

2021-22 Roche Pre-Budget Submission

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About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in-vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society with more than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed more than 98,000 people worldwide. In 2019, Roche invested around 12 billion US Dollars in research and development worldwide, including over AUD \$44million in pharmaceuticals in Australia.

Roche's pharmaceutical division in Australia employs over 300 people who are dedicated to the clinical development, registration, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to around 40 Roche medicines, and the company is the leading provider of cancer medicines in Australia by sales.

Roche's diagnostics division in Australia employs over 200 people and has a broad range of in-vitro diagnostics. It concentrates on leveraging advanced scientific knowledge and technological progress to increase the medical value of this offering. Roche Diagnostics serves customers spanning the entire healthcare spectrum - from research institutions, hospitals and commercial laboratories to physicians and patients.

Roche Diabetes Care has been pioneering innovative diabetes technologies and services for more than 40 years. More than 5,500 employees in over 100 markets worldwide work every day to support people with diabetes and those at risk to achieve more time in their target ranges and experience true relief from the daily therapy routines.

Being a global leader in integrated Personalised Diabetes Management (iPDM), Roche Diabetes Care collaborates with thought leaders around the globe, including people with diabetes, caregivers, healthcare providers and payers and aims to transform and advance care provision and foster sustainable care structures. By building and collaborating in an open ecosystem, connecting devices and digital solutions as well as contextualising relevant data points, Roche Diabetes Care enables deeper insights and a better understanding of the disease, leading to personalised and effective therapy adjustments.

For more information, please visit www.roche-australia.com.

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Executive Summary

The link between health and national economic prosperity has been clearly highlighted by the impact of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) pandemic (the pandemic) on the Australian economy. As such, the importance of continued Australian Government investment in healthcare and innovation to meet current and future healthcare needs and support economic growth cannot be understated.

A key investment opportunity relates to personalised healthcare (PHC), an evolution in healthcare driven by medical, scientific and technological advances that will revolutionise how and where healthcare is delivered. In this submission, Roche makes four key recommendations to increase and better coordinate current Government investment into PHC, assisting Australia to maintain its world leading health outcomes, support health system value, efficiency and sustainability, and foster economic growth and job creation. The pandemic has magnified the importance of reaping these benefits to assist Australia chart its way back to economic prosperity. Roche believes it is therefore timely to consider proposals that accelerate the adoption of PHC in the 2021-22 Budget process.

Roche's recommendations are based on its industry-leading expertise in PHC and informed by insights gained across Roche's pharmaceutical, diagnostic and diabetes care capabilities. With a high-quality universal healthcare system, an internationally renowned research sector comprised of world leading expertise in genomics and biotechnology, and assets in data and e-health, Australia is well placed to take advantage of PHC and reap the potential health and economic benefits.

PHC is a rapidly growing approach to healthcare which uses patient-level health data generated in various settings to individualise patient care. It brings together the capacity of digital technologies (such as data analytics and artificial intelligence) and advances in biosciences (such as genomics) to provide insights into the patient's lifestyle, environment and genes. These insights are then used to tailor healthcare to that individual patient, improving health and economic outcomes. PHC relies on precision medicine technologies which enable a more targeted approach to disease prevention, diagnosis, monitoring and treatment. Many of the technologies used to support the public health response to the pandemic were precision medicine technologies, adding a new dimension to the value of PHC.

The Government has recognised the importance of personalising healthcare and made significant investment in PHC-related activities. These include the development of key national strategic policies, funding research and infrastructure and commissioning the National Medicines Policy review which will encompass precision medicine technologies. Other countries such as England, France and the United States (US) have also recognised the benefits of, and are investing in, PHC.

While the transformational impact of PHC is already being realised, there are significant policy challenges associated with integrating the broad range of precision medicine technologies into our healthcare system. Given the rapid rate of evolution of these technologies, the capacity for adequate policy responses by Government is being compromised, leading to responses which are mostly reactive, fragmented and ad-hoc. The Government has an opportunity to address this critical strategic gap by committing dedicated resources to urgently develop a coordinated PHC Strategy to ensure that the benefits of PHC are not lost to Australia.

