VALUING LIFE

New Zealand Medicines Access
SUMMIT, WELLINGTON

www.valuinglife.nz

2024 WHITE PAPER

PREPARED BY

PATIENT VOICE AOTEAROA
HE REO TŪRORO O AOTEAROA

Medicines New Zealand

17 September 2024

Dear Valuing Life Summit Attendees

On behalf of our respective organisations and the summit organising committee, we are jointly writing to you to thank-you for your participation, inputs into, and feedback after, the inaugural Valuing Life New Zealand Medicines Access Summit held at Parliament on 29-30 April 2024.

All of your inputs and feedback have aided us in the generation of this whitepaper.

Since the summit, we have all been back to our core work, and this includes the government. So it has been positive to see government's June announcements around the additional increase in the medicines budget, and the July launch of the Minister's Letter of Expectation for Pharmac.

It was pleasing to see the government announcements align with some of the key findings from the summit that are presented in the whitepaper. But there is much more to do.

The whitepaper also highlights actions requiring meaningful and authentic multi-stakeholder engagement to be undertaken. In that regard, it echoes many OECD Health Directorate reports which state that public-private multi-stakeholder approaches are required to enhance prescription medicines access and optimal use; patient and health system outcomes; and health innovation.

We look forward therefore, to continuing the multi-stakeholder approach with you all on the proposed actions highlighted in the report. This will mean that the next Valuing Life Medicines Access Summit in 2025 will be able to build on the groundwork generated from the inaugural summit this year.

Ngā mihi mahana / Warm regards

Dr Malcolm Mulholland
Chair, Patient Voice Aotearoa

Mr Todd Krieble
Chair, Medicines New Zealand

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1.0 EXECUTIVE SUMMARY

The Valuing Life: New Zealand Medicines Access Summit, held on April 29-30, 2024, at New Zealand's Parliament Buildings, was a landmark event hosted by Hon David Seymour, Associate Minister of Health (Pharmac). Co-facilitated by Patient Voice Aotearoa and Medicines New Zealand, the summit aimed to address critical issues in medicines access.

Collaboratively creating the future.

The summit brought together a wide range of stakeholders including patient advocates, clinicians, representatives of the pharmaceutical industry, Government officials and academics. Presentations and discussions at the summit highlighted the complexities of medicines access in New Zealand and acted as a precursor to the four workshops held in the afternoon of the first day of the summit.

Workshop topics included were:

1. Enhancing HTA processes in New Zealand.

2. Building a fit-for-purpose Medicines Strategy for New Zealand.

3. Better stakeholder engagement in decision-making processes.

4. Health innovation optimisation in New Zealand (precision health, clinical research and horizon scanning).

This report focuses on the outcomes of these workshops, including key findings, and common themes.

Valuing Life - Medicines Access Summit 2024 Attendees

THEMES FROM THE WORKSHOPS

The discussions from the four workshops held at the Valuing Life: Medicines Access Summit provided the opportunity for a wide range of stakeholders to come together to debate the challenges currently faced in medicines access in New Zealand, and to identify opportunities to address those challenges.

Although the workshops covered different aspects of medicines access, review and synthesis of the records from each identified a number of common themes, leading to recommended actions. These common themes and recommended actions are presented below.

1.1 Amend Pharmac's Statutory Objective

1.1.1 Pharmac's statutory objective in the Pae Ora (Healthy Futures) Act is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

1.1.2 This objective has resulted in a primary focus on cost, distorted decision-making, and sub-optimal outcomes for patients. Pharmac's statutory objective needs to be amended to ensure there is a clear focus on outcomes, recognition of the role and value of investment in medicines, appropriate inclusion of societal benefit, and better integration of the funding of medicines into the wider health system.

1.2 Health Technology Assessment and Decision Making

1.2.1 The needs of patients, their families and whānau, and clinicians working in the New Zealand health system are not fulfilled by Pharmac's current Health Technology Assessment (HTA) methodology. The HTA methodology and decision-making process needs to evolve in step with international best practice and changing societal and patient needs.

1.2.2 Review and refinement of the current HTA methodology and decision-making process needs to enable flexibility of approaches, increase transparency and accessibility, enable consideration of patient input and lived experience, and allow wider government and societal impacts to be considered. The potential for streamlining and simplifying assessment and decision-making processes also needs to be addressed.

1.3 Greater Investment in Medicines

1.3.1 Current investment in medicines and health innovation is insufficient to ensure that public expectations are met, and New Zealand keeps pace with peer nations.

1.3.2 Greater investment is needed to enable medicines on Pharmac's Options for Investment (OFI) list to be funded and for New Zealand to make progress in funding other medicines that are already part of international standards of care.

1.4 Medicines Strategy

1.4.1 A comprehensive, future-focussed medicines strategy should be developed with a clear vision, mission, priorities, and targets. It needs to have a patient-centric focus and articulate long-term goals for investment and meeting of international standards of care.

1.4.2 The strategy should be developed through a multi-stakeholder approach.

Hon David Seymour, Associate Minister of Health (Pharmac)

1.5 Building on the Pharmac Review

1.5.1 The Pharmac Review was undertaken with significant engagement and input from the patient community and other stakeholders. The Review's findings were significant and important. However, it is unclear to what extent the recommendations of the Review have been appropriately implemented and what may still be outstanding.

1.5.2 The work of the Independent Review Panel must not be wasted. Pharmac and the Ministry of Health should revisit the Review findings and evaluate actions taken to date to ensure meaningful delivery of the Review's recommendations, in conjunction with the patient community.

1.6 Multi-Stakeholder Engagement with a Patient-Centric Focus

1.6.1 Multi-stakeholder engagement with a patient-centric focus is critical to working through the challenges that create blocks in the current system.

1.6.2 Effective stakeholder engagement needs wide-ranging and early involvement of patients, patient groups, consumers, industry and other parties, together with transparency and accountability, simplification of process, and appropriate resourcing.

1.7 A Cohesive System - breaking down silos

1.7.1 The funding of medicines must be seen within the context of consistent and cohesive approaches to funding across the health system, and not be siloed. Taking this approach would benefit all stakeholders in the health system by ensuring investment across the health system is optimised and flows through to broader societal benefits.

1.8 Clinical Trials, Precision Medicines and Horizon Scanning

1.8.1 The New Zealand medicines approval and funding system should actively identify and consider what patients, clinicians and society will need in the future and plan for it, rather than passively sitting back waiting for applications and falling behind.

1.8.2 Horizon scanning is needed to identify new health innovations, such as emerging technologies, and plan for their incorporation into the health system.

1.8.3 A structure and framework for a national precision health platform is needed, together with an enabling environment for clinical trials.

1.9 Benchmarking

1.9.1 Benchmarking New Zealand internationally is essential to ensure that New Zealanders have access to medicines that are standard of care in peer nations.

1.10 Collaboration and Learning from International Examples

1.10.1 New Zealand can benefit from international examples and should continue to engage with organisations worldwide to learn and adopt best practices and leverage collaborative opportunities to improve medicines access.

2.0 RECOMMENDED ACTIONS

2.1 Amend the Pae Ora (Healthy Futures) Act 2022 and associated regulatory framework:

- Amend Pharmac's statutory objective to:
  - Ensure a focus on best health outcomes.
  - Enable the appropriate incorporation of societal benefit.
  - Ensure that medicines funding decisions are consistent with overall health system priorities.
- Provide for the preparation of a medicines strategy.
- Include commissioning/procurement and reviewing of medicines in the Government Policy Statement on Health.

