to Universal Health Coverage: 2019 Monitoring Report, Geneva, p. 1, https://www.who.int/healthinfo/universal_health_coverage/report/2019/en/, accessed 23/10/2020.

A recent WHO report[8] highlights that while the number of people in the world covered by health coverage is projected to increase from 1.1 billion to 2.0 billion people between 2015 and 2030, world population growth means that the ratio of people benefiting from UHC will only reach 63% by 2030. This means that, currently, the world is not on track to meet its SDG target of a basic package of health coverage for every person in the world by 2030. Even more concerning is that between 2000 and 2015, the proportion of the global population spending more than 10% of their household budget on out-of-pocket healthcare expenses rose from 9.4% to 12.7%, and the proportion spending more than 25% of household income rose from 1.7% to 2.9%.

According to the WHO[9], the world spends US$ 7.8 trillion (A$ 10 trillion) a year on health, which accounts for around 10% of global GDP. The health sector also continues to grow faster than the global economy. Over the period from 2000 to 2017, the global health sector grew by an average 3.9% per year while the global economy grew by 3.0% per year. Public sector spending on health accounts for about 60% of health spending worldwide, although this varies between countries depending on income level. Of this global spend on healthcare, the world spends about US$ 1 trillion (A$ 1.3 trillion) each year on medicines, which is expected to rise to US$ 1.1 trillion (A$ 1.4 trillion) by 2024[10]. This would mean that global medicines spending accounts for around 14% of global health spending. Similarly, global medical device sales have been valued at US$ 425.5 billion (A$ 550 billion) in 2018, expected to reach US$ 612.7 billion (A$ 792 billion) by 2025[11]. This means medical devices represent about 5.5% of global health spending.

Pricing and value for money of medical technology

The price of medicines and medical devices and whether they represent value for money in health systems has been an ongoing issue of debate. Often, the debate falls into two perspectives: those who argue that medical technologies are too expensive and should have their prices reduced versus those who argue that sufficient price levels are necessary to stimulate the development and supply of such technologies to the community.

As debates rage about a fair-price for innovation with payers, medical technology companies have also worked to develop and implement new payment models and assessment frameworks to determine a fair price such as outcomes-based and serviced-based partnerships, risk sharing and value-based assessment. There have also been debates about the importance of intellectual property laws, both in terms of the development of new medical technologies, but also in terms of what can and should be patentable, such as the use of gene sequences and diagnostic tests[12].

A more recent policy development has been the push for the transparency of prices, particularly for medicines. Recent resolutions by the World Health Assembly[13] and campaigns by public health advocates and some governments have sought to publish more information on the actual pricing of medicines and how those prices are determined[14]. These developments raise several substantial issues for the future of healthcare[15].

International reference pricing (IRP) is a price control mechanism where a government sets the price of a medicine in their own country by reference to prices in other countries. IRP may be used formally or informally to set reimbursement prices, at launch or on a regular basis, as the primary criterion for price setting or as one of the many inputs used to inform the pricing decision.

IRP referencing Australia is, currently, under consideration in other countries, including the United States. If implemented, it will threaten patient access to medicines and vaccines in Australia. The new Biden Administration has set out a clear policy interest in reference pricing which will delay or prevent medicines and vaccines being brought to Australia or even stop them entirely. As such, it is imperative that the Government and industry work together to present a united position and create an understanding of the impact that such an approach would have on patients around the world.

The validity of health technology assessment in the context of universal health coverage

The development and expansion in the use of health technology assessment (HTA) around the world has progressed in tandem with the development of universal health coverage. The WHO defines HTA as: "the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology"[16]. The main purpose of conducting HTA is to inform decision making and its use has been growing through recent decades as more public and private funders adopt it to inform decisions about how to fund medical technologies.

However, in recent years there has been a growing sense that the traditional frameworks of HTA need to change. A combination of factors is accelerating debate about the validity of existing HTA models and the need for a 're-boot' of HTA[17], with discussions in countries with long-established HTA systems around the world about how HTA systems need to evolve[18]. Such factors include:

- The emergence of new personalised therapies and devices on the back of scientific research leading to much more effective treatments, technologies and cures for disease
- The increased blurring of the boundaries between medicines, devices and diagnostics that comes with this technological development presenting challenges for traditional HTA models and approaches
- Budget limits being strained by the range of emerging new technologies
- The impact of digital technologies and social media
- The growing opportunities from the use of real-world data and artificial intelligence

- The growing use of risk management, performance- or outcome-based reimbursement models facilitated by better data sources and digital technologies
- The push for greater patient engagement in the HTA process and with it calls for greater understanding, interaction and transparency in the process by patient representative groups
- The growth of the use of HTA in emerging and developing countries, presenting both challenges and opportunities for users of HTA systems to adapt to these markets, and
- The growing level of globalisation and cooperation at the international level between payers and HTA systems with a view to improve decision making but also presenting challenges in ensuring patient and community needs are met.

Such trends have also triggered development of new assessment models and processes, such as multi-criteria decision analysis[19] and patient input processes[20].

New roles and business models for private companies in healthcare

One sometimes underappreciated global trend is that private sector suppliers to health systems, such as pharmaceutical, vaccine, medical device and diagnostic companies are developing new business relationships and new ways of working with their customers and partners. For example, pharmaceutical companies are developing new pricing models for their medicines and vaccines through differential pricing models for countries with different income levels[21], developing pay-for-performance agreements[22] with payers for medicines in disease areas such as cancer and cardiovascular disease, or developing 'subscription' based pricing models for medicines such as insulin and antibiotics[23]. Medical device companies are developing new pricing and payment models in partnership with payers in areas like outcome guarantee models for reducing length of stay or preventing unplanned readmissions or building value beyond product service offerings in areas like remote monitoring, inventory management or operating theatre efficiency models to increase patient throughput, helping to address surgery waiting periods for patients[24].

Companies are also developing new partnership models with other stakeholders, such as public-private partnerships with governments, health providers and NGOs based on addressing the unmet needs and challenges of healthcare providers[25]. Such partnerships can cover things such as health system strengthening, training, supply chain integrity, access programs and service provision. The importance of greater interaction and collaboration between the public and private sectors, is being encouraged by the UN Sustainable Development Goals and in recent UN Declarations on Universal Health Coverage[26,27].

Conclusion

People living longer, an ageing population, human health improving, and ongoing breakthroughs and new medical technologies have all been part of the strengthening of health systems since the turn of the century. Accompanying these trends have been important policy and political considerations such as how much society should invest in healthcare, the best ways to utilise resources allocated to health, what constitutes value for money, fairness and equity in healthcare, the broad sustainability of healthcare systems, the role of medical technology in securing better health outcomes and the contribution of private sector industries that develop and provide these medical technologies.

Impact of COVID-19 and lessons for health systems

Many existing global health issues were graphically and tragically exposed in the global upheaval that is the COVID-19 pandemic.

After decades of often unheeded warnings about impending global pandemics together with the world's lack of preparedness and under-investment in health[28], the COVID-19 pandemic first emerged in December 2019, before quickly spreading around the world. Years of prioritising efficiency, cost-cutting and short-term outcomes ahead of resilience, investment and longer-term strategy were revealed by the emergence of COVID-19.

At the time of writing 243 million COVID-19 cases were reported worldwide 4.94m people had died from the virus[29]. The OECD estimates that the global economy contracted by 3.8% during 2020[30]. To combat the pandemic's social and economic effects, governments around the world spent US$ 12 trillion (A$ 15.5 trillion) in fiscal support measures and a further US$ 7.5 trillion (A$ 9.7 trillion) in monetary policy support[31]. Due to a combination of substantial government support combined with the rollout of COVID-19 vaccines, the OECD expects the global economy to rebound, projected to grow by 5.6% in 2021, although this forecast is heavily contingent on the speed and success of the vaccine rollout.

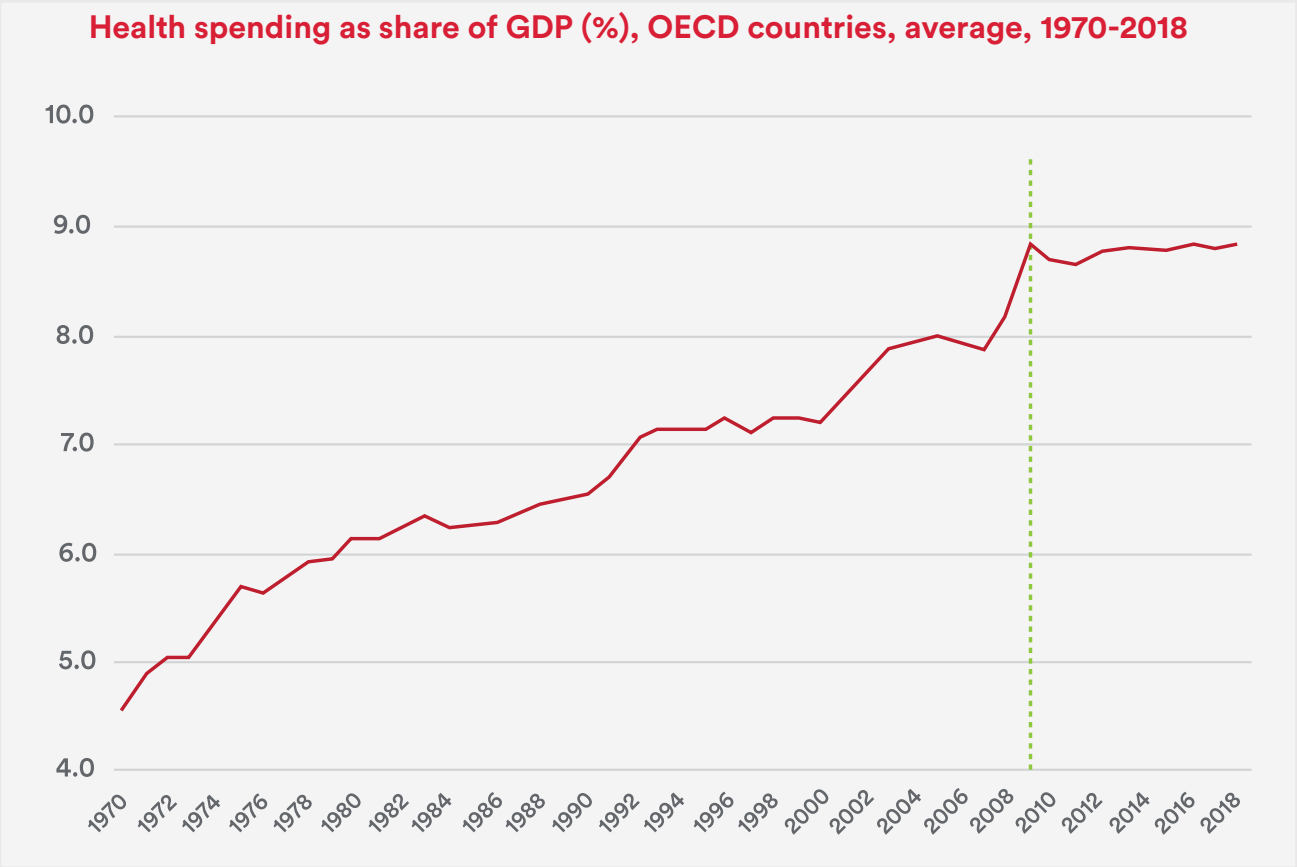
The impact of COVID-19 around the world has provided several lessons that highlight some of the longer-term issues in global health. The aftershock of the pandemic has demonstrated that our approach to health systems needs to be reconsidered in a longer-term context.