Beyond developing a PHC Strategy, there are other priority actions which would accelerate the adoption of PHC.

Firstly, existing Health Technology Assessment (HTA) methodologies need to be urgently reviewed to ensure they evolve in line with scientific, medical and technological advances. For some precision medicine technologies, current HTA methodologies have been rendered unworkable or inadequate. This need has been widely identified by independent expert reports, with the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) initiating a recent review to its HTA methodology for

this very purpose. More recently still, in Australia, the MBS Review Taskforce noted the need for reform to harness innovation to deliver contemporary care and the assessment challenges posed by new technologies. Importantly, it also noted that technological innovations such as personalised medicine and genomics have *“the potential to significantly change care and, while likely increase some costs, may lead to more targeted, cost-effective interventions”*.¹

Secondly, initiatives to encourage and accelerate the translation of PHC-related research funded by the Government into clinical practice are required. This would allow Australia to more rapidly reap the benefits of PHC and maximise the significant investment Government has already made in this regard.

Another ambitious but critical initiative to build on existing research investment will be establishing a national genomics service which, through a range of partnerships, can better link research and clinical care within a quality framework. The development of an ambitious health and infrastructure asset such as this would require multiple partnerships and funding sources but in turn would incentivise and accelerate research and advance clinical practice. It would also cement Australia as a genomics centre of excellence within the Asia Pacific region which can attract investment but also export knowhow. Roche’s experience in partnering with academia, clinicians, research institutions and Government demonstrate that such partnerships are possible with many benefits from sharing and building on established infrastructure to advance science for the ultimate benefit of patients.

As outlined in this submission, Roche believes increased investment in healthcare and innovation through PHC is key to ensuring our healthcare system delivers, and continues to deliver, quality health outcomes whilst strengthening the economy. Policies which actively reduce such investment could result in these benefits being lost to Australia. This is particularly important in the context of recent changes to medicine pricing policy in the United States (US) which are likely to have significant impact on innovative medicine availability in Australia as companies may decide to not bring such medicines to Australia or even withdraw existing innovative medicines from the Australian market.

Australia’s world-leading response to the pandemic, underpinned by national leadership and flexible and agile policy responses, provides us with the opportunity to consider how we can build on what we did well and how we could do things differently in healthcare. Through this Budget, the Government has a precious opportunity to set an ambitious, future-focused health policy agenda to build on the growing momentum of PHC and leverage current PHC investments and Australian capabilities to promote health and economic growth.

Recommendations

1. Develop a publicly available ten year strategic plan with priority actions co-created with stakeholders including clinicians, consumers and industry to implement adoption of PHC in Australia, overseen by a dedicated Section in the Department of Health.
2. Establish an independent expert committee including health economists, clinicians, consumers and industry to horizon scan and review HTA approaches for precision medicine technologies. A report on the HTA changes recommended should be completed by March 2022 to inform potential changes to relevant HTA guidelines.
3. Incentivise the translation of Government funded research in PHC into clinical practice.
4. Establish a national genomic service to bring research and clinical practice together within a quality framework.

Current Environment

The value of PHC and precision medicine technologies has been recognised for some time, with the Government making numerous investments into PHC-related initiatives.

Throughout 2020, the momentum in progressing with PHC slowed as Government rightly focused on managing the pandemic, providing national leadership and coordinating timely and flexible policy responses. As a result of the Government's considerable efforts, Australia's pandemic response has been one of the best in the world, mitigating economic damage and saving lives.

The pandemic had a significant impact on the Australian economy and highlighted the relationship between society, the economy, and health and therefore the importance of investing in healthcare to support economic prosperity. It also highlighted the value of precision medicine technologies which supported the public health response and the importance of the innovative medicines and health technology sectors which rapidly developed these technologies.