Responsibility: Minister of Health and Associate Minister of Health (Pharmac)

2.2 Review Pharmac's Health Technology Assessment (HTA) and decision-making process:

- Establish a review of Pharmac's Health Technology Assessment (HTA) and decision-making process.
- Ensure the review provides for multi stakeholder engagement (patients, industry etc.) for true collaboration.
- Reform HTA methodology and decision-making process to ensure:
  - Increased transparency and accessibility of HTA methodology, data, modelling, and decision-making.
  - Flexibility of approaches, together with simplification and streamlining.
  - Incorporation of patient input and lived experience.
  - Inclusion of wider government and societal impacts, taking a social investment approach.

Responsibility: Associate Minister of Health (Pharmac)

2.3 Greater investment in medicines:

- Provide for greater investment in medicines to enable Pharmac to fund the medicines on its Options for Investment (OFI) List.
- Enable Pharmac to make progress in funding other medicines that are part of international standard of care.

Responsibility: Minister of Health and Minister of Finance

2.4 Develop a Medicines Strategy:

- Establish a multi-stakeholder working group to oversee development of the medicines strategy.
- The strategy to include:
  - A clear vision, mission, priorities, and targets with clear outcomes and measures.
  - Long-term goals for investment (OECD average), and directions for the setting of benchmarks to ensure New Zealand meets international standards of care.
  - A clear statement of investment setting via allocative efficiency from within Vote Health or new investment.
  - Set direction for funding decisions to ensure that they are consistent with overall health system priorities i.e. enable a cohesive, cross system approach rather than the current siloed approach.
  - Horizon scanning activities such as identification of emerging technologies and planning for their incorporation into the health system.

Responsibility: Associate Minister of Health (Pharmac)

2.5 Pharmac Review:

- Revisit the Review findings and evaluate any actions taken subsequently to the Review.
- Ensure meaningful delivery of the Review's recommendations.

Responsibility: Associate Minister of Health (Pharmac)

2.6 Future-proofing the health system and access to innovation for patients:

- Commitment from the government to:
  - Provide the structure and framework needed for a national precision health platform.
  - Ensuring an enabling environment for clinical trials, including:
    - Adoption as appropriate of the "1-stop-shop" Australian approach for clinical trials.
    - Clear regulatory and investment pathways for medicines undergoing clinical trials.
    - Revision of R&D tax incentive scheme to ensure it has greater usability and is more attractive to international sponsors.

Responsibility: Minister of Health, Associate Minister of Health (Therapeutic Products Regulation), Associate Minister of Health (Pharmac), Minister for Science, Innovation and Technology, Minister of Revenue.

NB: The above set of actions is not exhaustive, but are the recommended common actions based on multiple workshops findings. For the full set of actions please refer to each workshop write-up and the section detailing specific actions with those responsible for implementing those actions.

Fiona Tolich, Patient Advocate

3.0 INTRODUCTION

3.1 ABOUT THE SUMMIT

The Valuing Life: New Zealand Medicines Access Summit, held on April 29 and 30 2024 in the Grand Hall of New Zealand's Parliament Buildings, was a landmark event. The summit brought together diverse stakeholders to start a dialogue about how to address the critical issues surrounding medicines access in New Zealand. The summit was hosted by Associate Minister of Health (Pharmac) Hon David Seymour on Day One and Todd Stephenson MP (Health Spokesperson, ACT New Zealand) on Day Two and was co-facilitated by Patient Voice Aotearoa and Medicines New Zealand.

3.2 THE SUMMIT - DAY ONE

Day One of the summit was attended by a wide range of stakeholders, including representatives from patient advocacy organisations, clinicians, government officials, the pharmaceutical industry, and academia. During his opening address, Minister Seymour announced an investment by the government of $1.774 billion over four years to Pharmac's budget to ensure continuity of currently funded medicines.







3.2.1 MORNING SESSION

3.2.1.1 The morning session of Day One set a robust foundation for consideration of why medicines access needs to be improved in New Zealand, including the need for further investment in innovative treatments for patients. A series of insightful presentations and discussions highlighted the complexities and challenges of medicines access in New Zealand from the perspective of patients and clinicians. Attendees heard from patient advocates, clinicians, an international expert on Health Treatment Evaluations, representatives from Pharmac's Pharmacology and Therapeutics Advisory Committee (PTAC) and Consumer Advisory Committee (CAC), and specialists in patient engagement in decision-making processes.

3.2.1.2 The first presentation of the morning session focussed on the personal experiences of two patient advocates who spoke about their challenging and, at times, harrowing journeys through New Zealand's medicines funding system. Their presentations highlighted the significant difficulties currently faced by patients and their families, including the inability to access critical medicines, limited funding for medicines, uncertainty and delays in decision-making, lack of transparency of the assessment and decision-making processes, and little or no involvement of patients in those processes. Their experiences provided a real-life context for the discussions at the workshops held later in the day.

3.2.1.3 This was followed by a panel presentation from clinicians working in the New Zealand health system across a range of specialities, including haematology, gastroenterology, diabetes, oncology, and paediatric neurology. The panel discussion covered the issues and challenges currently faced by doctors seeking to access medicines for their patients, and the need for change.

3.2.1.4 A presentation from Dr Tim Kanters, Senior Researcher from the Institute of Medical Technology Assessment and Erasmus University Rotterdam, the Netherlands, outlined how a societal perspective can be incorporated into Health Technology Assessment (HTA). The presentation included examples of how a societal perspective might be included in the assessment process, and demonstrated the potentially significant impact that such an approach could have on decision-making and the case for investment.

DR TIM KANTERS

3.2.1.5 The final session of the morning addressed how to improve patient engagement in decision-making, with a panel including patient advocates, clinicians, and consumer engagement specialists. This session highlighted the importance of engaging patients throughout the decision-making process, in a transparent and patient-centric way.

3.2.2 AFTERNOON SESSION

3.2.2.1 The afternoon session started with a panel discussion on how to improve multi-stakeholder collaboration and why it matters. This panel brought together expert representatives from Australia and New Zealand in the fields of academia, clinical practice and research, patient advocacy, and industry to explore the opportunities for multi-stakeholder collaboration that will lead to New Zealand patients having improved access to innovative treatments. The insights that New Zealand could draw from the Australian experience was an important component of this panel.

3.2.2.2 **This panel was followed by four concurrent workshops:**

1. Enhancing Health Technology Assessment (HTA) processes in New Zealand
2. Building a fit-for-purpose Medicines Strategy for New Zealand
3. Better stakeholder engagement in decision-making processes
4. Health innovation optimisation in New Zealand (precision health, clinical research and horizon scanning).

3.2.2.3 These collaborative workshops provided a platform for crucial conversations on topics critical to improving medicines access for patients in New Zealand. The chair of each workshop was supported by an expert panel, including representatives from academia and healthcare, government organisations (Ministry of Health, Pharmac and the Health Quality and Safety Commission), patient advocacy organisations and the pharmaceutical industry.

3.3 THE SUMMIT - DAY TWO

3.3.1 Day Two of the summit was not open to the pharmaceutical industry or government agency personnel and focussed on patient advocacy in New Zealand. An open invitation was sent to all Members of Parliament to attend the breakfast where patients with Stage IV cancer, rare disorders, and chronic illnesses shared their experiences and frustrations regarding medicine access. This was followed by a roundtable discussion with representatives of various patient advocate groups that centred on challenges and opportunities for each organisation. Rachel Smalley and David Downs shared insights based on their experiences about patient advocates engaging with media. Day Two ended with a discussion about the need to work as a collective and what that may look like into the future.

3.4 CONTENT OF THIS PAPER

3.4.1 This paper focuses on Day One of the summit, presenting a summary of the outcomes from each workshop, together with key findings, and common themes. The summaries are based on the notes recorded by the scribes and chairs of the workshops.

