# 2022-23 Roche Pre-Budget Submission

January 2022

# 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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose, and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials, and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested around $13.5 billion US Dollars in research and development worldwide, including over AUD $46 million in pharmaceuticals in Australia. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

Roche's pharmaceutical division in Australia employs over 300 people who are dedicated to pioneering life-changing healthcare for every Australian via the clinical development, registration, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to around 40 Roche medicines, and Roche is a continued leader in oncology.

Roche's Diagnostics division in Australia employees over 200 people and has a broad range of in-vitro diagnostics. Our efforts are concentrated 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. Roche Diabetes Care aims to transform and advance care provision and foster sustainable care structures. Under the brands RocheDiabetes, Accu-Chek and mySugr, comprising glucose monitoring, insulin delivery systems and digital solutions, Roche Diabetes Care unites with its partners to create patient-centred value. 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 better outcomes and true relief.

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

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# Executive Summary

Healthcare and economic prosperity are inextricably linked, and this has been thoroughly demonstrated by the ongoing economic uncertainty due to the SARS-CoV-2 pandemic. As such, the importance of continued Australian Government investment in innovative healthcare treatment, alongside expedited approaches to access momentous innovative health treatments, is imperative to meet future healthcare needs, to improve healthcare system efficiency, and to support economic growth.

A real opportunity exists to outline and fund policy programs and reforms in the Federal Budget which will boost investment into Personalised Healthcare (PHC) technologies, including precision medicines, diagnostics and digital healthcare tools. The release of recommendations from the Standing Committee into Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia (House of Representatives Inquiry), an ongoing review of the National Medicines Policy, as well as an upcoming independent review of Health Technology Assessment (HTA), has created a policy landscape of promising reform opportunities.

In this submission, Roche makes recommendations for the Federal Budget which would see many of Roche's existing PHC policy positions, and recommendations from the House of Representatives Inquiry supported, resourced, and implemented. Including these recommendations in the 2022-23 Federal Budget would also lead to improved health outcomes, support health system value, efficiency, sustainability and foster economic growth.

Recognising the expertise required to bring these new PHC innovations to Australian patients, Roche supports the recommendation from the House of Representatives Inquiry to establish and fund a Centre for Precision Medicine and Rare Diseases within the Department of Health. This Centre needs to have the capability and expertise to undertake a broad program of work, including ensuring fit-for-purpose HTA mechanisms for PHC technologies such as precision medicines, diagnostics and digital healthcare tools, and supporting a national genomic testing program. In order to achieve this, the Centre needs to deliver a ten-year strategy for how this work is delivered.

Roche also believes that this Budget needs to include the funding for the Independent HTA Review, which is due to begin in mid-2022, and that the funding should be sufficient so that the scope of the HTA review can be expanded to include a review of the Medical Services Advisory Committee (MSAC). Roche believes this is a crucial inclusion to ensure that HTA methodologies for PHC technologies, including co-dependent technologies, are viable in the long term. Concurrently, Roche believes a review of the HTA process for blood products should also be undertaken to ensure that methodologies for these products are aligned with other Australian HTA systems.

With a high-quality healthcare system, and an internationally renowned research sector comprising world leading expertise in genomics and biotechnology, Australia is well placed to take advantage of PHC, and reap the societal and economic benefits they can bring. To do so, Roche believes that the Government should look at the broader aspects of value in assessing these medicines, and investigate policy levers which will elevate Australia to become a leader in PHC in the Asia-Pacific region.

Through this Budget, the Australian Government has a unique opportunity to take advantage of the current health policy landscape, and set ambitious, future-focused PHC policies which builds on Australia's capabilities and promotes economic growth. Policies which actively reduce such investment could result in Australia missing out on meaningful economic benefits.

# Summary of Recommendations

**Establish the Centre for Precision Medicine and Rare Diseases**

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government establish a Centre of Precision Medicines and Rare Diseases within the Department of Health within this budget cycle, to ensure that there is sufficient understanding and expertise about precision medicines.
2. That the Australian Government clearly outlines the responsibilities of the Centre of Precision Medicines and Rare Diseases, and that funding of the Centre is sufficient to include the responsibility to establish a new, clear and certain HTA pathway for precision medicines.
3. That the Australian Government jointly fund a nationwide genomics testing program with the states and territories, run through the Centre of Precision Medicines and Rare Diseases.

In addition to these recommendations, Roche recommends that:

4. That the Australian Government also includes an added responsibility for the Centre to complete and publicly publish a ten-year strategy for PHC technologies such as precision medicines, diagnostics and digital healthcare tools in Australia in consultation with the relevant stakeholders.