The pandemic also catalysed transformational and enduring changes to the healthcare system, highlighting that previous hurdles and challenges could be rapidly resolved to support Australians' access to the latest medical and health technologies. There is an opportunity to build on these changes and the flexibility and agility which underpinned these responses as the journey to integrate PHC and precision medicine technologies into the healthcare system continues.

A recent development which may hamper Australia's ability to realise the benefits of PHC relates to proposed changes to the pricing environment for medicines in the US. As a result of these changes, companies may withdraw existing innovative medicines, including precision medicines, from the Australian market or decide not to launch products here. The local impacts of the US policy change would be exacerbated by the proliferation of local policies seeking to erode the value of innovation and therefore we would urge against the introduction of such policies.

PHC and its benefits

PHC is transforming healthcare by tailoring healthcare decisions to an individual based on what is most likely to work for them rather than on what is likely to work for the average patient population with that condition.

PHC uses patient-level health data generated in various settings and involves:

- generating and accessing deep and broad patient level data from multiple sources, including electronic health records, genomic testing, digital health technologies and advanced imaging;
- applying advanced analytics to derive meaningful insights into patients and their disease;
- using these insights to discover, develop and deliver personalised care plans.

PHC relies on precision medicine technologies which enable a more targeted approach to disease prevention, diagnosis, monitoring and treatment. Precision medicine technologies include:

- medicines (e.g targeted cancer medicines and immunotherapies);
- gene therapies;
- gene editing tools (such as CRISPR-Cas9);
- cell therapies;
- imaging devices;
- in-vitro diagnostic tests (e.g genetic and genomic tests, point of care tests);
- digital health technologies (e.g clinical decision support tools, digital diagnostics and remote disease monitoring tools); and
- artificial intelligence (e.g risk predictive algorithms).

PHC can improve patient and population-level health outcomes, deliver more efficient and sustainable healthcare and provide significant opportunities for economic growth. These benefits

are outlined further below.

a) Patient and population health benefits

PHC enables better health outcomes by:

- Targeting treatments to the cause of the patient's disease;
- Avoiding or reducing unnecessary or potentially harmful or expensive care;
- Providing earlier diagnoses, enabling earlier initiation of treatment which can improve health outcomes;
- Broadening treatment options by repurposing available treatments or facilitating the discovery of new treatments; and
- Driving more targeted and efficient research and development, thereby accelerating the discovery of new effective therapies or repurposing existing treatments.

Genomics is one of the most advanced precision medicine disciplines and genomic technologies are now able to rapidly sequence a large number of genes or all genes contained in human DNA (~22,000 genes) to identify mutations or other molecular alterations in a single test. Genomic testing is already benefitting patients with cancer (see Case Study 1) and rare diseases with future opportunities to improve health outcomes for complex conditions such as diabetes and cardiovascular disease.²

Case Study 1: Patient benefits

Genomic testing using next generation sequencing techniques (NGS) to analyse a patient's tumor sample can provide insights into the molecular drivers of the cancer's growth or other molecular information and identify the best treatment option for the patient. In lung cancer, identification of the molecular drivers of tumour growth has unlocked a number of high impact treatments for patients, greatly improving their prognosis and long-term outcomes. International cancer guidelines now recommend the routine use of NGS in lung cancer given the large number of molecular alterations that are able to be targeted for treatment by an approved medicine.³

The benefit of adopting a molecularly-guided treatment approach is shown by a recent study which found that patients with lung cancer who received molecularly-guided treatment as their first line of treatment were likely to survive three times longer than those who did not.⁴ This improved survival is significant in light of recent Australian data which shows that survival for lung cancer patients was only 18.6% at 5 years compared to 69.2% for all cancers combined.⁵

At a population level, precision medicine technologies have played a critical role in supporting global and local responses to the pandemic and it is reasonable to anticipate that the importance of these technologies will continue given the expected changes in infectious disease transmission patterns.⁶