The need for investment and resilience in health systems

Even before COVID-19, there was growing recognition that the world had not invested enough in healthcare. Organisations such as the WHO and the World Bank were warning that countries, particularly lower-income countries, needed to lift their investments in health if the world was to achieve its health targets under the UN Sustainable Development Goals, including the provision of universal health coverage for everyone by 2030[32].

While health policy had seen greater prominence on the international policy agenda before COVID 19, this had not translated into sufficient investment in health systems. For example, in OECD countries the growth in health spending as a share of GDP has stagnated since the Global Financial Crisis (Figure 8). Overall health spending has been stable at around 8.8% of GDP for the last decade ever since the Global Financial Crisis precipitated widespread cost cutting in healthcare systems across the developed world.

Figure 8



Source: "Shawview Consulting Chart. Data source: OECD. "OECD Health Statistics 2019 - Frequently Requested Data", spreadsheet, http://www.oecd.org/health/OECD-Health-Statistics-2019-Frequently-Requested-Data.xls, November 2019, accessed 24/4/2020."

This defies the previous trend going back half a century or more which saw OECD countries all gradually investing more of their income in health as their economies grew. While varying from country to country, over the last decade governments across the developed world have stemmed this growth in health spending even as their populations grew and aged.

The inability of health systems to deal with the outbreak of COVID-19 around the world has also highlighted a lack of resilience in these health systems and triggered a global re-think on the balance between cost-cutting, efficiency, resilience and investment in healthcare[33]. Insufficient investment in resources and lack of built-in redundancy into health systems has left them exposed in dealing with major outbreaks like COVID-19. Scenes from around the world of overcrowded intensive care units and hospitals, insufficient personal protective equipment and a lack of investment in vaccines and treatments have demonstrated the lack of resilience and preparedness in health systems worldwide.

New debates on health policy and funding

The demonstrable failures of health systems in many countries, have triggered a re-assessment of the value of health system investment. There has been a growing discussion about the value of having excess capacity in health systems, with growing recognition that more needs to be done to ensure health systems have built in redundancy to cope. Rather like areas of defence spending where much is invested in defence technologies and supplies with the hope they will never need to be used, similarly there is a realisation that health systems also need to have higher levels of investment in the hope they will never be used. Some economists have referred to this as a shift from 'just in time' economics to 'just in case' economics[34].

Health policy considerations have also focused on the role of emergency preparedness versus longer term healthcare management. The evidence is that various recommendations and warnings over several decades about the need to be sufficiently prepared for pandemics and medical emergencies has gone unheeded by payers, governments and health policy makers[35]. Even lessons learned from previous outbreaks such as SARS in 2003, H1N1 in 2009, or the Ebola outbreak in 2014-15 were not taken up or given sufficient priority in health policy discussions and investment.

Intergenerational issues and the value of a life

The lockdowns and social containment measures used by countries to stop the spread of COVID-19 have highlighted issues of intergenerational equity. The virus predominately had its most severe impact on the elderly. Mortality rates by age group varied dramatically. Historically, the pattern demonstrated the world over was that older generations suffer higher death rates from COVID-19 than younger generations[36]. Countries have introduced substantial rules and restrictions to protect the population, particularly the elderly, but this has had a substantial adverse economic impact on jobs and employment which have been more widespread across national economies and disproportionately affected younger generations[37]. This, in turn, has triggered debates over whether younger cohorts of the population should suffer economic hardship to protect society from an infectious disease whose worst health impacts to date have disproportionately affected older generations.

The historic societal costs of responding to COVID-19, be they social restrictions, economic rescue packages or substantial up-front investment commitments in medical technologies, have also highlighted issues in the decisions society makes about the value of a life. The debates about HTA and the value of life that were already under way before COVID-19 have now become more relevant because of the actions taken by payers, governments and other agencies to respond to the pandemic.

In normal pre-COVID times, HTA used standard assessments of cost per Quality Adjusted Life Year (QALY) thresholds to decide on medical technology interventions on the assumption that informed choices needed to be made about the allocation of limited resources to competing treatment options and diseases. The COVID-19 response has raised questions about the traditional cost-effectiveness thresholds used for HTA decision making[38], as governments around the world have committed vast resources to respond to the pandemic absent of the normal HTA processes that accompany healthcare decision making in many countries.

This raises obvious questions about the validity of the 'normal' HTA processes and values used to decide funding medical technologies and health interventions. If medical interventions for other health conditions have been rejected over many years by HTA committees using lower economic values of life compared with that used in response to COVID-19, what does that say about the values and decision-making processes used by those committees? It raises the question of whether HTA committees in many countries would have recommended or rejected the various interventions governments around the world adopted to 'flatten the curve' and protect the population from COVID-19.

Conclusion

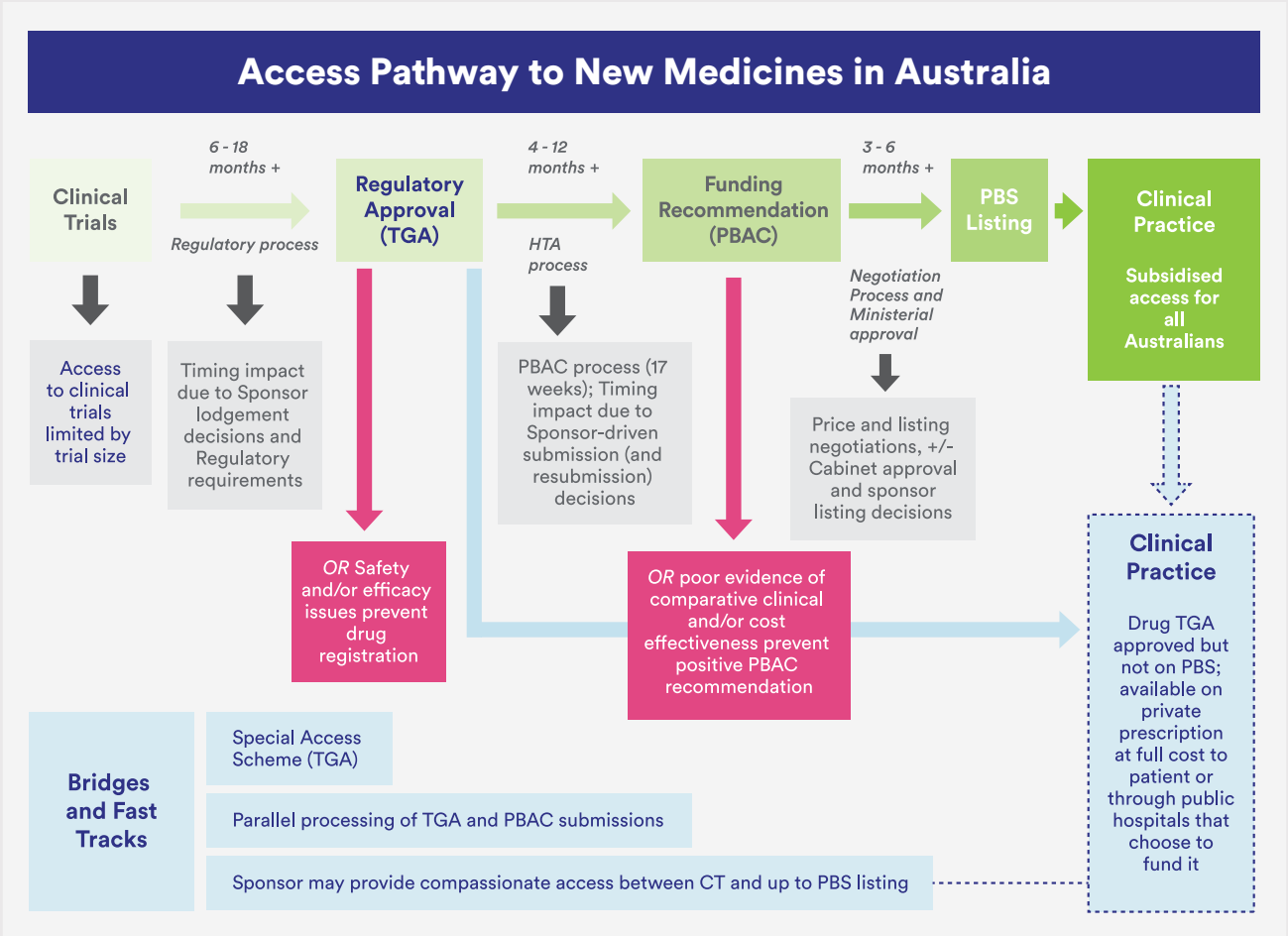
The COVID-19 pandemic has put further pressure on policy debates already occurring in global health policy. Whether it the value and level of health spending, the pricing of medical technology or the economic and social issues of intergenerational equity, COVID-19 has thrown a spotlight on to these issues. The emerging questions about how countries can sufficiently provide healthcare for their citizens have been thrown into the open by COVID-19. Key among these are how countries can and should invest in medical technologies now and in the future.

Australian medicines policy and funding

Australia's systems of providing medicines and vaccines to the Australian community principally involves two schemes at the federal level of government:

- the Pharmaceutical Benefits Scheme (PBS) – designed to provide subsidised access for Australians to prescription medicines, and
- the National Immunisation Program (NIP) – providing free access for Australians to recommended vaccines.

Figure 9



The PBS is a national scheme delivered by the federal government to provide subsidised access to medicines for all Australians. For a medicine to be listed on the PBS, it needs to be assessed and recommended to the Minister for Health for listing by the PBAC. Once recommended and after price negotiations between the government and sponsoring company are finalised, the medicine is listed for subsidy on the PBS. This means that when prescribed that medicine, Australians will pay a general co-payment, or lower concessional co-payment if they qualify, while the Federal Government will subsidise the rest of the cost of that medicine. From 1 January 2021, the general patient co-payment for Australians obtaining medicines on the PBS was $41.30, while the concessional co-payment was $6.60[39].