**HTA review for Precision Medicine**

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government ensures that the independent HTA Review is sufficiently resourced to run in the 2022/23 financial year, to complete a thorough and comprehensive review of the HTA system for precision medicines.

**HTA review for co-dependent technologies and blood products**

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government ensures that the Independent HTA Review is sufficiently resourced to include a review of MSAC processes, including HTA methodologies for genomic tests and digital health tools, so that the broader issues of timely and affordable access to these PHC technologies can be addressed.
2. That the Australian Government ensure funding for a review of the HTA process for blood products, along with the National Blood Authority and state and territory governments, to better align with the HTA system for other products.

**Health system and economic benefits**

Roche recommends:

1. That the Australian Government commits to fund the Independent HTA Review so that a review of the broader dimensions of value, including societal value, and economic value can be incorporated (beginning in July 2022).
2. That the Australian Government commits to provide funding to the Department of Health to investigate the opportunity for Australia to become a leading provider and contributor of PHC products and services in the Asia-Pacific.

# Personalised Healthcare in the context of rare diseases and areas of high unmet clinical need.

PHC is transforming healthcare by tailoring decisions to an individual based on what is most likely to work for them rather than what is likely to work for the average patient population with that condition. The range of PHC technologies which are critical to enabling PHC is very broad, and it includes:

- medicines (e.g. targeted cancer medicines, immunotherapies),
- gene therapies,
- cell therapies (e.g. chimeric antigen receptor T-cells (CAR-T)),
- imaging devices, in-vitro diagnostic tests (e.g. genetic and genomic tests),
- digital health technologies (e.g. clinical decision support tools, digital diagnostics and remote monitoring tools),
- artificial intelligence such as risk-predictive algorithms,
- gene editing techniques such as CRISPR-Cas 9, and
- Real World Evidence (RWE) and advanced data analytics.

Many of these technologies represent key innovations with the potential to significantly improve patient outcomes, and they are expected to transform healthcare across the next decade. For many patients, a PHC approach is not only relying on new technologies; it also represents broadening the use of existing treatments or indeed identifying whether treatment is actually unnecessary.

PHC technologies are making a significant impact by providing the diagnostic and digital health tools and treatments which can deliver and support better patient care in rare diseases. They also represent a broadening use of existing treatments, or identifying whether treatment is actually necessary.

# Establish the Centre for Precision Medicine and Rare Diseases

Roche is of the view that in order to accelerate the introduction of PHC in Australia, particularly precision medicine, the Government needs to follow a three step process, as outlined by Roche in its submission to House of Representatives Inquiry:

1. Establish a dedicated section of the Department of Health for precision medicines, with the responsibility to develop a publicly available ten-year strategic plan, with priority action co-created with stakeholders, on the adoption of PHC in Australia.
2. Establish an independent committee of innovative health technology experts, clinicians, consumers and industry to horizon-scan and review HTA approaches for precision medicine technologies.
3. Clarify HTA requirements and pathways for emerging medical technologies including digital healthcare technologies, artificial intelligence, gene and cell therapies.

In November 2021, the House of Representatives Inquiry released their report: *The New Frontier - Delivering better health for all Australians* to the Australian Government which had recommended very similar actions. A number of recommendations[1] were specifically about precision medicine, including a recommendation that the Australian Government establish a Centre for Precision Medicine and Rare Diseases within the Department of Health. This Centre would[2]:

- Provide Australians with timely access to new drugs and medical technologies,

- Advise the Department of Health and Australian Medical Research Advisory Board on research priorities,
- Provide education and training for patients,
- Include a comprehensive horizon scanning unit, and
- Advise on the establishment of a dedicated regulatory HTA pathway for cell and gene technologies, in consultation with stakeholders, and advise government on the effectiveness of these pathways.

The Committee made it clear in their opinion, that the Department of Health should be supported to expand its understanding and expertise of precision medicines, so that Australians have timely access to these transformative therapies including for rare diseases where there are limited treatment options.[3] Roche agrees with this recommendation, and believes it is imperative for the Australian Government to establish the Centre within the Department of Health as soon as possible.

The Committee also outlined a recommendation that this Centre should build on the Medical Research Fund Genomics Mission, and should jointly fund a national testing program to provide equitable testing nationwide.[4] Roche has previously raised the issues with a 'one test, one gene, one drug' approach which would avoid a number of genetic tests that can identify a large number of genetic mutations simultaneously never being recommended for reimbursement, and so, strongly supports this recommendation.