3.4.2 As the workshops were conducted under the Chatham House rule; comments were not attributed to any specific panel member or workshop attendee. Appended to this paper are the write-ups from the four workshops which represent a composite of notes taken by the two scribes* present at each.

* One scribe was provided by Patient Voice Aotearoa and one by Medicines New Zealand

3.5 SUMMIT ORGANISATION, CONTRIBUTORS, SPEAKERS, AND PANEL MEMBERS

Patient Voice Aotearoa and Medicines New Zealand thank the organising committee for their work planning the summit and Hon. David Seymour and Todd Stephenson MP for hosting the summit.

Additionally, Patient Voice Aotearoa and Medicines New Zealand extend sincere thanks to the speakers and workshop panellists whose contributions were instrumental in making the summit a platform for meaningful exchange and progress toward better medicines access. A special thanks goes to patient advocates Fiona Tolich and Emma Purchase for sharing their personal stories.

More information about the summit can be found on the valuinglife.nz website. Understandably, the summit attracted significant stakeholder and media interest, underscoring the importance of the discussions being had. Regrettably, due to limited space, the organising committee were unable to accommodate all who wished to attend.

PATIENT VOICE AOTEAROA
HE REO TŪRORO O AOTEAROA

Dr Malcolm Mulholland, Chair

Patient Voice Aotearoa (PVA) is a collective of advocate organisations representing more than a million patients with cancers, rare disorders, diabetes, and other life-limiting conditions. Our mission is to raise awareness, promote policy changes, and engage with politicians to ensure that there is equitable access to essential medicines for all New Zealanders.

PVA advocates for a commitment from the Government for significant change to the health system to improve access to and funding for medicines, the reform of Pharmac, and to set a clear strategic direction for future medicines' access in New Zealand. PVA believes every New Zealander must
have access to essential and affordable medicines if we are to improve health outcomes and help to reduce the pressure on New Zealand's overburdened health system.

PVA has a shared vision: In New Zealand every patient has the opportunity to lead a healthy life, where medicines are viewed as an investment, and there is access to new and breakthrough medicines that are part of standard treatment in other countries. It is our aim to shape a brighter tomorrow for patients in Aotearoa.

Medicines New Zealand

Todd Krieble, Chair

Established in 1961, Medicines New Zealand Incorporated (formerly the Researched Medicines Industry Association – RMI), is the professional and trade organisation of New Zealand's research-based pharmaceutical industry representing innovative biopharmaceutical companies.

Our members are engaged in the research, development, manufacture and marketing of modern prescription medicines that are recognised as life changing, breakthrough or leading therapies.

Medicines New Zealand advocates to improve access to modern medicines for New Zealand patients including raising public awareness of the benefits that modern medicines and vaccines can bring as part of a high-quality public health system.

We work with key health-based decision makers and a wide range of stakeholders to discuss our industry perspectives. We inform and educate using only fact-based arguments with a goal of improving access to modern medicines for New Zealand patients.

SUMMIT SPEAKERS AND PANEL MEMBERS

Dr John Baker - Diabetes Specialist, Endocrinologist - Middlemore Hospital and Chairperson, Diabetes Foundation Aotearoa

Libby Burgess - Chair, Breast Cancer Aotearoa Coalition (BCAC)

Ben Campbell-MacDonald - Manager Pharmaceutical Assessment Team, Pharmac

Chris Carswell - Editor in Chief, *PharmacoEconomics* and *The Patient* for Springer Nature Journals

Sue Chetwin CNZM - Chair of the Pharmac Review, Consumer Advocate

Dr Greg Cook - Director of Access, Policy and Advocacy, Bristol Myers Squibb Australia and New Zealand

Dr Dragan Damianovich – Medical Oncologist - Auckland Hospital and Auckland Oncology and Bowel Cancer NZ Medical Advisor

Tony Davison - Business Unit Manager, Boehringer Ingelheim New Zealand

David Downs - CEO, NZ Story and Patient Advocate

Marina Dzhelali - Executive Committee, New Zealand Association of Clinical Research (NZACRes)

Andrew Gaudin - CEO, Pharmacy Guild of New Zealand

Vanessa Gascoigne - Director, Merck Sharp & Dohme (MSD) New Zealand

Sarah Hogan - Deputy Chief Executive (Wellington), Principal Economist, NZIER

Dr David Hughes - Chief Medical Officer, Pharmac

Dr Peter Jansen - CEO, Health Quality and Safety Commission (HQSC)

Dr Tim Kanters - iMTA Erasmus University, Netherlands

Stuart Knight - Former General Manager, Roche New Zealand, Australia, Portugal, Hungary

Katrina Lapham - Director Strategic Market Access and Policy, Biointelect

Dr Rob Weinkove - Clinical Director, Malaghan Institute of Medical Research and Clinical Haematologist, Wellington Blood and Cancer Centre

Professor John Zalcberg - All.Can Australia Board Director, Department of Epidemiology and Preventative Medicine, Monash University & Dept of Medical Oncology, Alfred Health, Melbourne, Australia

Dr Ben Lawrence - Head of Department of Oncology, Faculty of Medical and Health Sciences, University of Auckland

Dr Robyn Manuel - Chair, Pharmac Consumer Advisory Committee (CAC)

Dr Lee Mathias ONZM - Independent Director, former Chair HPA, Medicines New Zealand and Counties Manukau DHB

Alexander Muelhaupt - General Manager, Roche Pharmaceuticals New Zealand

Dr Gina O'Grady - Paediatric Neurologist, Starship Hospital

Stella O'Brien - NICE Tech Appraisal Committee, Patient Representative UK

Christine Perrins - Advocacy Adviser, Cystic Fibrosis New Zealand

Emma Purchase – Patient Advocate

Maree Roberts - Deputy Director-General Strategy Policy and Legislation, Ministry of Health

Dr Christian Schwabe - CEO, New Zealand Clinical Research

Rachel Smalley - Patient Advocate

Dr Richard Stein - Gastroenterologist and Chair, Crohn's and Colitis New Zealand

Dr Jane Thomas - Pharmac Pharmacology Therapeutics Advisory Committee (PTAC) Chair

Professor David Thomas - Founder and Chief Science and Strategy Officer, Omico Australia

Dr Rodger Tiedemann - Associate Professor, University of Auckland and Consultant Haematologist, Auckland Hospital

Fiona Tolich - Patient Advocate

Professor Ian Town - Chief Science Advisor, Ministry of Health

Richard Vines - Chair, Rare Cancers Australia

Jo Watson - Deputy Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), Australia

WORKSHOP SUMMARIES

4.0 WORKSHOP ONE

Enhancing Health Technology Assessment (HTA) processes in New Zealand

5.0 WORKSHOP TWO

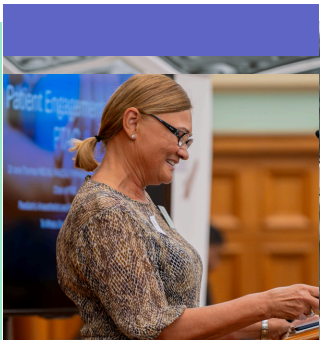
Building a fit-for-purpose Medicines Strategy for New Zealand

6.0 WORKSHOP THREE

Better stakeholder engagement in decision-making processes

7.0 WORKSHOP FOUR

Health innovation optimisation in New Zealand (horizon scanning, precision health and clinical trials)



4.0 WORKSHOP ONE

ENHANCING HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESSES IN NEW ZEALAND

4.1 This workshop focussed on potential enhancements that could be made to existing HTA processes in New Zealand. The incorporation of societal perspectives and a more holistic approach to accounting for costs and benefits was explored, as was the opportunity for evolving practice overseas to be informative of the New Zealand system. Barriers to meaningful change in health technology processes were also identified. Workshop attendees were given a selection of relevant references as pre-reading materials. See the appendix for details on these materials.