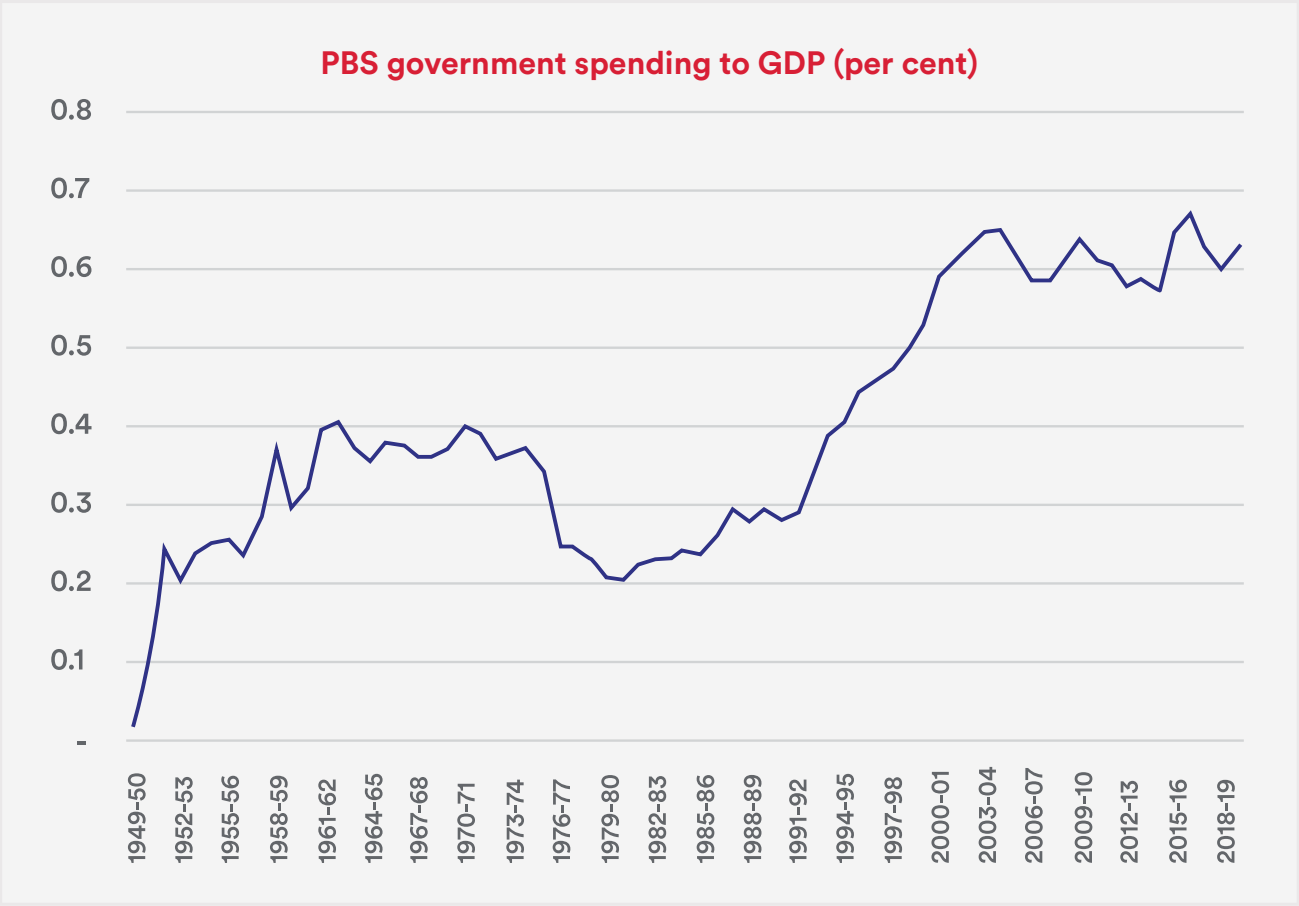
Australia's National Immunisation Program[40] (NIP) is a joint federal-state government program that provides free access to all Australians for vaccinations on the program's Schedule. The program is designed to increase national immunisation coverage to reduce or eliminate diseases in Australia that are preventable by vaccination. The NIP is available for babies, young children, teenagers and older Australians. The program also targets people of all ages who are at greater risk of serious harm from certain diseases. Vaccinations can be obtained through a variety of providers including general practitioners, school programs, immunisation clinics and other health centres.

Trends in medicines and vaccines funding

The PBS accounts for around 0.65% of Australia's GDP and this has been stable since the beginning of the century after higher growth during the 1990s (Figure 10). More generally, Australia has invested an increasing share of its national income in medicines and vaccines over the years as the country's income has grown and as more technological breakthroughs in medicines and vaccines have enabled treatment and prevention of an increasing range of diseases. This trend is broadly consistent with other high-income countries.

In financial year 2019-20, the Federal Government spent $12.6 billion on the PBS, or $9.8 billion in net terms once rebates paid by pharmaceutical companies back to the government are considered[41]. The rebates

Figure 10



Source: Shawview Consulting analysis. Data sources: Department of Health. 2019. PBS Expenditure and Prescriptions Report 1 July 2018 to 30 June 2019, https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report, accessed 7/12/2020; ABS cat. 5206.0. Australian National Accounts: National Income, Expenditure and Product, Table 3: Expenditure on Gross Domestic Product (GDP): Current Prices, data spreadsheet, https://www.abs.gov.au/statistics/economy/national-accounts/australian-national-accounts-national-income-expenditure-and-product/sep-2020/5206003_Expenditure_Current_Price.xls, accessed 7/12/2020; Reserve Bank of Australia. Australian Economic Statistics 1949-50 to 1996-97, Occasional Paper No. 8, Table 5.1a Expenditure on Gross Domestic Product at Current Prices, https://www.rba.gov.au/statistics/xls/op8/5-1a-b.xls, accessed 7/12/2020. Note: Break in GDP series between 1958-59 (RBA series) to 1959-60 (ABS series).

are the difference between a medicines published price, the price listed on publicly accessible pricing information, and a confidential, effective price, which is lower. Every quarter the manufacturer pays the difference back to the government. This arrangement allows Australia to have access to medicines at lower prices without affecting the price for the product in other global markets. Although the scheme has grown over the decades since its inception in 1948, growth has been relatively low by historical standards over the last decade.

While the level of funding for the PBS has increased over decades, so too has the number and types of medicines that the scheme reimburses for the Australian community. In 2020 there were 902 different medicines listed on the PBS[42], compared with 139 medicines when the scheme began in 1948[43].

The types of medicines have also changed. In 1997 the top 20 medicines reimbursed by the PBS by cost were largely small molecule, chemical medicines to reduce cholesterol and blood pressure and address the symptoms of breathing problems, whereas today the top 20 medicines are predominately biologic, monoclonal antibodies to treat various types of cancers, inflammatory diseases, eye diseases and osteoporosis or anti-virals and other medicines to cure hepatitis C and prevent strokes (Table 1).

Figure 11

Table 1: Top 10 medicines on PBS by cost to Government, 1997 vs 2020

Rank	1997			2020		
	Medicine	**Disease**	**$m**	**Medicine**	**Disease**	**$m**
1	Simvastatin	High cholesterol	184.8	Aflibercept	Macular degeneration	372.8
2	Omeprazole	Gastric ulcers/reflux	151.7	Nivolumab	Cancer	340.0
3	Ranitidine	Gastric ulcers/reflux	91.8	Pembrolizumab	Cancer	331.5
4	Enalapril	High blood pressure	79.9	Adalimumab	Inflammatory diseases/ arthritis/psoriasis	318.7
5	Ipratropium bromide	Wheezing/COPD symptoms	66.5	Denosumab	Osteoporosis	236.8
6	Amlodipine	High blood pressure/ angina	52.0	Sofosbuvir + Velpatasvir	Hepatitis C	223.3
7	Captopril	High blood pressure/ heart failure	49.1	Ustekinumab	Inflammatory disease/ Crohn's diseases/psoriasis	209.7
8	Salbutamol	Asthma	47.7	Ranibizumab	Macular degeneration	204.7
9	Famotidine	Gastric ulcers/reflux	44.1	Apixaban	Stroke prevention	201.3
10	Pravastatin	High cholesterol	38.0	Glecaprevir + Pibrentasvir	Hepatitis C	186.5

Source: Department of Health and Family Services. 1998. Australian Statistics on Medicines 1997, AGPS, p. 14, https://www.pbs.gov.au/statistics/asm/1997/asm-1997.pdf, accessed 8/12/2020; Department of Health. 2020. PBS Expenditure and Prescriptions Report 1 July 2019 to 30 June 2020, Excel tables, https://www.pbs.gov.au/statistics/expenditure-prescriptions/2019-2020/Expenditure-prescriptions-report-tables-2019-20.xlsx, accessed 6/12/2020. Note: 2020 is financial year 2019-20.

Similarly, the NIP has grown in scope and cost along with the number and type of vaccines available to the Australian community. The annual cost of the program has increased from less than $50 million in the mid-1990s to reach over $400 million by 2020, with the cost of the program increasing as new vaccines to prevent additional diseases were added[44]. Today Australians enjoy free access to a series of immunisations given at specific times throughout their life. Vaccines to prevent some diseases have been available for many years including those for diphtheria, polio and tetanus, while other vaccines to treat other diseases have been added more recently to immunise against diseases that was simply not possible up until a few decades

ago, to prevent diseases like human papillomavirus (leading to cervical cancer), measles, pneumococcal and meningococcal disease[45].

Figure 12

Table 2: Top 20 Commonwealth Government program expenses, 2019-20

Rank	Program	$ million
1	Revenue assistance to the States and Territories	62,027
2	Economic Response to the Coronavirus	55,179
3	Income Support for Seniors	50,104
4	Medical benefits	24,881
5	Assistance to the States for public hospitals	22,560
6	Job Seeker Income Support	20,128
7	Aged Care Services	19,757
8	National Disability Insurance Scheme	18,676
9	Family Tax Benefit	18,333
10	Income Support for People with Disability	17,781
11	Non-government schools national support	13,918
12	***Pharmaceutical benefits, services and supply****	***13,432***
13	Defence Force Superannuation Benefits	9,786
14	Income Support for Carers	9,375
15	Public Sector Superannuation - Benefits	8,513
16	Government schools national support	8,387
17	Child Care Subsidy	7,921
18	Fuel Tax Credit Scheme	7,343
19	Army Capabilities	7,298
20	Air Force Capabilities	6,652

Source: Australian Government. 2020. Budget Paper No. 1, Statement 6: Expenses and Net Capital Investment, p. 6-10, https://budget.gov.au/2020-21/content/bp1/download/bp1_bs6.docx, accessed 20/1/2021. *- Note: Pharmaceutical benefits includes NIP and RPBS but excludes the effect of revenue returned to government through rebates paid by pharmaceutical companies.

With regards to the availability of vaccines for immunising Australia's population, since 1997 the Australian Technical Advisory Group on Immunisation (ATAGI) has provided advice to the Government on vaccines for inclusion on the NIP and on the Australian Standard Vaccination Schedule which are then subject to a tender process. ATAGI has advised the Minister for Health on the NIP and other immunisation issues. In 2005 the legislation was changed to transfer the role of providing advice to the Minister on which vaccines should be included in the National Immunisation Program from ATAGI to the PBAC. Since that time ATAGI has played a parallel advisory role, providing advice to the PBAC which, in turn, is responsible for advising the Minister. This shift effectively introduced HTA into the assessment process for vaccines in Australia before they progress to the tender procurement stage in the NIP, in a somewhat similar way to the way HTA operates in the PBS.

Shifting the focus from finances to access

Recent reviews and parliamentary inquiries[52] have examined a recurring theme in the PBS about whether the current evaluation systems are well-equipped to evaluate and reimburse new medicines in a timely manner. While Australia does a reasonable job of eventually providing subsidised access to Australians for new medicines, there are several issues here. Data from several sources suggests that, in fact, Australia is typically behind other OECD countries in listing new medicines on the PBS and takes longer than many OECD countries to do this.

Figure 13: Stakeholder perspectives on public subsidy access challenges

For example, Medicines Australia's Medicines Matter report released in 2020 indicates:

- That while many OECD countries get 60% of their new medicines reimbursed within six months, Australia only manages to get 22% through
- It takes Australia 12 months to get 60% of new medicines through its reimbursement assessment system on the PBS
- While countries like Japan, Germany, Austria and Great Britain get around 60% of their new medicines reimbursed within three months of registration, Australia only manages to get 2% reimbursed within three months
- 40% of the new medicines reimbursed in Australia take at least 12 months to be reimbursed (the highest in the sample of OECD countries reviewed) and 23% - nearly one quarter – of new medicines assessed take 18 months or more
- The average time to get a new medicine reimbursed in Australia is 391 days, below the OECD average and between two to three times longer than countries such as Japan (101 days), Germany (121 days), Austria (155 days) and Great Britain (167 days)
- The time it takes to get new medicines reimbursed in Australia varies by therapeutic area, ranging from an average 219 days for asthma and COPD medicines up to an average 496 days for cancer medicines and 528 days for cardiovascular medicines
- There are examples of medicines for cancer, cardiovascular disease and diabetes that have taken over 1,000 days to be reimbursed in Australia, and
- In 2020 there were 33 medicines that were not reimbursed in Australia but reimbursed in at least one other OECD country and, in many cases, these medicines were reimbursed in many other OECD countries but not Australia.

Other studies also show that historically Australians have not had the highest level of access to new medicines compared to their counterparts in other industrialised countries[53].