Case Study 2: Population health benefits

Genomics and its associated technologies informed public health responses to the pandemic by identifying transmission chains and enabling the development of tests to detect the virus based on its genomic profile.⁷ Diagnostic tests were developed including point of care tests to enable diagnosis when a more rapid turn-around than possible with laboratory based tests was required.⁸

Laboratories around the world used machine learning techniques to create new drug candidates or predict if existing drugs may work as a vaccine against COVID-19.⁹ Some countries, including Australia, developed apps to trace individuals who may have been exposed to the virus to support their contact tracing activities.

b) Health system benefits – efficiency, reduced costs and sustainability

PHC technologies can enhance the value and efficiency of care and result in overall healthcare savings.¹⁰

Notably, in its December 2020 report, the MBS Review Taskforce recently noted that technological innovations such as personalised medicine and genomics have “*the potential to significantly change care and, while likely increase some costs, may lead to more targeted, cost-effective interventions*”.

A recent McKinsey report estimated that digital health interventions, which mostly comprise precision medicine technologies, could save the healthcare system in the US nearly \$500 billion in one year if fully adopted.¹¹ Despite the differences between the Australian and US healthcare systems, this figure provides a useful indicator of the magnitude of the benefits which could be realised through improved efficiency and delivery of care using digital technologies.

Case Study 3: Health system benefits

A report by the National Oncology Alliance highlighted a recent study conducted in Australia which found that replacing current standard of care testing for infants suspected of having a genetically driven disorder with genomic testing more than tripled the number of diagnoses at one third of the cost of achieving that diagnosis over current testing methodologies, resulting in savings of around \$2,180 per additional diagnosis.¹² This means that better patient outcomes were achieved at a lower cost to the healthcare system, representing a more efficient allocation of funds than current standard of care testing.

The sustainability of the healthcare system is being challenged by the growing number of older Australians and those suffering from a chronic disease, resulting in increased demand for healthcare services and rising costs. With these increasing trends, PHC and precision medicine technologies have been recognised as being a key enabler of our healthcare system’s sustainability as they assist the reorientation of healthcare from a model focused on treating illness to one focused on prevention and wellness. This reorientation is essential if Australia is to continue to maintain its good health outcomes into the future.¹³

In addition to promoting disease prevention and wellness, PHC technologies can also reduce the costs associated with these demographic trends by enabling earlier diagnosis, identifying treatments most likely to work (or cause harm) or improving chronic disease management, thereby reducing the need for more costly medical interventions.

Case Study 4: Health system benefits

Diabetes is a significant health problem in Australia with direct healthcare costs estimated to be around \$1.7 billion per year. The indirect health costs may be as high as \$14 billion per year and include reduced productivity, absence from work, early retirement and premature death.¹⁴

A number of recent innovations in PHC technology for diabetes treatment and management may alleviate some of this healthcare cost burden. A recent German study in type-2 insulin dependent patients found clinical and economic benefits to adopting an integrated personalised diabetes management (iPDM) approach compared to the control group. iPDM combined structured self-monitoring of blood glucose, use of diabetes management software and collaborative patient-physician communication and support of therapeutic decision-making.

This approach led to better blood glucose control (which reduces diabetes related mortality and morbidity), more timely treatment adjustments and increased patient adherence¹⁵ and resulted in savings of €2839.92 per Quality Adjusted Life Year Gained.¹⁶ This approach could be useful in Australia given recently published data indicates that Australia has had limited success in reducing the occurrence of diabetes-related complications and improving quality of life.¹⁷

c) Economic benefits

Given Australia’s research strength in biotechnology and genomics, coupled with rich data from the public

healthcare system, the Government is in a unique position to promote Australia as a leading provider of precision healthcare products and services to the region¹⁸ as a means of promoting economic growth.