4.2 Three core questions were covered during this workshop:

What does a good HTA process look like?

What adjustments, if any, would be required in New Zealand to achieve this outcome?

What actions are needed to start the enhancement processes, and who would be responsible for them?

4.3 The workshop was led by an expert panel:

- **Workshop Chair: Sarah Hogan**
  NZIER Deputy Chief Executive (Wellington) and Principal Economist
- **Ben Campbell-MacDonald**
  Manager of Pharmaceutical Assessment Team at Pharmac
- **Chris Carswell**
  Editor in Chief of *PharmacoEconomics* and Editor in Chief of *The Patient* for Springer Nature Journals
- **Dr Greg Cook**
  Director of Access, Policy, and Advocacy for Bristol Myers Squibb (BMS) Australia and New Zealand
- **Christine Perrins**
  Advocacy Adviser at Cystic Fibrosis New Zealand
- **Dr Jane Thomas**
  Chair of the Pharmacology and Therapeutics Advisory Committee (PTAC)

4.4 Summary

The view of the panel and participants in this workshop was that the morning sessions of the summit had highlighted the critical importance for all stakeholders of transparency in good HTA process and decision-making. Timeliness and certainty were also identified as essential for all stakeholders but especially for patients - "so people can decide what they are doing in life."

Reflecting on these opening comments, and the common desire for transparency, timeliness, and certainty, a workshop panellist voiced the opinion that there is a significant dichotomy between theory and practice in New Zealand's HTA framework for medicines. The needs of patients, their families, and clinicians working in the New Zealand health system are not fulfilled by Pharmac's current HTA methodology and mode of operation. Instead "[the] focus on cost comes up everywhere and the societal perspective seems to be missing." This dichotomy was explored by the workshop attendees and, in the hour that followed, there were spirited discussions of the three set questions.

The challenges of reforming New Zealand's current HTA methodology, including the practicalities and potential unintended impacts of incorporating societal perspectives into HTA, were debated. At times there was consensus and, at other points, clear differences in perspectives were identifiable. Crucially, when there was divergence in the perspectives expressed, it was possible to identify the current barriers to meaningful change in the HTA process in New Zealand. Through exploration of these barriers, recurrent themes emerged for systemic change to support the HTA methodology and process to evolve and be refined in step with international best practice and changing societal and patient needs.

However, participants were clear that, in a resource constrained funding environment, improvements in HTA methodology and increased transparency in decision-making processes alone will not be sufficient to improve certainty and timeliness of access to medicines. There was wide consensus that the current Pharmac system of HTA is unable to meet the needs of patients because of the limited budget available to it. Greater investment in medicines is needed for change to the HTA system to be successful. There was also a strong message that the HTA system can only work efficiently if it is properly integrated with the rest of the health system.

The need for change to Pharmac's statutory objective, as set out in section (68 ss(1)(a) of the Pae Ora (Healthy Futures) Act), was also identified. Change to this objective is necessary because adherence to it as currently set has resulted in a primary focus on cost, distorted decision-making, and sub-optimal outcomes for patients. Additionally, as set, this objective blocks Pharmac from making procedural change that would allow greater flexibility to Pharmac's processes, for example the incorporation of societal costs and benefits, and stimulate an allocatively efficient approach to funding decisions. Pharmac's statutory objective should be amended to ensure there is a clear focus on outcomes, recognition of the role and value of investment in medicines, appropriate inclusion of societal benefit, and better integration of the funding of medicines into the wider health system.

A strong view was expressed that the Pharmac Review was undertaken with significant engagement and input from the patient community and stakeholders, and that the Review's findings were significant and important and should not be wasted. The Review's findings should be revisited, and actions taken to date evaluated to ensure meaningful delivery of the Review's recommendations, in conjunction with the patient community.

4.5 What does a good HTA Process look like?

4.5.1 Adoption of a comprehensive, cohesive, whole-of-system approach to HTA methodology:

4.5.1.1 Genuine consideration of flow-on impacts in the health system.

4.5.1.2 Incorporation of societal perspectives including productivity impacts when appropriate. It may not be appropriate to incorporate productivity perspectives into HTA of treatments for all health conditions or patient groups (for instance children).

4.5.1.3 Pharmac's operations resourced sufficiently to enable their practice to keep pace with the changing treatment environment (horizon scanning of new health technologies e.g. precision and genomic therapies etc.).

4.5.1.4 The need for HTA methodology to evolve and be refined in step with international best practice and changing societal and patient needs.

4.5.2 Multi-stakeholder approach – and a "user-friendly" system:

4.5.2.1 Straightforward and accessible.

4.5.2.2 Patient voice and perspective is front and centre and "lived experience" is accounted for.

4.5.2.3 Recognition of different populations' needs.

4.5.2.4 Multidisciplinary – greater incorporation of perspectives from health and allied professionals.

4.5.2.5 Openness to different stakeholders' objectives in support of more transparent, collaborative, and less transactional relationships.

4.5.2.6 Greater transparency to ensure that healthcare consumers and clinicians are sufficiently informed and enabled to contribute meaningfully to the process in a timely way.

4.5.2.7 Stakeholders have greater visibility, not just over the whole process but also over what is used in the HTA model and how it is being used, and clarity around the factors which have impacted upon funding decisions.

4.5.3 Greater investment in medicines through a whole of system approach and amendment of Pharmac's statutory objective:

4.5.3.1 Increased flexibility of methodological approaches.

4.5.3.2 Statutory objectives for Pharmac that appropriately recognise the role and value of medicines within the broader health system.

4.5.3.3 Removal of the legislated budget cap, which is unique to Pharmac within the health system, distorting decision-making and leading to suboptimal outcomes for patients, and inefficiencies within the health system.

4.5.3.4 Cohesive and allocatively efficient budget allocation across Vote: Health.

4.5.4 The recommendations of the Independent Pharmac Review should be delivered on to provide genuine change - the work of the Review should not be wasted.

4.6 What adjustments, if any, would be required in New Zealand to achieve this outcome?

4.6.1 Key drivers of improvements in HTA process were seen as being:

4.6.1.1 Multi-stakeholder approach: A system that supports a multi-stakeholder approach and genuine engagement with those impacted by decisions.

4.6.1.2 An active and future focussed HTA system: A system that considers what patients and clinicians need rather than passively waiting for applications.

4.6.1.3 Benchmarking: With peer countries to ensure that New Zealand's standard of care and access to medicines is appropriate.

4.6.1.4 Sufficiently resourced HTA agency: In addition to sufficient funds for medicines procurement, the operational resourcing for Pharmac staff and systems must be sufficient to support continuous improvement and adherence to best practice.

4.6.1.5 Legislative change: Pharmac's statutory objective (specifically section 68 ss(1)(a) of the Pae Ora (Healthy Futures) Act) must be amended to allow greater flexibility to Pharmac's processes and to enable an allocatively efficient approach to funding decisions across the health system.

4.6.1.6 Procedural and operational flexibility: The system needs to be flexible and open to new ideas and methods of doing things, although it was acknowledged that Pharmac is improving in this regard.

4.6.1.7 Pharmac's guideline for cost utility analysis i.e. the Prescription for Pharmacoeconomic Analysis should be reviewed and updated to ensure it is fit for purpose:

a. Consideration should be given to the appropriate adoption of HTA practices found to be beneficially impactful in international jurisdictions. For example, incorporation of broader societal perspectives and productivity benefits (such as in the Dutch model). Consideration would need to be given to how any equity and distributional fairness concerns which may arise would be addressed.