Issues in the PBS listing process

Defenders of the current system have suggested that the reasons why such problems might exist include the quality of clinical evidence for complex medicines, such as new cancer medicines, and arguments about the cost-effectiveness and benefit of medicines given the prices being requested for new medicines[54]. This leads to PBAC rejecting submissions from companies for listing on the PBS and requires companies to re-submit medicines for evaluation in a new submission. The result is that often medicines will require multiple re-submissions before being recommended by PBAC.

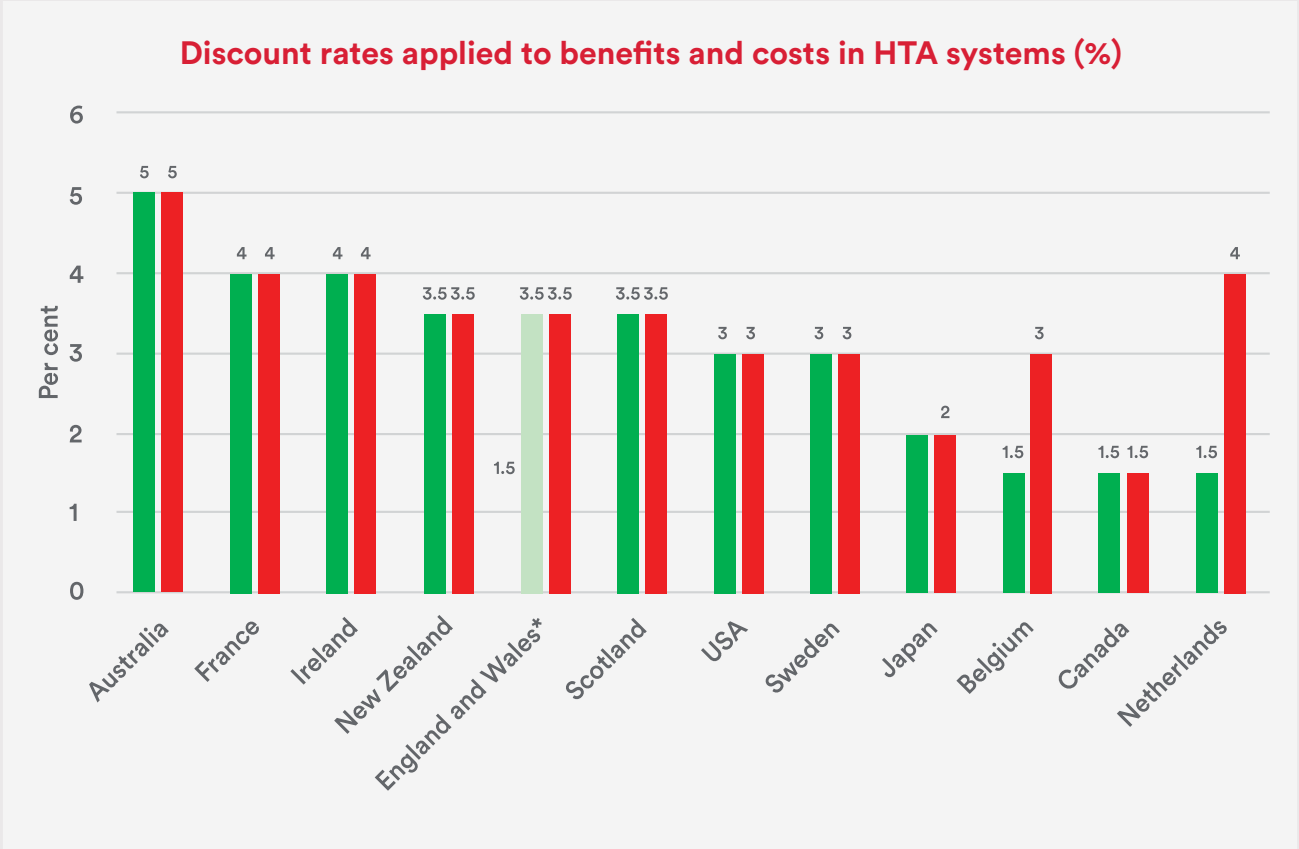
The PBAC listing process is rigorous and robust but delays the listing of new medicines. The development of new technologies, such as cell-based and gene-based therapies, provide increasing challenges for the existing HTA evaluation system for medicines. It is therefore important to ensure that Australia's system for evaluating new medicines and vaccines will be 'fit for purpose' in the future.

There are issues in the listing process for the PBS that are worthy of further consideration that suggest a need to reform PBS funding policy, methodologies and administrative processes. These issues include:

- Time and submission rejections – while the formal PBAC evaluation system operates over a 17-week cycle, in practice submissions made by companies to have medicines listed on the PBS often must go through multiple submissions before PBAC will finally recommend a medicine for listing[55]

- Cost-effectiveness thresholds – the PBAC uses a cost-effectiveness framework, often using a cost per QALY approach, where the incremental improvement in QALY per dollar spent is required to be below a certain threshold. While Australia does not have a formal, published cost-effectiveness threshold, it may be that the thresholds (and therefore effective price levels) used by PBAC in Australia are low compared to other similar countries[56]. The PBAC's implicit cost effectiveness threshold has remained unmoved at around $52-75k/QALY since its inception[57].
- Discount rates and valuing short-term over the long-term – Australia's PBAC uses perhaps the highest discount rates among high-income countries that utilise HTA in their decision making on medicines for reimbursement (Figure 6). Using high discount rates essentially devalues the longer-term costs and impacts of medical technologies, which may in turn undervalue the longer-term savings to the health system and economy-wide benefits of such technologies[58]. This will particularly disadvantage medical technologies such as preventative health measures, pandemic preparedness, vaccination, long-term treatments for chronic diseases and treatments with curative potential such as gene editing technologies.

Figure 14



Source: Devlin, N. & Scuffham, P. 2020. "Health Today Versus Health Tomorrow: Does Australia Really Care Less About its Future Health Than Other Countries Do?", Australian Health Review, June, https://doi.org/10.1071/AH20057, accessed 12/12/2020

- Comparators should be those being used in clinical practice. The right comparator for reimbursement assessments is the one which is most likely to be replaced in clinical practice, not the lowest priced treatment. Johnson & Johnson has experienced the application of the lowest priced comparator medicines being used as price benchmarks for the purposes of evaluating new innovative medicines for funding under the PBS. This is where the default existing medicine used to compare against a proposed new medicine is automatically chosen to the cheapest one, regardless of its role in

actual clinical practice. This is an example of a policy change that has happened since the NMP was released in 2000. For many years prior, the PBAC Guidelines indicated that the PBAC should choose the comparator medicine as the one most likely to be replaced in clinical practice by the new medicine, rather than the comparator that had the lowest price. This change in comparator policy was introduced as a fiscal cost saving measure. The practice undermines the very purpose of innovation - the competitive system to drive discovery that leads to superior treatments for patients. The devaluing or erosion of the prices of innovative medicines creates a range of pressures for companies, making it difficult to seek reimbursement of medicines on the PBS. In some cases, they may choose not to list a medicine on the PBS despite positive recommendation or even de-list their products occasionally due to non-viability.

- Lack of priority/weight given to societal/productivity impacts – the potential benefits and costs of a medicine or vaccine at a society- or economy-level are not given high weighting in PBAC decision making and are not normally accepted by PBAC. According to the PBAC Guidelines[59], while companies can provide supplementary analyses of economic or productivity gains stemming from a proposed medicine, such gains are not accepted in the submission's base case. History suggests that productivity benefits are usually given little or no weight in PBAC decision making[60]
- Interaction between medicines and medical devices – one of the major technological changes occurring within medicine technology is the increasingly complementary and blurred roles between medicines, medical devices and diagnostics. For treatments such as the emerging opportunities from cell and gene technologies, it is becoming increasingly irrelevant to talk about separate medicines or devices or diagnostics when these can be combined to provide patients with new treatment options. However, Australia's different evaluation systems for medicines and devices often lead to administrative delays and inconsistencies in decision making, potentially delaying patient access to treatments[61], and
- Transactional rather than problem-solving approach – while difficult to measure, anecdotal feedback from industry suggests that the PBAC processes are 'transactional', in that the focus is primarily on processing the applications rather than finding solutions to overcome listing problems in applications for PBS listings[62]. Regardless of whether this just reflects limited time and resources available to the PBAC and the Department of Health to address issues in individual submissions in-depth, there is a sense that a renewed regular, in-depth dialogue between PBAC and industry is needed to discuss and work through the common problems and issues at a system level. Such dialogue has been facilitated in the past through vehicles such as former annual PBAC-industry meetings and Joint Medicines Policy Conferences[63] and it may be well overdue for a reinstatement of some of these forums to work through some of the various issues.

In the post-PBAC process, where positive PBAC recommendations are taken for price and budget negotiation between the Department of Health and the sponsoring pharmaceutical company, there are also issues to consider. The system has changed within the last 10 years or so, in part due to the abolition of the former Pharmaceutical Benefits Pricing Authority (PBPA) which, while not perfect, provided some level of overview and consistency in process and decision making for the Department of Health when it negotiated prices and risk sharing arrangements with companies.

Australia's robust but long evaluation system of listing new medicines and relatively low-price levels are suggested as reasons for the substantial delays in providing new medicines to Australians. Companies have indicated that the combination of an, at times, torturous evaluation process coupled with issues about valuing new medicines by international standards means that it is increasingly difficult for pharmaceutical companies to bring new medicines to Australia compared with other countries[64]. Moreover, the growing introduction and cascading of price cuts in the F1 formulary for new medicines has led to substantial price reductions for new medicines on the PBS. This has perhaps contributed to the problems and delays in Australians getting access to new medicines.

Outcomes-based reimbursement in medicines

One area where Australia has tried, with tentative steps, to update its medicines funding systems is through the use of outcomes-based reimbursement of medicines. Originally introduced as Managed Entry Schemes in 2011 which met with limited use by industry, the scheme was rejigged in 2015 to become the Managed Access Program. The basic principle with these schemes is to institutionalise the option that the PBAC could recommend a price based on the current level of evidence, with companies having the opportunity to bring forward more robust cost-effectiveness data at a later date seeking a higher price. One example where this was used was in pembrolizumab for melanoma, where the sponsoring company was able to provide more data after listing on the PBS to justify the price being paid.

Such schemes are the first tentative steps to use post-market, real-world evidence for outcomes-based reimbursement in Australia. However, there is an opportunity to use such facilities more widely. Innovative new purchasing and reimbursement models such as outcomes-based reimbursement or value-based contracting allow payers, providers, and manufacturers to share risk, with the goal of providing better health outcomes for patients while minimising the cost of care. These models are becoming more widespread in medicine funding worldwide because they provide greater flexibility, focus on the ultimate outcomes of healthcare, increasing efficiency and driving down costs[65].

Making the most of our great medical ideas

Australia's scientists, universities, medical research institutes, public laboratories, medical research charities and private sector companies have a well-deserved reputation for conducting excellent scientific and medical research. With some notable exceptions, however, Australia has not been able to realise the economic and health benefits of much of this work. Australia continues to lag in its commercialisation of research. There are a range of reasons, institutional, jurisdictional and economic that have led to this outcome.

The Australian Government continues to support research and development through a range of important policies. These range from National Health and Medical Research Council and Medical Research Future Fund funding to the Research and Development Tax Incentive and now a stronger focus on manufacturing via the Modern Manufacturing Initiative and the recently announced Patent Box tax incentive. There is also work being done to better drive clinical trial outcomes.

Collaboration, between industry, academia and government will always be the lifeblood of developing new medicines and medical technologies to the benefit of patients. More work needs to be done to drive these collaborations. The other key element is to recognise that research and development occurs in a global context and is affected by access decisions, pricing and the level of interest expressed by government. Australia needs to consider its ambition for maximising the benefits from its research, development and manufacturing capacity.