PHC-enabling technologies such as artificial intelligence, the Internet of Things (which connects the physical and digital worlds through connecting computer devices to allow the transfer of data) and precision medicine are driving the Fourth Industrial Revolution.¹⁹ The opportunity of the Fourth Industrial Revolution leverages many of Australia's existing competitive strengths and economic imperatives leading to the creation of new markets, products and services. As such, PHC and precision medicine are prominent strategic opportunities for Australia, with an estimated market for precision healthcare solutions in the Asia-Pacific generating annual revenues worth \$30–50 billion within a decade.²⁰ Furthermore, the global market for precision medicine is growing quickly – it was valued at \$43.98 billion USD in 2018 and is expected to grow to \$86.25 billion USD by 2025.²¹

In terms of regenerative medicines (which include cell and gene therapies), MTP Connect predicts that if Australia were to capture 5% of the global market, this could generate \$6 billion in annual revenue and create approximately 6000 jobs.²² In terms of digital health, which encompasses many precision medicine technologies, McKinsey estimates that the global market was valued at around \$350 billion in 2019 with an expected annual growth of around 8%.²³

Roche is of the view that in order to accelerate the introduction of PHC in Australia, the Government needs to better coordinate and leverage existing investments and capabilities. Our recommendations on priority actions that could be introduced as part of the Budget are outlined below.

Develop a PHC Strategy

The Government has recognised the importance of PHC for the future of healthcare and developed key strategies including:

- The *National Health Genomics Policy Framework 2018-2021* which outlines the issues that need to be addressed to enable the uptake of genomics in clinical practice in Australia;
- *Australia's Long Term National Health Plan* which commits to implementing a 10 year plan for primary care, including access to and research relating to many precision medicine technologies. The Plan also establishes a *National Preventive Health Strategy* which includes precision medicine technologies; and
- The *National Digital Health Strategy* which provides a vision for how to expedite the development of Australia's digital health foundations in a coordinated manner across jurisdictions and the public and private sectors.

The Government has also committed to a review of the National Medicines Policy to ensure it remains fit-for-purpose and expands beyond medicines to consider the rapidly growing range of precision medicine technologies. This review is currently scheduled to commence in 2021.

The above initiatives involve related or overlapping activities and complex policy considerations to appropriately integrate PHC into healthcare. For example, some of these technologies challenge the definition of value and how that value is assessed for reimbursement purposes using existing HTA processes. Other challenges include having the necessary workforce capacity and capability to use these technologies to deliver quality care when and where it is required and maximising the value of the data being collected across various settings.

The fragmentation of responsibility for the policy issues within and across Government Departments can delay or reduce the efficiency with which these challenges are resolved. For example, in genomics, of the six organisational groups within the Department of Health, four have responsibility for different elements of genomics policy, spread amongst various Branches within these groups. Other Departments such as the

Department of Industry and the Australian Digital Healthcare Agency also have a role in genomic health policy. Continued separation of activities, coordination and accountabilities for genomics policy is not efficient, risks duplication and inconsistencies in outcomes, hampering Australia's capacity to reap the benefits of PHC.

Roche considers it may be more efficient for Government to develop a comprehensive PHC strategy, based on the consolidation of all current PHC related initiatives across Government, identify implementation progress and gaps in activity across key areas. The Strategy should be co-created with stakeholders and be presented to Government by March 2022, and its development be overseen by a dedicated Section in the Department of Health.

Recommendation

Develop a publicly available ten year strategic plan with priority actions co-created with stakeholders including clinicians, consumers and industry to implement adoption of PHC in Australia, overseen by a dedicated Section in the Department of Health.

Review HTA for precision medicine technologies

The assessment for reimbursement of precision medicine technologies using existing HTA methodologies is challenging due to inherent features of the technologies, evolving clinical trial designs and the increasing stratification of diseases resulting in smaller patient populations being studied.