4.6.1.8 Integration of the HTA system and process with the rest of the health system:

a. For the HTA system and process to work efficiently, it is critical that it is not siloed from the rest of the health system and arbitrarily hamstrung by the statutory objective of a capped budget that other health entities do not have to fulfil.

b. Health costs are already considered in Pharmac's methodology, but there are concerns that these are not incorporated as consistently or comprehensively as they should be in support of an allocatively efficient approach to funding decisions.

c. New Zealand should not have an Options for Investment (OFI) List. It is a failing of the current HTA process.

4.7 What actions are needed to start the enhancement processes, and who would be responsible for them?

4.7.1 Many participants in the discussion expressed the view that successful reform of the system will rest upon willingness by the Government and key public officials to acknowledge that the current system does not work and to address both the level of funding and the funding model.

4.7.2 Greater investment in medicines: There was majority agreement by workshop attendees that the current Pharmac system of HTA is unable to meet the needs of patient and clinician stakeholders in the system because of the limited budget available to it through the current funding model.

4.7.2.1 Timely access is important and is a high priority for most people. As a first step, the funding of those medicines which have already been evaluated and found to be cost effective should be prioritised (the OFI list medicines).

4.7.2.2 The incorporation of societal perspectives was seen by some attendees as a means for building the case for greater investment into medicines, i.e., providing leverage for increasing the Pharmac budget through demonstration of the impacts that the investment will have more broadly in terms of other government programmes and objectives, and overall societal benefits.

4.7.2.3 There must be a more cohesive and open approach taken to the funding of medicines within the health system, and that key to this is a shift from the current focus on cost-containment to a focus on optimising investment decisions. Patients' needs as exemplified by "lived experience" should be determinative of the health and social outcomes that are valued in cost-utility analysis and should be central to cross-system decision-making.

4.7.3 Consultation, Collaboration and Communication - it was recognised that significant change in the Pharmac funding approach could have unexpected consequences and trade-offs may have to be made. A multi-stakeholder approach must be taken to reforming and rebuilding the system to mitigate against unintended consequences which may exacerbate health inequities (for instance in the case of people with disabilities), and to ensure that the system meets primary expectations that those with the greatest health need are provided for.

4.7.3.1 Public engagement and consultation may be necessary to understand what people want from the system and what New Zealanders think is "fair" with respect to medicines access.

4.7.3.2 Reform of the system should incorporate co-design by key system stakeholders impacted by decisions made including patients, clinicians, and industry, as well as allowing for input by expert academics, policy makers, and others.

4.7.4 Review the Pharmac Review and deliver on its recommendations:

4.7.4.1 There was a strong view expressed that the patient community had made an immense investment into the consultation process run through the Independent Review of Pharmac and that the review findings were significant and important. Pharmac and the Ministry of Health must be accountable for revisiting the review findings and evaluating any actions taken subsequent to the review with a sincere objective of progressing meaningful delivery of the review's recommendations in conjunction with the patient community.

5.0 WORKSHOP TWO

BUILDING A FIT-FOR-PURPOSE MEDICINES STRATEGY FOR NEW ZEALAND

5.1 This workshop focussed on establishing core themes and elements for a modernised medicines strategy that will allow greater certainty for all health sector stakeholders and help future-proof the health system. Workshop attendees were given a selection of relevant references as pre-reading materials. See the appendix for details on these materials.

5.2 **Three core questions were covered during this workshop:**
What should a good Medicines Strategy look like and have as core elements?

What adjustments, if any, would be required in New Zealand's existing 2007 strategy to achieve this outcome?

What actions are needed to start the enhancement processes, and who would be responsible for them?

5.3 **The workshop was led by an expert panel:**

- **Workshop Chair: Dr Lee Mathias ONZM**
  Independent Director, former Chair at HPA, Medicines New Zealand and Counties Manukau District Health Board
- **Libby Burgess**
  Chair of Breast Cancer Aotearoa Coalition (BCAC)
- **Vanessa Gascoigne**
  Director for Merck Sharp & Dohme (MSD) New Zealand
- **Andrew Gaudin**
  Chief Executive of Pharmacy Guild of New Zealand
- **Dr Peter Jansen**
  Chief Executive of Health Quality & Safety Commission
- **Maree Roberts**
  Deputy Director-General, Strategy Policy and Legislation at the Ministry of Health
- **Professor John Zalcberg**
  All.Can Australia Board Director, Department of Epidemiology and Preventative Medicine, Monash University & Dept of Medical Oncology, Alfred Health, Melbourne, Australia

5.4 **Summary**
This workshop established the clear need for a multi-stakeholder approach to be taken in the development of an updated medicines strategy to replace the 2007 version. Workshop attendees considered that some key elements could be retained and updated from the existing 2007 document. However, they noted that they would hope to see action of these matters in an updated strategy as it appeared that only limited progress was made on implementation of the actions under the 2007 Strategy and associated Action Plan (2015-2020).

It was agreed that there was also a need for better articulation of the vision, mission, priorities, and targets for the new Medicines Strategy. These elements would all need to be better communicated within the new strategy to ensure that the role of medicines is not siloed within the public health system. The formation of a multi-stakeholder working group to support the generation of a suitable Medicines Strategy was considered a major first step. This should be actioned by the Associate Minister of Health with responsibility for a medicines strategy and be ratified by the Minister of Health.

The updated strategy needs to be patient-centric and include good use of data, benchmarking, and clear articulation of long-term goals for investment levels and meeting of international standards of care. It should include a horizon scanning platform to help optimise the medicines procurement process and ensure that the broader health system is prepared for the integration of future health technologies. It should also be guided by focussing on patient pathways through the health system, better collaboration (domestic and international) and include clear lines of responsibility, with robust deliverables and milestones.

Benchmarking New Zealand's medicines budget against the OECD average was also seen as important as New Zealand's budget for medicines was considered to be grossly inadequate compared to that average. Without an adequate medicines budget, it will not be possible to be ambitious in a Medicines Strategy.

To ensure there is accountability for delivery of the medicine's strategy, modifications of the Pae Ora (Healthy Futures) Act 2022 may be necessary, for example:

- The Government Policy Statement (GPS) on Health should include the optimised procurement/ commissioning, access, and reviewing of medicines. This would allow the medicines to be embedded into the National Health Plan (NHP) and then into policies and actions for the health system so that all stakeholders would be engaged and accountable.
- Changing Pharmac's statutory objective to focus on best health outcomes not cost containment.
- Having a Medicines Strategy as an additional strategy in the legislation (this latter point was a matter of some debate for the attendees).

The view of the panel and attendees of this workshop was the Valuing Life: Medicines Access Summit 2024 was the first step in the development of an optimised Medicines Strategy. Multi-stakeholder generation of an updated medicines strategy will be required to aid preparedness for the future, and that engagement is therefore a critical success factor.

5.5 What does a good medicines strategy look like and have as core elements?

5.5.1 Consideration of the problems that need to be solved, and the choices, priorities, trade-offs, and critical factors is needed. Attendees noted that a good strategy will help decision-makers make trade-offs and choices. However, it was also noted that this could be achieved without a strategy, so it is important to be clear what the objective of the strategy is.

5.5.2 There was consensus that trade-offs need to look at the wider system, beyond just health (i.e. economic and productivity impacts and broader societal impacts). It was also the consensus view that a well-constructed strategy was needed, rather than just the use of 1-2 actions around medicines access.

5.5.3 Patient-centric: The strategy needs to contain mechanisms that deliver outcomes in a timely manner, decrease delays, and help optimise the broader health system. Factoring in the broader non-health impacts on patients, families, and whānau (i.e. indirect benefits and societal impacts) of good medicines access is also needed.