Long-term effectiveness of Australia's medicines policy system

Australia's medicines policy system was already facing several structural issues and challenges prior to the onset of the COVID-19 pandemic in 2020, including a raft of new pharmaceutical and vaccine technologies presenting methodological and budgetary challenges to the system, a growing and ageing population and an, at best, inconsistent priority to industrial development.

A more considered and long-term approach to Australia's medicines policy system is needed. While concerns within government circles over recent decades have focussed on the financial sustainability of the PBS, increasingly the issues of its health and industrial sustainability are coming to the prominence. Given the relative financial sustainability of the PBS and NIP, particularly when compared to other

parts of the health system, there is now fiscal 'head room' to focus more on how the schemes can capitalise on new technologies for the benefit of the Australian population.

Australia is overdue for a more considered assessment of its long-term issues and potential with respect to its medicines policy system, its innovation and technological development. The experience of managing Australia's PBS and NIP programs over recent decades shows that where industry, government, patient groups and other stakeholders work collaboratively on developing strategies and resolving key issues, better public policy is the outcome. The Parliamentary Inquiry[60] and the National Medicines Policy Review61 have provided the opportunity for dialogue between government, industry, patients, the community and other stakeholders on the role of programs like the PBS and the NIP going forward. To deliver on the full potential of medicines these opportunities must address:

- The role of such schemes going forward and how should they evolve in the context of providing universal health coverage in Australia given changing demographics, economic circumstances, technologies, health outcomes and industrial priorities?
- Australia's potential to be world-leading in terms of community access to new medical technologies like new medicines and vaccines and what does that mean?
- Australia capacity to develop its biopharmaceutical innovation sector further in coming years and how might that be achieved?
- How Australia might resolve some of the policy, procedural and methodological issues concerning the reimbursement and subsidy of new medicines and vaccines and what are the best ways to achieve this?

Such consideration, allowing Australians access to future medicine and vaccine technologies would be a welcome step forward.

Australian medical device policy and funding

COVID-19 has educated Australians on the critical nature of medical devices, as well as the breadth of their definition. Personal Protective Equipment (PPE) such as masks, gowns, face shields and gloves, as well as ventilators and monitoring equipment, became hot commodities as countries raced to shore up their medical stockpiles.

Antiquated references to prostheses and devices do little justice to the enormous range of life-saving medical technologies that are vital to the functioning of the healthcare system and to improving the lives of millions of patients around the world. The broad range of these products and their application in a healthcare setting contribute to the problem of enabling an evidence based, approval and assessment framework that rewards the innovation, efficiencies and outcomes that these devices deliver.

Australia's system of funding and providing medical devices is a mix of public and private sector regulation and delivery. There are varying definitions of medical devices, particularly given the rapid technological developments occurring in the sector. Even Australian government agencies use different definitions to define a medical device[67], while the WHO has a standard definition of medical devices[68]. Essentially, medical devices are devices or equipment that treat or aid patients with disease or injury, devices and equipment used to diagnose disease or injury, or devices and equipment used to control or monitor human processes.

Australia's medical technology industry employs around 19,000 people and comprises about 400 companies, the majority of which are small-to-medium-sized enterprises (SMEs). The industry's gross value added was around $1.9 billion in 2016 and the Australian market for medical devices, valued at US$ 4.6 billion (A$ 5.9 billion) in 2016 is ranked 10th largest market in the world[69].

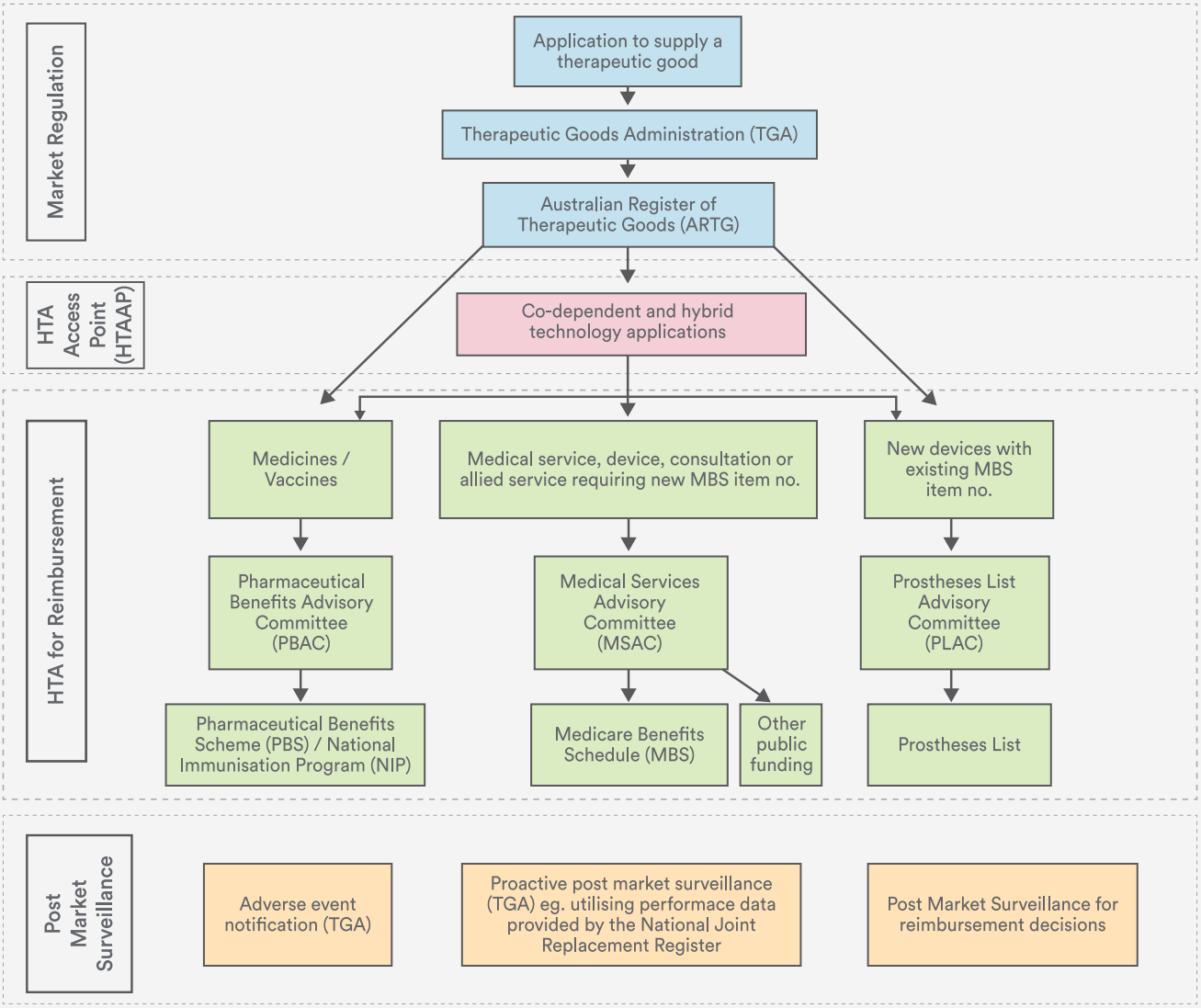
Funding of medical devices in Australia

Australia's system of funding medical devices[70] with both public and private sector roles and various committees and organisations is complex and has been described as facilitating perverse economic incentives creating different levels of access for the public[71]. While devices are funded by the public sector through the Commonwealth's Medical Benefits Scheme (MBS) and by state and territory governments through the public hospital system, the private sector also plays a key role in ensuring Australians can access to medical devices through private health insurance.

Decisions on funding medical devices at the federal government level through the MBS are made by the Minister for Health following recommendations from the Medical Services Advisory Committee (MSAC), while private health insurance funds are required under federal legislation, the Private Health Insurance Act 2007, to fund all medical devices listed on the Prostheses List.

Recommendations on what to include on the Prostheses List are made by the Prostheses List Advisory Committee (PLAC). To varying degrees, both MSAC and the PLAC utilise HTA frameworks to make their recommendations in a similar way that the PBAC makes recommendations for medicines and vaccines to be listed on the PBS and NIP. As with medicines and vaccines, regulatory approval to sell or market a medical device in Australia is controlled by the federal government's TGA (Figure 7).

Figure 15: Australia's HTA system for market entry and reimbursement – medicines and devices



Source: Australian Government. 2020. Budget Paper No. 1, Statement 6: Expenses and Net Capital Investment, p. 6-10, https://budget.gov.au/2020-21/content/bp1/download/bp1_bs6.docx, accessed 20/1/2021.

*- Note: Pharmaceutical benefits includes NIP and RPBS but excludes the effect of revenue returned to government through rebates paid by pharmaceutical companies.

The Private Health Insurance Act 2007 guarantees that when a patient who is a member of a private health fund has a procedure in the private system and the surgeon accesses a medical device listed on the Prostheses List then the insurer is required to pay a benefit where the member has the relevant coverage.

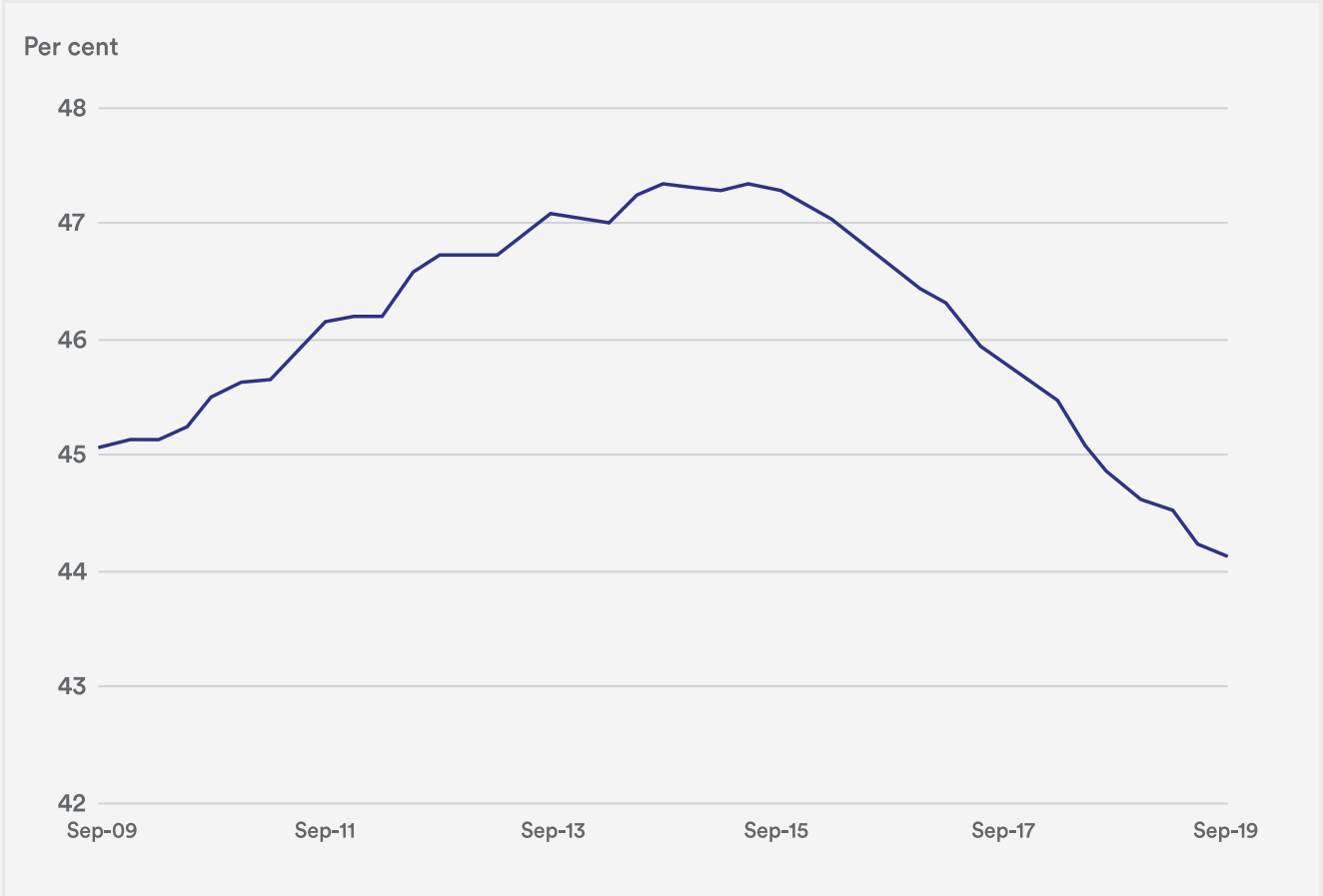
The Prostheses List ensures that surgeons can choose the best available prostheses for privately insured patients without the options being restricted by health funds. It is an essential part of the private health insurance offering which demonstrates why people choose private health - to receive the top level of care as determined by their doctor.