In addition to the Committee recommendations, Roche believes that the Centre should also work collaboratively with stakeholders on the development of an overarching precision medicines strategy. Given the rapid growth in precision medicine technologies and the complex policy challenges they face beyond just regulation and reimbursement (such as ethics, health system integration, and equity of access), a long term strategy would systematically and efficiently address these challenges.

## Recommendations

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government establish a Centre of Precision Medicines and Rare Diseases within the Department of Health within this budget cycle, to ensure that there is sufficient understanding and expertise about precision medicines.
2. That the Australian Government clearly outlines the responsibilities of the Centre of Precision Medicines and Rare Diseases, and that funding of the Centre is sufficient to include the responsibility to establish a new, clear and certain HTA pathway for precision medicines.
3. That the Australian Government jointly fund a nationwide genomics testing program with the states and territories, run through the Centre of Precision Medicines and Rare Diseases.

In addition to these recommendations, Roche recommends that:

4. That the Australian Government also includes an added responsibility for the Centre to complete and publicly publish a ten-year strategy for precision medicines in Australia in consultation with the relevant stakeholders.

# The Independent HTA Review

## HTA for precision medicine

As outlined above, both Roche and the House of Representatives Inquiry Committee have put forward recommendations about a dedicated section of the Department of Health for precision medicines, which would clarify and establish a HTA pathway for new therapies including cell and gene therapies. The Committee was of the clear view that precision medicine approval pathways will require a different application assessment than current approaches designed for treatments of common conditions.[5]

In 2021, a Strategic Agreement was signed between the Commonwealth and the medicines industry in Australia represented by Medicines Australia and the Generic and Biosimilar Medicines Association. As a part of the agreement with Medicines Australia, an independent policy and methods review of Australia's HTA system was agreed to.

The House of Representatives Inquiry Report noted its support for this key measure in the Strategic Agreement, and within its report, specific HTA reforms were included that it recommended the Independent Review Committee consider when the review begins in July 2022.[6] Among them, the Committee recommended that the review reassess relevant aspects of the HTA process to ensure there are future pathways for treatments and therapies such as precision medicines, which do not fit neatly into the current system.[7]

The inherent features of these technologies, evolving clinical trial designs, the increasing stratification of disease with smaller patient populations, makes existing HTA methodologies difficult to navigate. The recommendations from Roche and from the House of Representatives inquiry Report highlight the challenging nature of assessment for reimbursement of precision medicine technologies using existing HTA methodologies, and Roche supports a thorough examination of HTA in Australia.

### Recommendations

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government ensures that the independent HTA Review is sufficiently resourced to run in the 2022/23 financial year, to complete a thorough and comprehensive review of the HTA system for precision medicines.

## HTA review for co-dependent technologies and blood products

There are also many methodological issues associated with the HTA for co-dependent technologies that make the process unworkable, which Roche highlighted in its submission to the House of Representatives Inquiry.[8] The assessment approach for co-dependent technologies (i.e. those where one technology relies on the use of another to achieve its intended effect) needs review to ensure that access to these technologies is not unnecessarily delayed.

Roche believes that the Independent HTA review must look at the challenges in conducting assessments that hamper reimbursement of co-dependent technologies. This includes[9,10]:

- Small patient populations, lowering robustness of clinical evidence
- Evidence may not be available to the current evidentiary standard, and
- Methodological challenges with the technology

There are also challenges with timing and alignment through different pathways for co-dependent technologies, which can delay timely access to these technologies. As one cost-effectiveness HTA assessment can rely on, or influence the outcome of, the other HTA cost-effectiveness assessment, a convoluted, circular process can occur.

To address this, Roche believes that the independent HTA Review must consider these issues, and that a review of the Medical Services Advisory Committee (MSAC) should be included in the HTA Review. This would also provide the opportunity to ensure MSAC methodologies and guidelines are keeping pace with the growth in digital health technologies and their rapid rate of iterative innovation. The House of Representatives Inquiry also made the recommendation to include MSAC in the Independent HTA Review to the Department of Health in their Report.[11]

Additionally, Roche's experience with an innovative product to treat a blood disease has highlighted similar challenges in navigating HTA processes where it was unclear whether the National Blood Authority or the MSAC was the correct pathway. The Committee also put forward the recommendation that the Department of Health, alongside the National Blood Authority, and State and Territory Governments reform the HTA process for blood products to better align with the HTA system.[12]

If some of these issues are resolved through the review, there could be more treatments made available for patients with rare diseases or in other patient populations with high unmet need in a more timely manner. These issues relate to broadening the scope of how the full benefits to the health system and economy of a technology are valued, which are discussed further below.