5.5.4 Clear vision, mission, and priorities/targets: It was noted that the new strategy should also look at having something clear and aspirational for the vision to unite all stakeholders, but also that priorities/targets need to include elements of efficiency and effectiveness. The elements of effectiveness and efficiency need to be better focussed on by the public/Government entities that will deliver outputs resulting from the actioning of the strategy. A good strategy also needs to give clarity concerning appropriate investment to enable delivery of the strategic goals for medicines being accessed and implemented into the broader health system.

5.5.5 Multi-stakeholder collaboration: Multi-stakeholder engagement was seen by attendees as a critical success factor in the generation and delivery of a suitable Medicines Strategy and the ongoing policies and actions. This includes public-private collaboration.

5.5.6 Inclusion of innovation as a core theme: As medicines innovation will drive change and needs to be monitored (e.g. horizon scanning), procured and implemented in a timely manner once the innovation is available to the New Zealand health system.

5.5.7 Benchmarking against the OECD average medicines budget or higher: In comparison to other OECD countries, New Zealand's overall health budget as a percentage of GDP is adequate but the medicines budget is grossly inadequate compared to the OECD average. As a result, New Zealand is missing out on a large number of medicines. Without a medicines budget that reflects the OECD average, it will not be possible to be ambitious in a Medicines Strategy.

5.6 What adjustments, if any, would be required to New Zealand's existing 2007 strategy to achieve this outcome?

5.6.1 Modernisation of the strategy to deal with current and future health systems and medicines. This would require the following areas to be added:

5.6.1.1 A multi-stakeholder, health technology horizon-scanning platform needs to be embedded across the entire health system. This would ensure the entire health system is aware of and optimises current options and can plan for the impacts of future health technologies.

5.6.1.2 Inclusion of patient-reported outcomes and quality of life measurements/ metrics, alongside hard scientific data.

5.6.1.3 Focus on patient pathways, including patient-reported outcomes/quality of life perspectives at the centre of the strategy. i.e. 'patient-centric'.

5.6.1.4 Mechanisms for transformation and how to establish pathways for change.

5.6.1.5 Milestones with accountability for deliverables.

A focus on primary prevention and keeping people healthy. Prevention up front in a primary setting leads to less spending later in the health system i.e. hospitalisation.

5.6.2 The following themes need to be made more explicit in the updated strategy:

5.6.2.1 Partnership with patients and patient/consumer needs being valued, with a central focus of the update including the need to build the strategy around optimised patient pathways through the health system.

5.6.2.2 Multi-stakeholder-centric approach and language being used (including public-private partnerships) more than is currently indicated. This would need to be led by good use of data to help break down existing silos in the health system.

5.6.2.3 Industry needs to be recognised as a key stakeholder and New Zealand needs to aim for industry to thrive and be part of the system.

5.6.2.4 Strong commitment from the Government and other stakeholders including patients, prescribers, and industry to make the strategy an active document and capture all spillover benefits to New Zealand's public health system e.g. vibrant clinical trials and health innovation ecosystem.

5.6.3 The strategy needs to focus on the goal of providing solutions to those with highest health needs (highest health inequity). Attendees suggested that the update of the Medicines Strategy, has to indicate any structures proposed to deliver on the goal of decreasing high needs/inequity.

Quality use of medicines including in a preventive and prophylactic mode. Timing of use and having the right medicine at the right time is important. But prevention in the context of New Zealand's ageing population and general health needs to be better considered. For instance, the role of medicines/vaccines in enhanced prophylaxis/immunisation.

5.7 What actions are needed to start the enhancement processes, and who would be responsible for them?

5.7.1 To initiate enhancement processes, several actions are necessary:

5.7.1.1 Build an inclusive and collaborative multi-stakeholder medicines working group to update the medicines system, including the strategy.

Minister of Health and Associate Minister of Health (Pharmac), including those accountable for medicines strategy, would be responsible to initiate this multi-stakeholder working group, with representation from patients, officials, health practitioners (pharmacists, doctors, nurses), and industry.

5.7.1.2 Widening of the contents of the strategy, not just on optimal use of medicines. Inclusion of elements including:

a. Having an agreed vision, mission, values, and objectives together with actions to achieve the mission and assign responsibility for each. For example, is the vision to be a world leader, a fast follower or just average? Does the investment track enable the achievement of the vision?

b. Embedding horizon scanning and the role of medicine innovation in the strategy that focusses on the impact and embedding of innovation in the health system.

c. Mechanisms to collaborate more closely, domestically, must be explicitly stated in the strategy. This would aid in breaking down the silos between the public health system entities, the private sector, patients, and officials.

d. Consideration of opportunities to collaborate and engage internationally around pharmaceutical innovation.

Minister of Health and Associate Minister of Health (Pharmac) need to take responsibility for changing the settings in the existing strategy so that the above is enabled.

5.7.1.3 Inclusion of the Medicines Strategy as an amendment into the Pae Ora (Healthy Futures) Act.

Minister of Health and Associate Minister of Health (Pharmac) to take responsibility for this change to the Pae Ora (Healthy Futures) Act.

5.7.1.4 Commissioning/procurement and reviewing of medicines should be explicitly incorporated in the Government Policy Statement (GPS) on Health as an integral part of prioritised planning.

a. This would then flow into the National Health Plan (NHP) and supporting policies and actions in the health system. Thus, ensuring all stakeholders would be engaged and accountable.

Minister of Health and Associate Minister of Health (Pharmac/Medicines Strategy) to take responsibility for this change to Pae Ora (Healthy Futures).

5.7.1.5 Amend the Pae Ora (Healthy Futures) Act regarding Pharmac's statutory objective so that focus is on best health outcomes that are reasonably achievable i.e. removal of the phrase "from within the amount of funding provided".

Minister of Health and Associate Minister of Health (Pharmac) to take responsibility for this change to Pae Ora (Healthy Futures).

5.7.1.6 Clear statement of investment settings is needed to articulate this in updated Strategy either via allocative efficiency from within Vote Health or new investment.

Associate Minister of Health (Pharmac) to take lead on investment setting, supported by Health officials.

5.7.1.7 Pharmac to be mandated to use broader measurements such as societal impacts (indirect costs) and a social investment approach in its health technology assessments processes.

a. Allowing for better allocative efficiency cases to be made around medicines in the overall health system and productivity setting for the country.

Associate Minister of Health (Pharmac) responsible for working with Pharmac to update assessment tools to include broader societal impacts, supported by health officials.

6.0 WORKSHOP THREE

BETTER STAKEHOLDER ENGAGEMENT IN DECISION-MAKING PROCESSES

6.1 This workshop focussed on investigating the key enablers necessary to allow all stakeholders, but particularly the patient/consumer voice, the ability to have input into decision-making processes undertaken on medicines procurement. Workshop attendees were given a selection of relevant references as pre-reading materials. See the appendix for details of these materials.

6.2 **Three core questions were covered during this workshop:**
What does good consumer engagement in decision-making processes around medicines look like?
What adjustments, if any, would be required in New Zealand to achieve this outcome?
What actions are needed to start the enhancement processes, and who would be responsible for them?

6.3 **The workshop was led by an expert panel:**

- **Workshop Chair: Sue Chetwin CNZM**
  Chair, Independent Pharmac Review Panel
- **Tony Davison**
  Business Unit Manager at Boehringer Ingelheim New Zealand
- **Dr David Hughes**
  Pharmac's Chief Medical Officer
- **Dr Robyn Manuel**
  Chair, Pharmac's Consumer Advisory Committee
- **Dr Roger Tiedemann**
  Associate Professor of Medicine, University of Auckland
- **Fiona Tolich**
  Patient advocate for Spinal Muscular Atrophy (SMA) sufferers in New Zealand
- **Richard Vines**
  Chair of Rare Cancers Australia

6.4 **Summary**
Inclusive collaboration and patient engagement are essential for ensuring effective decision-making processes for medicines. However, simply including patients alone will not lead to meaningful progress. All relevant stakeholders, including patients, government representatives, healthcare providers, and industry experts must be part of the process and engagement must start early. Enhanced transparency in the decision-making processes, together with predictable timelines, is also needed to provide greater certainty. But, while patient engagement and speed are critical, substantial improvement will require greater investment in medicines to increase certainty and improve access. Silos within the health system need to be broken down to support integrated healthcare delivery.