There are approximately 11,000 items on the Prostheses List.

In 2019-20, more than 3.1 million medical devices on the Prostheses List were provided to patients during procedures in the private healthcare system representing an investment by private health insurers of around $2.1 billion into improved health outcomes for their policyholders.

The Federal Government invests $6.3 billion each year to provide a private health insurance rebate to encourage Australians to take-up and keep their private health cover. Each year the Minister for Health approves the rate at which private health insurance premiums can rise, based on submissions provided by the private health insurance industry. This process is opaque, and no public evidence is provided to justify the annual increases. With Australian families spending an average of over $1760 per member per annum on private health insurance, it follows that there is some sensitivity around those costs continuing to grow each year, particularly when those increases have often been larger than CPI. That patients continue to pay large out-of-pocket costs during an episode of care and that there are many more exclusions in their private health insurance coverage, policyholders are increasingly dropping their coverage due to lack of perceived value. Hospital coverage is now at the lowest level since June 2007. This decline has been driven by younger and healthier people who are either dropping their insurance policies or are refusing to sign up in the first place. This, in turn, has triggered debates about affordability and the financial sustainability of the Australian medical device funding system[72].

Figure 16: Hospital treatment coverage (as share of population)[73]



The private health insurance industry points to increased utilisation and rising cost of healthcare, including the cost of medical devices, as reasons for the annual premium increases. The Private Health Insurance (PHI) lobby group also claims that the cost of medical devices is the largest driver of health insurance premium increases [74]. However, insurer costs for prostheses have been flat for four years, and policy holders are receiving around 350,000 additional devices every year for roughly the same expenditure as in 2017.

The PHI lobby continue to overstate the significance of medical device costs contribution to premium increases. The largest contributors to growing PHI expenditure have been hospital benefits and allied health benefits. In 2018, private health insurers collected a total of $23.9 billion in premiums, of which they spent 86% on benefit payments. Over the previous 5 years, total benefit payments have grown by nearly $5 billion, representing about 81% of total growth in premium revenue. Hospital costs account for the lion's share of benefit payments, followed by allied health expenses. Together, these two categories of spend represent 75% of all benefit payouts. Surgeon costs represent an additional 9.5% and medical devices represent 10%.[73]

While average benefits for prostheses have declined, insurers have collected 50% more profit from each of their members between 2013 and 2018. This has far outpaced the 21% growth in benefits paid out. Operational costs have also outpaced benefit payouts, growing by 28%.

Industry agreements and funding reforms to medical devices in Australia

In 2017 the Australian MedTech industry association, the Medical Technology Association of Australia (MTAA), signed a Strategic Agreement[75] with the Federal Government on behalf of its members, to secure pricing stability for the industry and to ensure access to technologies for patients, surgeons and hospitals. This Agreement, mirroring policy developments in the pharmaceuticals sector, provided for benefit reductions – or price cuts – on a range of medical devices listed on the Prostheses List of up to 20% in return for no further policy changes over the five-year life of the Agreement, together with commitments to process reforms to improve the timeliness of approvals and listings of new medical devices. The 2017 Agreement was projected to save the private health insurance industry $1.1 billion over the life of the Agreement[76].

The MTAA-Commonwealth Government agreement triggered a range of reviews and consultations on further reform to the process of funding medical devices in Australia. While the initial 2017 Agreement provided a suite of price reductions and savings, private health insurers have argued that more comprehensive, longer term reform is required to keep the cost of medical devices down. The private health insurance industry argues that prices in Australia are too high, and that greater efficiency and transparency should be put into the system[77].

In the May 2021 federal budget, the Government signalled its intention to reform the Protheses List (PL) which if implemented would significantly alter the state of the medical devices sector in Australia and result in private health insurers having more of a say of what type of medical device is used for a patient rather than the treating clinician who is the medical expert.

In the lead up to the federal budget the Federal Government released a consultation paper[78] on potential reforms to the Prostheses List system and the HTA decision making process around medical devices in Australia.

The consultation paper suggests two options for reform:

1. Consolidate the Prostheses List using Diagnostic Related Groups (DRGs) prostheses subcomponents and revise benefit setting, with administration of benefit setting moved to the Independent Hospital Pricing Authority (IHPA), or
2. Consolidate and redesign the Prostheses List with extensive changes to pre-and post-listing assessment and benefit setting processes, with administration maintained by the Department of Health.

The Federal Government has now proposed a system where the price for a medical device in the private system is linked directly to the price paid in the public hospital system. The Government has proposed using state procurement data sourced directly from the Independent Hospital Pricing Authority (IHPA) to create a baseline of public pricing for the private system.

This proposal fails to recognise the reason a price differential exists in the first place between the public and private systems. In the public system price is based on a mass procurement and the outcome of price is led by the scale of demand. What it fails to consider if the extra service provided in a private clinical setting, surgeon choice for the best device for their patient and the fact that reducing the cost of a device in the private system will not, as it has been shown before, result in lower private health insurance premiums for consumers.

Currently the medical devices industry, through the MTAA, is committed to working with the Federal Government to find a workable solution to the data set used to calculate the price differential in the private and public systems so that there is a fair but different price in the private hospital which reflects the extra benefit and service provided.

The proposed reforms also focus on resolving unclear definitions of what should be included on the Protheses List and improving the transparency and administration of the process to have devices included on the PL. The options proposed would effectively extend the HTA processes seen in pharmaceuticals to medical devices. Other reform proposals to the funding of medical devices that have been proposed through several review processes in recent years include the introduction of price disclosure of the actual market price to government, reference pricing of devices – either internally in Australia or international reference pricing, and competitive tendering[79]. Again, these potential reforms are intended to reduce prices and increase competition and transparency, however there is no actual proof that this will happen. In fact, it is likely that creating a system where pricing is linked to public system will result in the overall med tech sector in Australia shrinking in size and less innovative medical devices being brought here by companies forced into continual price erosions.

The industry holds real concerns that such reforms could reduce treatment options for Australian patients and doctors, and potentially lead to less competition in the market, not more, with fewer participants in Australia's medical device market and industry[80]. Moreover, it could be argued that the very presence of the Prostheses List itself lends a degree of transparency in the privately funded device market that may be absent in the publicly funded market.

Are the HTA processes for medical devices fit for purpose?

A complicated system of evaluation and funding agencies and committees exists for medical devices in Australia. In addition to the regulatory approval stage undertaken by the TGA, there is the PLAC for the Prostheses List process for private sector funding and the MSAC process for publicly funded devices through the Medical Benefits Scheme. In addition, there are clinical advisory groups that play a role, together with the role of the PBAC in evaluating pharmaceuticals and vaccines for public funding which sometimes overlaps with the MSAC process, particularly where complementary tests and devices related to particular medicines are being evaluated.

Moreover, although HTA can be applied to the evaluation of medical devices for funding decisions, there are issues that mean that HTA may not be as applicable for medical devices compared to pharmaceuticals. The key differences that complicate the use of HTA in devices include[81]:

- Double-blinded clinical trials are often not practicable for medical devices
- The effectiveness of a medical device can be highly dependent on the skill of the clinician implanting or using it
- Medical devices have shorter product lifecycles than pharmaceuticals, with frequent incremental changes made to products over time (which can quickly make collected evidence obsolete)
- Some medical devices have a very low volume of use which limits the quantity of evidence that can be collected, and
- HTA is not an efficient mechanism for reducing prices of a product after listing (i.e. post-market review).

The same issues that can potentially confound the use of HTA in pharmaceuticals discussed earlier (e.g. excessively low cost-effectiveness thresholds, lack of consideration of societal or productivity benefits, unduly high discount rates and lack of acceptance of real-world data) can present similar problems for medical devices[82]. Several of the HTA methodological and policy issues being debated in HTA for pharmaceuticals are also relevant to the current dialogue concerning the use of HTA in medical devices (e.g. use of real-world data over time rather than relying on clinical trial data, consideration of broader productivity benefits, appropriate societal valuation)[83].

Another issue is the interaction between the MSAC and PBAC process particularly with the growth of drug-device medical technologies. There are a range of new technologies already on the market that combine a medicinal treatment with a device, perhaps through a prerequisite diagnostic test being required for pharmaceutical treatment or a drug delivery device that implants medicine inside the body such as a drug eluting stent or insulin monitoring and dosing meter. A complication in Australia is that various stakeholders have commented that the administration and processes of these two related, but separate, committees are not well coordinated. For example, submissions from companies to the current House of Representatives review on listing new drugs and medical technologies have highlighted examples where such administrative delays have resulted in patient access to new technologies being delayed[84].

Outcomes-based purchasing for medical devices

Outcomes-based purchasing or value-based contracting in medical devices also represents an opportunity that should be explored further. These models represent opportunities for payment for medical devices to be based more on their ability to achieve their primary health outcomes, rather than simply the supply of the device itself. Reform of Australian medical device funding should consider greater uptake of such innovative funding models going forward in both public and private hospitals.

Similar initiatives are already being explored by the Independent Hospital Pricing Authority (IHPA). In 2018, IHPA trialled an innovative funding model which reduced the funding paid to a hospital for any episode where a hospital acquired complication (HAC) occurs. Under this model, funding is reduced to reflect the incremental cost of the HAC, which is the additional cost of providing hospital care that is attributable to the HAC. This approach recognises that the presence of a HAC increases the complexity of an episode of care or the length of stay, driving an increase in the cost of care. One of the complications included in IHPA's list is surgical site infections (included under the category of healthcare-associated infections)[85].

For state governments, adopting a value or outcomes-based procurement strategy, rather than a lowest priced strategy focused on continuously cutting the base price of products, offers state governments the opportunity to unlock substantial shared benefit for patients and clinicians, while also assisting to manage healthcare budgets and reducing waste.

Currently, procurement processes prevent medical technology suppliers to work closely in partnership with government on value-based initiatives which can deliver greater savings by improving the quality and safety of care, including on value beyond product services designed to reduce complications, prevent readmissions, reduce length of stay, increase operating theatre efficiency and reduce the incidence of device revisions.

For medical technology suppliers, this approach requires richer understanding of the problems that healthcare providers are trying to solve when it offers solutions instead of just responding to the technical tender specifications, and is becoming more common globally, particularly in Europe[86]. In the European Union, coverage with evidence development is commonly used for MedTech risk sharing agreements. This is seeing MedTech manufacturers shifting from volume-based agreements to outcomes-based agreements[87].