## Recommendations

In line with the recommendations outlined in the House of Representatives Inquiry Report, Roche recommends:

1. That the Australian Government ensures that the Independent HTA Review is sufficiently resourced to include a review of MSAC processes, including HTA methodologies for genomic tests and digital health tools, so that the broader issues of timely and affordable access to these PHC technologies can be addressed.
2. That the Australian Government ensure funding for a review of the HTA process for blood products, along with the National Blood Authority and state and territory governments, to better align with the HTA system for other products.

# Health system and economic benefits

The sustainability of Australia's health system is being challenged by a growing number of older Australians, and those suffering from a chronic disease, which results in increased demand for health services. While some costs may increase with personalised medicine and genomics, PHC technologies will significantly enhance the value and efficiency of care, and may lead to more targeted cost-effective interventions and overall healthcare savings.[13,14]

Some estimates for some digital interventions estimate savings of nearly $500 billion in one year in the United States if fully adopted[15], which provides a useful indicator of the magnitude of benefits which could be seen in Australia despite its differences to the US system. Reorientation to PHC and

precision medicine technologies are recognised as a key enabler of healthcare system sustainability and are essential if Australia is to continue to maintain good health outcomes into the future.[16]

In order to ensure that Australia continues to be well positioned to access new precision medicine technologies, broader dimensions of value, including societal value, need to be included, and encouraged, in assessments for reimbursement. This is because the extent of indirect benefits of newer technologies can be significant and should be quantified as part of the cost-effectiveness evaluation as this ensures the evaluation is more reflective of the overall value of the technology to society.

The House of Representatives Inquiry Committee noted in the Inquiry Report that the Committee was of the opinion that the HTA process should take a broader view of the costs and benefits associated with a medicine being evaluated for reimbursement, and that it should ascribe more value to long term benefits.[17] The Committee indicated that these matters should be considered as part of the Independent HTA Review, as continuing with the current approach could forgo opportunities to adopt technologies that may lead to a more efficient, effective, and affordable healthcare system.

While investing in PHC can lead to system sustainability, Australia could also position itself for broader economic benefits from PHC. Given Australia's research strengths in biotechnology and genomics, coupled with rich data from the public health system, Australia could be a leading provider and contributor of PHC products and services to the Asia-Pacific region, with the potential to generate annual revenues worth $30 to $50 billion dollars.[18]

## Recommendations

Roche recommends:

1. That the Australian Government commits to fund the Independent HTA Review so that a review of the broader dimensions of value, including societal value, and economic value can be incorporated (beginning in July 2022).
2. That the Australian Government commits to provide funding to the Department of Health to investigate the opportunity for Australia to become a leading provider and contributor of PHC products and services in the Asia-Pacific.

# Concluding comment

The Federal Budget provides an opportunity to build on existing investments in PHC, by establishing dedicated resources within the Department of Health to strategically plan on incentivising these healthcare solutions and investigating HTA pathways for timely access. The independent HTA Review will also provide opportunities for the Australian Government to investigate the HTA pathways for precision medicines, as well as for co-dependent technologies, and for blood products.

This Budget also provides an opportunity to look at the broader benefits of PHC, and ensure that Australia has 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. 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.

# References:


1. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 1. Page xxxi

2. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 2. Page xxxii

3. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Page 229

4. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 2. Page xxxii

5. Ibid.

6. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 30. Page xliv

7. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 29. Page xliii

8. Roche Submission to the House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into the Approval process for new drugs and novel medical technologies. October 2020.

9. Faulkner et al 2019. *Are Global Health Systems Ready for Transformative therapies?* Value Health 22(6):627 - 641

10. OECD 2017. *New Health Technologies: Managing Access, Value and Sustainability*

11. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 31. Page xlvi

12. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Recommendation 7. Page xxxiv

13. World Economic Forum. 2020. *Precision Medicine Briefing*. Page 16

14. MBS Review Taskforce Report December 2020

15. McKinsey & Company. 2020. "*Healthtech in the fast lane: What is fueling investor excitement?*" Page 5

16. CSIRO. 2018. "*Future of Health*". Page 5.

17. House of Representatives Standing Committee on Health, Aged Care, and Sport Inquiry into Approval Processes for New Drugs and Novel Medical Technologies, 2020. *The New Frontier - Delivering better health for all Australians.* Page 164

18. AlphaBeta. 2018. "Digital Innovation – Australia's $315b opportunity." Page 6