New Zealand can benefit from international examples and should continue to engage with organisations worldwide to learn and adopt best practices and leverage collaborative opportunities to improve medicines access. International experts can provide valuable perspectives, and sharing data and processes can prevent duplication of effort, although a local focus should not be forgotten.

The view of the panel and attendees of this workshop was that the Valuing Life: Medicines Access Summit 2024 is stage one of a larger process and a commitment to meet again, and act, is essential. Without follow-up, these efforts will be in vain. Preparation for the next stage needs to ensure that the commitments made in stage one are met and the foundations laid are built on.

New Zealand can achieve equal or better access to medicines than peer countries. Funding and system changes are the keys to moving forward successfully.

6.5 What does good consumer engagement in decision-making processes around medicines look like?

6.5.1 Wide ranging involvement: Including patients, citizens, and consumers, and all other stakeholders who are vital to Heath Technology Assessment (HTA).

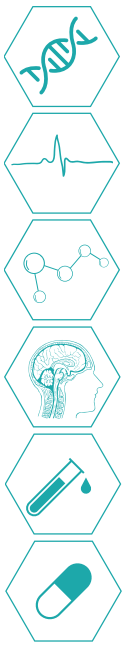
6.5.2 Patient evidence:

6.5.2.1 Gathering quantitative evidence direct from patients.

6.5.2.2 Patient story telling – qualitative insights through personal stories which are compelling and provide context.

6.5.3 Financial support for patient groups: in Australia, patient groups are expected to participate in HTA, but funding for these groups remains an issue.

6.5.3.1 If patients and patient groups are to be involved more heavily in New Zealand, a panellist suggested that research grants should factor in support for the work of these groups during the HTA process.



6.5.4 Consumer involvement: attendees agreed that early involvement of consumer groups and making sure consumer priorities are understood form an important part of collaborative efforts to ensure relevant and applicable assessment.

6.5.5 Transparency and accountability: decisions should be consistent, transparent, and accountable. Combining patient voice assessments with standard HTA should ensure comprehensive data is considered in these processes.

6.5.6 International comparisons: Australia and Canada both have models and methods that can inform New Zealand's HTA practices.

6.5.6.1 For example, the Canadian Agency for Drugs and Technologies in Health (CADTH) model emphasises transparency and stakeholder feedback, something the majority of attendees agreed was important.

6.5.7 Global collaboration: there is value in international collaboration and incorporation of global expert perspectives, especially for patient data if local data is not available.

6.5.7.1 For example, if there are experts internationally (e.g. clinicians or patient advocates) that are able to bring perspectives New Zealand might not have, such as, where they have treated patients with a medicine that is being considered for funding.

6.5.8 Local focus: despite the benefits of international data, New Zealand is not the rest of the world.

6.5.8.1 A focus on local communities, such as Māori and Pacific populations, is still essential and should not be forgotten.

6.5.9 Benchmarking: continuous benchmarking against international standards would address many consumer concerns, help New Zealand keep pace with global advancements and improve the local pharmaceutical landscape.

6.5.9.1 Implementation of a mandatory benchmarking process to compare New Zealand's pharmaceutical offerings with international standards, could ensure continuous improvement and alignment with global advancements.

6.5.10 Medicines need to be seen as an investment, not a cost.

6.5.10.1 Discussions involving patients, industry representatives, and Pharmac could benefit from input from Treasury to provide a balanced view of long-term economic impacts of investment in medicines, such as reduced hospitalisations and broader societal benefits.

6.5.11 Alignment: all stakeholders, including patients, industry, and Pharmac share the common goal of improving patient well-being. Strategic alignment and collaborative efforts are essential to achieve positive outcomes.

6.5.12 Enhanced assessment process: strengthening the assessment process is essential to ensure more comprehensive and fair evaluation of medicines. Measures to strengthen assessment include:

6.5.12.1 Incorporation of "patient voice".

6.5.12.2 Equity must feature prominently in HTA processes to ensure that decisions benefit all communities equally.

6.5.12.3 Implementation of an equity measure to address disparities in access to medicines for Māori and Pacific communities.

6.5.13 Process Improvements: Both significant and incremental improvements should be considered. Small adjustments can make a substantial difference over time.

6.5.13.1 Predictable timelines: establishing more predictable timelines for the assessment process can improve efficiency and transparency.

6.5.13.2 Addressing how stakeholder input translates to decision-making processes.

6.5.13.3 Resolving resourcing issues: addressing resource shortages to clear assessment backlogs is critical.

6.5.14 Broad Health and Social Costs: Expanding the assessment of costs to include societal perspectives, in addition to health system costs, can provide a more complete understanding of the value of medicine. This broader view can help to justify investment in new treatments.

6.6 What actions are needed to start the enhancement processes, and who would be responsible for them?

6.6.1 To initiate enhancement processes, several actions are necessary:

6.6.1.1 Collaboration and communication: Pharmac should not operate in isolation. Breaking down silos within the government and across sectors is essential, as well as ensuring all relevant stakeholders are involved in discussions.

6.6.1.2 Streamlining Pharmac's application process: the current application process is lengthy and complex. It should be clear, concise, and accessible to the general public.

6.6.1.3 Economic considerations: engage in discussions about the economic consequences and benefits of decisions related to medicines, including evaluating long-term impacts on health and society.

6.6.1.4 Government perspective shift: overcome inherent silos within the Government to foster alignment and change perspectives.

6.6.1.5 Regulatory adaptation: consider revising laws and regulations that govern Pharmac to facilitate a more flexible and collaborative operational environment.

6.6.1.6 Treasury's role: provide clear and actionable data to the Treasury to enable effective participation and ensure economic evaluations and budgetary decisions are based on solid evidence.

6.7 Responsibility for the actions

6.7.1 Pharmac

6.7.1.1 Collaborative Initiatives: lead efforts to foster collaboration and break down internal and external silos.

6.7.1.2 Streamline Processes: simplify the application process and make it more accessible to and understandable for the public.

6.7.2 Government and governmental agencies (including Ministry of Health and Treasury)

6.7.2.1 Policy and Regulation: review and amend laws and regulations to support a more collaborative and flexible Pharmac.

6.7.2.2 Integration and Support: facilitate integration across departments and provide necessary support to accelerate Pharmac's initiatives.

6.7.2.3 Economic Evaluation: Treasury (and other relevant departments) should use clear, measurable data to evaluate the economic impact of medicines investments.

6.7.3 Stakeholders (Patients, Industry, Healthcare Providers):

6.7.3.1 Data Contribution: provide comprehensive data and lived experiences to support decision-making.

6.7.3.2 Active Participation: engage in discussions and collaborations with Pharmac and government bodies.




7.0 WORKSHOP FOUR

HEALTH INNOVATION OPTIMISATION IN NEW ZEALAND (HORIZON SCANNING, PRECISION HEALTH AND CLINICAL TRIALS)

7.1 This workshop focussed on determining what the critical success factors are to optimise implementation of three key health research and innovation platforms in New Zealand:

1. A unified health technology horizon scanning system
2. A precision medicines/health platform
3. A "1 stop shop" for clinical trials.

7.2 **Three core questions were covered during this workshop:**
What are the critical success factors for best practice health innovation optimisation in clinical trials, precision medicines, and horizon scanning?