> *"Procurement in the healthcare sector is clearly moving away from traditional lowest price procurement strategies and product buying. Instead, it is moving its focus towards quality, services and solutions"*[88]. **Deloitte, How to Eat the Value-Based Procurement Elephant**

In Australia, individual hospital sites are beginning to see the benefits of this partnership approach, and if adopted systematically through whole-of- health procurement processes, could see state health systems facilitate a process where suppliers are continuously competing on improving outcomes for patients and hospitals, not just on cutting prices.

How Johnson & Johnson is delivering clinical and economic value to healthcare providers:

Case Studies

Diagnostic for Delivering Efficiency within the NEOS* Service at Nottingham University Hospitals Trust (NUH)

Objectives

NUH required a partner to support with quality, efficiency and financial improvements within the Nottingham Elective Orthopaedic Service (NEOS).

The Trust required particular support with:

- Increasing available capacity in theatres
- Optimising patient flow, scheduling and discharge processes
- Improving the referral network and driving increased market share within local CCGs.

Solutions

As well as PMO support, we identified a number of program specific modules to support the delivery of targeted outcomes including:

Patent Pathway
An Optimised Discharge workstream to reduce variation in discharge processes, reduce medical and surgical outliers and enhance patient flow.

Theatre Efficiency
A Best-In-Class Scheduling module and Visual Theatre module to decrease theatre downtime, increase theatre utilisation and help ensure consistency in pre-operative processes.

We also proposed to develop a primary care focused shared decision making tool and development of a GP liaison service to improve the referral network.

Results

Following the diagnostic, a number of measurable improvement area (to be implemented over a six month period) were shared with the Trust, including:

Increased patient throughput by 13 patients per week; delivering an additional £2.45M in additional revenue

Aligned to these tracked deliverables, we also outlined improvements in softer measures such as:

- **Staff engagement/satisfaction**
- **High-potential staff development**
- **Skills legacy transfer**
- **Transformation support** (GIRFT deployment, Sustainability and Transformation Plan execution).

*NEOS - Nottingham Elective Orthopaedic Service

Nottingham University Hospital NHS Trust

Case Studies

Co-Creation of Care4Today Orthopaedic Program at Guy's and St Thomas' Hospital Trust (GSTT)

Objectives

For patients undergoing total hip and total knee arthroplasty, GSTT wanted to improve:

The Trust required particular support with:

- Clinical and Service performance
- Patient Experience
- Patient Outcomes
- Reduce Length of Stay (LoS).

"Patients having a hip or knee are now able to go home just one or two days after surgery, having previously spent up to a week in hospital."

Mr Peter Earnshaw
Consultant Orthopaedic Surgeon and Clinical Director of Surgery, GSTT

Solutions

We worked with the Trust to develop and implement **Care4Today Orthopaedic Program – a digital platform** aimed to enhance patient care pathways; integrating health services and multi-media components within existing clinical protocols and evidence-based best practises.

We **collaborated with key stakeholders and patient champions** to map current patient care pathways, facilitated regular workshops and interviews, and attended regular steering committee meetings.

The program featured **health-service components** (e.g. modified joint school, accelerated physical therapy and an outreach service) and various **digital components** (e.g. patient website, HCP website, exercise DVDs). The program is also integrated with the Trust's Electronic Health Record system to improve flow of information throughout the patient care pathway.

Results

- **1.2-2.5 days reduction** in Total Hip Replacement LoS
- **0.6-2.0 days reduction** in Total Knee Replacement LoS
- Estimated **hospital cost savings of >£250,000** in the 18 months post-implementation
- **Improved Patient Experiences** in education; confidence; expectations; recommendations and general satisfaction.

NHS
Guy's and St Thomas'
NHS Foundation Trust

Developing medical devices innovation and industry in Australia

One lesson coming out of the 2020 COVID-19 pandemic was both the capability and gaps in Australia's medical device sector. Amid the worldwide scramble for PPE in the first half of 2020, Australia's inadequate supplies, limited manufacturing capability and over-reliance on international supply chains were revealed. There were extended periods where Australian federal and state governments were concerned that they were not going to be able to acquire sufficient PPE[89] as many other countries adopted strategies to secure PPE in a global scramble[90]. A report by the CSIRO Futures for MTP Connect in 2017 even warned about the potential for global pandemics as a potential risk that the Australian medical technology sector needed to be prepared for and anticipate[91].

Australia's medical device industry managed to pivot to manufacture more PPE domestically during the COVID-19 pandemic whilst other manufacturers outside the industry managed to repurpose and retool in innovative ways to become medical device suppliers[92]. This was an example of Australian industry's ability, seen over many decades, to play to its strengths and quickly adapt to small scale, tailored production runs[93].

The long-term question for Australia is what an internationally competitive, efficient and innovative medical devices sector could and should look like. CSIRO Futures identified opportunities for the Australian medical device industry in the areas of smart, personalised medical devices, implants and bionics, as well as medical diagnostics and information platforms[94]. Questions such as the breadth and diversity of its supply chains, export competitiveness on international markets, the variety of export destinations it has, and its scale, clinical trials, integration with global value chains, efficiency and level of innovation are all worthy of further analysis and debate. Australia has some internationally successful medical device manufacturers supplying global markets, together with successful research and development collaborations. The country has opportunities to drive change and build on its existing strengths and successes in both manufacturing and in research and clinical trials.

Going forward in medical device funding

To the untrained eye the processes for evaluating and funding Australians' access to medical devices can appear confusing. Even to the trained eye, the processes can be complex and need reform. However, different stakeholders are at odds and do not agree on reform options. Therefore, it is difficult to discern a long-term strategy and the Federal Government is caught in the middle trying to balance affordability against ensuring Australians' access and encouraging innovation.

Recent efforts to craft industry agreements together with ongoing consultation processes have provided perhaps the first steps in driving a positive reform program in the post-COVID era. The issues of funders wanting value for money, manufacturers wanting sustainable returns for innovative products and Australians wanting access to the latest treatments are not unique to medical devices, but they are complicated by the diversity of medical devices, manufacturers, funders and providers across the health system.

A sustained and collaborative dialogue among the stakeholders across the medical devices funding system should be a priority. The work done by the medical devices sector, the Federal Government and other stakeholders is a good start, but a more sustained policy dialogue and development process is required. There are some fundamental disagreements between some of the stakeholders on the way forward that would benefit from more constructive dialogue informed by evidence-based policy development.

The processes for assessing the value of medical devices in the Australian health system need a more coordinated and collaborative reform agenda. Overlapping committees, convoluted processes, methodologies out of step with evolving technologies, inefficiencies in procurement systems, risks to patient and doctor choice and arguments over pricing and funding levels seem to increasingly characterise the

Australian policy dialogue. All of this shows a system under pressure, the same as is occurring in many other areas of health in many countries, and the results often manifest in delays to decision making on funding devices and Australians either missing out on the best devices or having to pay more themselves.

For the medical devices industry, an efficient and sustainable business environment in Australia over the long-term is critical. This means not just focussing on ensuring short-term efficiency, nor necessarily prioritising lowest cost but, rather, building a policy and business environment that ensures efficient and innovative device suppliers can thrive, provide the best medical devices Australians and the Australian health sector needs whilst building an internationally competitive industrial sector and innovation eco-system in Australia.

Taking the debate forward: options and recommendations for Australia

The implications of the COVID-19 pandemic for health systems around the world including in Australia will be sustained and far-reaching. However, as Australians we need to recognise the lessons for our health system, economy and medical technology sector as we look towards the post-COVID world. The already existing trends and pressures in global health policy have been accelerated and exacerbated by the COVID-19 pandemic. These present both challenges and opportunities for Australia's medical technology sector and broader health system.

To get to the front of the queue there must be genuine partnerships between governments, healthcare providers, clinical and patient groups and industry based on ensuring timely and affordable access to transform patients' lives. We need to make the social and economic value proposition for funding healthcare to shape an access environment that is less focused on cost-containment and more geared towards addressing patient needs in a timely manner and foster a climate of innovation.

Build genuine partnerships between governments, healthcare providers, clinical and patient groups and industry based on timely access and improving outcomes

One of the key reasons Australia was so successful in managing the COVID-19 pandemic in 2020 was the unprecedented collaboration, cooperation and dialogue between government, industry and other stakeholders across the health sector. The different stakeholders in Australia's health sector were forced by dramatic circumstances to jettison old habits and find new ways to work together. They developed new ways to manage delivery of healthcare in the face of the biggest test of the health system in Australia's history. Governments, businesses, industry groups, healthcare professionals, experts and others all worked together to secure enough PPE, monitored and managed medicines supply chains, found sufficient test kits and rapidly developed manufacturing capability in things like masks and ventilators.

Australia dropped the usual arm's-length way of working between government and business in healthcare and shifted our interactions to being based on problem-solving. The level of dialogue, discussion and collaboration that occurred between the public and private sectors was extraordinary and not the usual drawn out, piecemeal, adversarial process arguing over an evaluation, a price point or a budget parameter that is so often seen. Rather, it was a problem-solving approach where both sides – industry and government – worked together to identify and implement solutions to solve practical issues in the health system.

Australia needs to learn from this exceptional moment in time at the height of the COVID-19 crisis and rediscover a new way of working together for the betterment of the PBS, NIP, MBS and Prostheses List.

Before COVID-19, the system of evaluating and funding medical technologies – be it for medicines, vaccines, devices or diagnostics – was increasingly cumbersome, transactional and even, at times, adversarial. While the Australian evaluation system has always been tough by international standards, increasingly the approach has been one where companies, governments and funders are incentivised to push the system to its limits. COVID-19 shifted the discussion between the public and private sectors to 'Here's a problem, how do we solve it?'. This has been refreshing and business has responded positively to it.

Australia should adopt this new way of working more regularly in healthcare because COVID-19 has focused the attention of every nation on its healthcare system and because many of the pressures in the system will be better solved through this collaborative approach, whilst maintaining the integrity and rigour of the system, together with building competition between suppliers.

Review Australia's evaluation and funding systems for medical technology

Even before the COVID-19 pandemic, the policies and process for evaluating and funding medical technology in Australia were overdue for review. On a range of evaluation issues for medicines, vaccines and medical devices Australia looks increasingly out of step with high income countries on a range of evaluation issues such as acceptable cost-effectiveness thresholds, the value of a life, discount rates, stringent adherence to traditional randomised clinical trial evidence, slow introduction of performance-based reimbursement and the valuation of non-health, social and productivity benefits. Moreover, the evaluation processes themselves are at times cumbersome and overlapping. Meanwhile funding policies in medicines, vaccines and devices have undergone varying degrees of reform over recent years without a broader stocktake on the policy goals of health financing more generally.

Due to the country's size, pricing policies, challenging access regime and international pressures, Australia is already becoming a less important country in the international health market. The international pressures in global health such as the push to universal health coverage, the growing importance of emerging markets, post-COVID investments in healthcare and growing tensions in countries' pricing models mean the pressures will only increase. For example, Australia is already falling down companies' launch sequence for life-saving medicines and medical devices. Australians risk having to wait longer for medical technologies to be listed in the US, Europe, Japan, China, other parts of Asia and Latin America before they get introduced here in Australia. This is a natural response to Australia's tough, protracted, low-cost environment.

There will, of course, be different views on this and there will be people within the health system who will continue to promote the tough stance taken with the healthcare industry in Australia. However, it is timely for a broader look at these issues. For example, personalised cancer treatments, known as CAR-T therapies, are a prime example of a new healthcare innovation that has faced difficulties from health assessment bodies because the evidence base for these therapies does not conform to traditional evaluation frameworks and expectations.