Experts and published literature outline the need for existing HTA methodology to evolve to cater for the scientific, medical and technological changes which have rendered existing methodologies unfeasible or inadequate for some technologies. For example, the assessment approach for co-dependent technologies (i.e those where one technology relies on the use of another to achieve its intended effect such a genomic test and a medicine that is linked to the finding from that test) needs review to ensure that access to genomic tests or the linked medicine is not unnecessarily delayed. Further detail on these challenges are outlined in Roche's submission to the Parliamentary Inquiry into the approval processes for new drugs and novel medical technologies in Australia (pages 18 – 22). Without an urgent HTA review, the benefits of these technologies to Australian patients may be delayed or altogether unavailable.

In recognition of the range of HTA issues posed by new technologies, on 6 November 2020, the NICE, which undertakes HTA reviews of health technologies in the UK, released a consultation paper outlining a review of its methodology in response to "*developments in science and technology leading to rapid changes in healthcare and health technology evaluation*". The MBS Review Taskforce also recently noted the need for reform to better harness innovation. We would therefore urge the Department of Health to recognise the need for a review of HTA processes, taking into consideration the feedback provided to the above Parliamentary Inquiry as a starting point.

Roche recommends that an independent committee comprising relevant experts, including consumers, be established to horizon scan for emerging technologies that are likely to pose HTA challenges and consider how they may be assessed. This will ensure that PHC-enabling technologies are considered in a timely and pragmatic manner and that Australia continues to operate an equitable and efficient healthcare system that delivers world-class outcomes for patients.

Recommendation

Establish an independent expert committee including health economists, clinicians, consumers and industry to horizon scan and review HTA approaches for precision medicine technologies. A report on the HTA changes recommended should be completed by March 2022 to inform potential changes to relevant HTA guidelines.

Incentivise Translation of Research into Clinical Practice

The Government has invested significantly in PHC-related research, including funding the Australian Genomics Health Alliance and the Genomics Futures Health Mission under the Medical Research Futures' Fund (MRFF) to conduct a range of genomics research activities. For example, under the MRFF, the Government and Roche co-funded ASPIRATION, a research study collecting evidence on genomic testing of lung cancer patients in Australia.

Activities which encourage the translation of research findings into clinical practice will enable the benefits of PHC to be realised more quickly and ensure Government derives maximum value from its significant MRFF investment. These activities could include:

- Incentivising the development of translational strategies for research findings by abridging, simplifying or expediting grants processes for academics and clinicians;
- Funding collaborative research between academics, clinicians and industry to focus on integrating PHC into practice;
- Where research involves specific health technologies, the Department of Health expediting the pathways for their HTA evaluation following conclusion of the research;
- Funding clinical groups to develop practice guidelines that assist the translation of research into practice;
- Embedding public reporting of translational research rates as key a performance indicator to the MRFF's reporting requirements; and
- Including translational research requirements and transparency of how the research was embedded into practice as a key component of a PHC Strategy.

Recommendation

Incentivise the translation of Government funded research in PHC into clinical practice.

Establish a National Genomics Service

Given the significant Government investment in genomics, the highly successful genomics research agenda and the complexity of implementing genomics in clinical practice, Roche recommends establishing a national genomic service, initially focused on rare diseases and cancers as these are the areas with the most evidence of health benefit from genomic testing.

The service would accelerate the translation of genomic research into clinical practice within a quality framework that builds scientific and medical knowledge, evidence and capability by bringing together a range of clinical services required for quality, integrated, streamlined multidisciplinary patient care, education, training and research. It would also ensure better value from genomic data holdings and facilitate academic and industry partnerships.

The development of an ambitious health and infrastructure asset such as this for Australia would require multiple partnerships and funding sources but in turn could incentivise and accelerate research. It would also cement Australia as a genomics centre of excellence within the Asia Pacific region which can attract investment but also export knowhow.

Recommendation

Establish a national genomics service to bring research and clinical practice together within a quality framework.

Conclusion

Investing in PHC can result in improved health outcomes, health system sustainability, economic growth and job creation, assisting to strengthen Australia's economic position. This Budget provides an opportunity to build on existing investments in PHC and the changes catalysed by the pandemic to build a resilient and future-focused healthcare system.

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