Making the economic case for funding health

Historically, the health sector collectively has not done a good job of making the case for why spending on healthcare is good for the economy, be it in Australia or internationally. It has taken a global catastrophe like the COVID-19 pandemic to demonstrate the economic implications of what happens when we do not have access to medical technologies or make sufficient investment in our health systems.

In other areas of spending, such as education, infrastructure and road safety, the economic case for investing has been made and is generally accepted by decision makers and economists. The health sector, broadly defined, has not been successful in making its economic case. Like investments in other areas of the economy, appropriately managed spending on health is an investment in both the health and economic welfare of Australians.

Even before the COVID-19 pandemic there were efforts to change the conversation led by organisations like the World Bank and WHO arguing the case for universal health coverage and urging governments to invest in healthcare. The pandemic has only served to illustrate the importance of healthcare in protecting society and the economy.

Around the world, the COVID-19 pandemic has revealed just how unprepared health systems in most countries have been, Australia included. Unprepared not just for pandemics, but unprepared generally for the necessary depth, resourcing and resilience to cope with the global forces affecting humanity. These include growing and ageing populations, technological transformation in areas like digital and genetic technologies, the rise and fall of globalisation, climate change and the shift in economic and social weight to emerging markets.

For years health systems around the world have been run by many countries for the here-and-now, operating just on the margin of making do with what money is available. While a major concern for governments and private funders has been increasing efficiencies and identifying savings in health spending, COVID-19 has revealed that there may have been not enough investment in health.

The health sector together – public sector providers, private industry, healthcare professionals and patient groups – should become better at demonstrating the economic value of healthcare to Australian society and argue the case to those who decide funding levels for health services.

Build Australia's industrial capability and innovative research in medical technology

There are substantial opportunities for developing the medical technology industry in Australia and learning the lessons from the COVID-19 experience. Australia is very good at medical science and in inventing new medical technologies. Whether it is a vaccine for cervical cancer, the bionic ear, spray-on skin, the plastic spectacle lens, an electronic pacemaker, the ultrasound scanner or the use of penicillin in medicine, Australia has a proud track record of inventing new medical technologies.

However, while Australia has great people, excellent science and exciting emerging companies, what Australia has not been good at is developing its innovation and industrial systems more broadly. Australia already has some important public policy initiatives today, but these do not have the scale, effort and priority that Australia needs. The COVID-19 pandemic revealed that Australia lacks major capacity to develop and manufacture medicines, vaccines, medical devices and diagnostics, despite having the some of the best science and technology to do so.

Australia needs to have more conversations about how to drive new investment in Australia's medical technology industry. Strategies to encourage research, clinical trials, commercialisation, innovation, public-private collaboration, competitiveness and scale in global value chains should all be examined.
For example, in the 1980s and 1990s as part of Australia's economic restructuring program substantial programs were introduced to support the development of Australia's pharmaceutical and life sciences industry. Perhaps Australia needs to revisit this kind of thinking and identify how to capitalise on the country's strong tradition in health and medical research to build more domestic capability in medical technology research, development, investment and production in Australia.

Global supply chains will continue to be critical to Australia's future health system. The country cannot and should not try to be self-sufficient in all things. However, if Australia is serious about looking at a long-term post-COVID economic recovery plan, then investment and development of Australia's medical technology sector needs to be at the forefront of that conversation.

Five Actions to Improve Access to Medicines for Australians

1. **Limit PBAC's remit to health technology assessment and cost-effectiveness.** Questions of budget impact, pricing, business viability and investment should be the remit of a separate oversight body.

2. **The Government should undertake a review of the QALY range considered acceptable for cost-effectiveness to ensure it is aligned with international best practice.** PBAC should avoid an over-reliance of long-term extrapolations of outcomes which are dependent on multiple assumptions where actual evidence is available when quantifying overall benefit.

    a. The value of life metric used in health assessments is significantly lower than other areas of government. For example, an estimated QALY of $75,000 for PBAC submissions between 2005-2009, compares with a QALY of $199,832 for the cost per road fatality

    b. This would reduce Australia's risk profile regarding proposed plans to integrate an international price referencing mechanism into the Medicare pharmaceutical drug programmes in the United States. International reference pricing creates significant sovereign risk for Australia and, without Government action, could result in Australia falling further behind in the launch sequence for new medicines. The impact of Australia's approach to valuing innovative medicines without regard to the international context increases the likelihood of delays in bringing medicines here and a framework will need to be established between the Government and industry to manage these issues.

3. **Adopt a discount rate that appropriately reflects the long-term value of the intervention to the Australian community**, in line with international best practice (for example, the UK and New Zealand use 3.5% and Canada uses 1.5%)

    a. This will ensure that benefits and savings associated with preventing or treating long-term diseases are not devalued.

4. **Ensure PBAC appropriately considers social and economic value impacts of a medicine or intervention** [for example, flexible application of RWE; consistent inclusion of Patient Reported Outcome Measures (PROMs); recognition of productivity gains through labour force participation; QoL measures; incorporating direct and indirect costs] and consider the totality of the available evidence rather than taking an absolute position on any given endpoint or study

    a. We request that the Australian Government amend the PBAC Guidelines to clarify that, in the exercise of PBAC's functions, it will formally recognise and take into account the incremental value which new technology offers for patients from alternative evidentiary sources such as Australian and international real-world evidence

    b. This would involve the Government and industry working together to:
        i. Amend the PBAC Guidelines and the procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme to incorporate agreed methodologies to enable patient benefits (in addition to traditional measures of safety and effectiveness) to be measured and evaluated
        ii. Agreed methodologies for the transparent inclusion of second order effects or outcomes.

5. **Build early patient involvement into the PBAC process.** Patient preferences need to be considered at the start of the reimbursement process to better define clinical position of new treatments and relevant target populations. This will create a smoother review process that has a better chance of delivering a first-time recommendation and ultimately faster access for patients

    a. Incorporate Patient-reported Experiences measures (PREMs) as a quality indicator of patient care and safety and Patient-reported outcome measures (PROMS) to support patient-centred and value-base care by providing a way of measuring health outcomes from the patient perspective. Ensure PREMS and PROMS are weighted appropriately.

Five actions to Improve Access to Medical Devices for Australians

1. **Establish a Strategic Agreement between the Federal Government and the medical device industry to support access to world-class medical devices**, including providing for a stable, evidence-based evaluation mechanism for pricing of medical technologies in the private healthcare system that values innovation and ensures early and consistent access by patients and surgeons to a wide range of medical technologies.

2. **Adopt a broad assessment of value-based on clinical benefits and health outcomes** - State and Federal Departments of Health and Health Technology Assessment bodies (PBAC, MSAC) should fully engage with the med-tech sector in a solution-oriented consideration about the appropriate level of evidence generation expected for medical devices, including novel devices across the spectrum of current technologies and those in the pipeline.
    a. This would then be codified and clearly laid out in the MSAC Framework, Guidelines and website documentation
    b. The Federal Government should commit to a similar model for MSAC-recommended procedures and devices as exists for the PBS, i.e., committed funding with no offset required within the health portfolio and stronger commitments to timelines for post-MSAC review and implementation with transparent reporting on the status of MSAC recommendations.

3. **Maintain a stable reimbursement policy environment** which ensures surgeons can choose the best available medical devices for privately insured patients through the Prostheses List. It is essential that Australian patients are able to take advantage of the revolution in medical care by having a regulatory, reimbursement, healthcare, research and industry environment that enables the timely, effective and equitable access to the next wave of innovation in MedTech.

    The Prostheses List is the only appropriate mechanism for ensuring consistent access to essential medical technologies in the private healthcare system. The purpose of the PL is to ensure privately insured patients have access to TGA registered and clinically effective medical technologies used in hospital treatment or hospital-substitute treatment. Patient access is the primary test of its function and there can be little doubt that patient access will be negatively impacted in a situation where an increasing number of products can be funded only at the discretion of Private Health Insurers.

    Policy makers must maintain a stable and predictable reimbursement policy environment which ensures surgeons can choose the best available medical devices for privately insured patients through the Prostheses List without the options being restricted by private health insurers, and without placing out-of-pocket costs on consumers.

4. **It is recommended State Governments undertake a review of value-based procurement methods** with the intention of integrating an evaluation methodology into current procurement processes which considers the true value of medical devices and encourages greater partnerships between public health providers and suppliers of medical technology. Development of the Strategy should include:
    a. Committing resourcing and capability, including clinical and health economics experts to measure the value proposition of a product, service or solution and to measure patient-relevant outcomes and total cost of care.
    b. Undertaking internal collaboration between healthcare providers, health procurement agencies and policy makers engaging on clinical and administrative pain points and to identify shared commitments and goals which can be baselined and tracked with sufficient and relevant data
    c. State and territory governments should also be required under their reporting responsibilities for the National Health Reform Agreements to transparently outline their processes for adopting value and outcomes-based procurement.

Government and industry should work together to scope, trial and implement initiatives to drive system improvements in the public hospital sector aimed at increasing procedure efficiency and productivity, improve health outcomes for patients, manage elective surgery back-logs and increase the safety performance of hospitals.

a. Public healthcare providers to open a regular dialogue with the medical technology industry on what the highest priority challenges which could be addressed in through value-based procurement activity.
b. State Governments commit initially to value-based procurement pilotscommissioning outcomes which improve the patient and clinician experience, as well as support the sustainability of the health system, such as reducing the length of stay, preventing avoidable readmissions, or reducing infection rates in hospitals.
c. Once established, state governments can set targets which oblige public health procurement agencies to deliver a greater number of value-based tenders based on delivering outcomes which improve patient safety, lead to higher quality care and contribute to the sustainability of the system

5. **Governments must create an environment that fosters local development and manufacture of medical technologies AND support a diversified global supply chain** to safeguard Australia's access to vital technologies in the event of disruptions (such as pandemics, natural disasters, and ingredient shortage).

New Federal and state government industry development funding sources should be established and used to create new collaboration hubs between government and academic research institutions working in partnership with the MedTech and biotech sectors.

Industry-university partnerships are the key to identifying and developing the opportunities that can deliver new life-improving treatments to patients and economic benefits for all Australians. Australian Governments should support Australian-based accelerators that will help reduce risk, identify value targets, increase revenue and develop a pipeline of skilled talent.

Internationally, there are a number of examples where anchor institutions and companies have successfully co-located with researchers, start-ups, business incubators and accelerators to deliver rapid innovation through the convergence of disparate skills, perspectives and resources. This could also be achieved in Australia via the establishment of long-term, place-based, mutually beneficial partnerships between the Australian medtech and biotech industry, the University sector and the health sector.

This will help transform Australia's research and commercialisation capabilities to tackle some of the most difficult and complex health challenges of our time. The establishment of Accelerators/Precincts will include the opportunity for private sector and industry co-design and co-investment that will facilitate the essential mentoring, networking support and commercialisation training necessary to foster early-stage research talent.

Conclusion

Australia needs to embrace a strong, supportive approach to medical technology in its policy and evaluation frameworks when it comes to medicines, vaccines and medical devices. Growing international pressures together with growing domestic needs and opportunities make this as important as ever. Australia has unique talents and a well-deserved reputation for sensible healthcare and excellent science and research in medical technologies. The opportunity is now there to take the country to the next level in health policy and funding to build a better society and economy for all Australians.

Footnotes

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and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. Note: Products which may be considered to be medical devices in some jurisdictions but not in others include: disinfection substances; aids for persons with disabilities; devices incorporating animal and/or human tissues; devices for.in-vitro fertilization or assisted reproduction technologies". Source: WHO. "Medical Device – Full Definition", https://www.who.int/medical_devices/full_deffinition/en/, accessed 4/2/2021.
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