What adjustments, if any, would be required in New Zealand to achieve this outcome in each area (clinical trials, precision health/medicines, and horizon scanning)?

What actions are needed to start the enhancement processes in each of the three areas (clinical trials, precision health/medicines, and horizon scanning), and who would be responsible for them?

7.3 **The workshop was led by an expert panel:**

- **Workshop Chair: Dr Christian Schwabe**
  CEO & Senior Research Physician, New Zealand Clinical Research (NZCR)
- **David Downs**
  CEO, NZ Story and Patient Advocate
- **Marina Dzhelali**
  Executive Committee Member, New Zealand Association of Clinical Research (NZACRes)
- **Katrina Lapham**
  Director of Strategic Market Access and Policy, Biointelect
- **Dr Ben Lawrence**
  Head of Oncology, Faculty of Medical and Health Sciences, University of Auckland
- **Alexander Muelhaupt**
  General Manager, Roche Pharmaceuticals New Zealand
- **Professor David Thomas**
  Founder and Chief Science and Strategy Officer, Omico Australia
- **Professor Ian Town**
  Chief Science Advisor, Ministry of Health

7.4 **Summary**
The need for long-term commitment, funding, and a non-partisan approach, from the government is an important building block for the success of optimising the benefits health innovation can bring for New Zealand. By developing and providing policies and strategy to enhance horizon scanning, precision health and the clinical trial environment in New Zealand, industry, patients, and the government would reap the benefits.

Multi-stakeholder engagement is also vital in the success of developing and implementing new policies and strategies. While it is positive that government has indicated that work has begun for each health innovation area, it is important that the government seeks feedback and engagement from all relevant stakeholders in each area.

The view from the panel and attendees of this workshop is that New Zealand does not need to start at zero and the Valuing Life: Medicines Access Summit 2024 is a template for how all stakeholders are able to come together to discuss how to improve New Zealand's health innovation environment to ensure it will be fit for the future. There is no need for New Zealand to "reinvent the wheel" when it comes to the development of a precision health platform or a "1-stop-shop" for clinical trials, when it is simpler to take existing international models and adapt them to fit the New Zealand environment.

7.5 What are the critical success factors for best practice Health Innovation Optimisation in clinical trials, precision medicines, and horizon scanning?

7.5.1 **Health innovation optimisation enabler:**

The following enablers were noted for all three health research and innovation areas:

7.5.1.1 Pathway for drug approval and funding:

a. The government needs to provide the industry with a clear pathway for funding of new technologies and therapies once they have completed the clinical trial phase.

b. There needs to be development of a framework which provides certainty for the industry to be able to invest in the country. Without such a pathway, there will be no public: private partnership.

7.5.1.2 Involvement of commercial partners to support optimised delivery.

7.5.2 **Clinical trials:**

7.5.2.1 Supportive regulatory environment is critical: one which is robust, consistent, pragmatic, and speedy.

a. Clinical trials have a major role to play in supporting a successful long-term health innovation strategy.

b. New Zealand has a positive track record with speed, data quality, and expertise.

7.5.2.2 Public health providers: increase public health providers ability to support more clinical trials.

7.5.2.3 Competent sites: create more sites by providing access to information, quality systems, standard operating procedures (SOPs), tools, and resources.

7.5.3 **Precision medicines:**

7.5.3.1 A national approach is needed, including adequate resources in the regions.

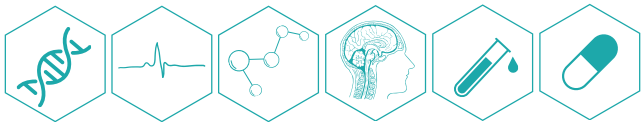
7.5.4 **Horizon scanning:**

7.5.4.1 Managing expectations: with new technologies arising through horizon scanning, expectations need to be appropriately managed, e.g., in terms of access to future medicines.

7.5.4.2 Time period: an agreed time period for horizon scanning, whether that would be 5 or 10 years.

7.5.4.3 Prevention and early intervention: need to encompass prevention and early intervention and not limit horizon scanning to technologies such as diagnostics and medical.

Ongoing dialogue: as patients can access both accurate information and misinformation through the internet, it is important that information is shared and made easily available to all stakeholders.



7.6 What adjustments, if any, would be required in New Zealand to achieve this outcome in each area (clinical trials, precision health/medicines, and horizon scanning)?

7.6.1 Multi-stakeholder engagement: wider involvement of stakeholders, including patient advocates and Non-Governmental Organisations (NGO) in consultations.

7.6.2 Resourcing: increasing resources in government/government agencies.

7.6.2.1 Appropriate resourcing at government levels to be able to conduct horizon scanning.

7.6.2.2 Sufficient resourcing is needed for screening and clinical trial delivery.

7.6.3 Strategy and policy: development of strategies and policies to provide structure and certainty for stakeholders including:

7.6.3.1 A long-term health strategy.

7.6.3.2 A medicines strategy that encompasses horizon scanning and a pathway to making new health innovations accessible to patients.

7.6.3.3 Providing a better environment and infrastructure for clinical trials to be run in New Zealand.

7.6.4 Access: improved access to proven, innovative treatments. The health system should not be relying on clinical trials to provide "standard of care treatment" for patients when effective medicines are available. Additionally, the need for long-term post-trial provision of medicines on a compassionate access basis presents an ethical risk for sponsors and an equity issue for the health system.

7.6.4.1 Providing a clear pathway for drug approval and funding at the end of the clinical trial process and when new technologies emerge.

7.6.5 Global competition: the government needs to be aware that the global clinical trials environment is competitive and there is a need to make New Zealand more attractive.

Consider making changes to the research and development tax incentive scheme for clinical trials to make it more attractive for global companies to bring trials to New Zealand.

7.7 What actions are needed to start the enhancement processes in each of the three areas (clinical trials, precision health/medicines, and horizon scanning), and who would be responsible for them?

7.7.1 To initiate enhancement processes in each of the three areas, several actions are necessary, with the government and government agencies, such as teams in the Ministry of Health and Health New Zealand taking the lead and responsibility in ensuring the actions are followed through.

7.7.2 **Collaboration and communication:**

7.7.2.1 Ensuring input from all relevant stakeholders is included in the consultation process, strategy development, and delivery.

7.7.3 **Resourcing Improvements:** for horizon scanning to be successful the government needs to increase resources for systematic scanning activities.

7.7.3.1 Commitment from the government to provide the structure and framework needed for a precision health platform and "1-stop-shop" for clinical trials.

7.7.4 **Approach:** New Zealand does not have to start at ground zero, adaptation and utilisation of other international models to fit the New Zealand environment is possible. For example:

7.7.4.1 Exploration of the Australian Omico model and how it could work in the New Zealand environment.

7.7.4.2 New Zealand could base its horizon scanning efforts on those of other countries, such as the UK, Canada, and Singapore who have started horizon scanning.

8.0 CONCLUDING REMARKS

In the intervening period since the Valuing Life: – Medicines Access Summit, there have been multiple developments that promise to improve medicines access for New Zealanders. On 24 June 2024, the Coalition Government announced additional investment to Pharmac of $604 million over four years to fund new medicines covering cancer, infections, respiratory conditions, osteoporosis, sexual health, dermatology, inflammatory conditions, and mental health. The following day, 25 June 2024, the first reading of the Therapeutic Products Act Repeal Bill took place in Parliament and the Government restated its commitment to the development of new legislation that would modernise the outdated Medicines Act 1981, and provide better regulation to ensure New Zealanders have timely access to medicines.

On 1 July 2024, the Ministry of Health released the Government Policy Statement (GPS) on Health 2024- 2027, setting the direction for the health system and the Government's priorities for the next few years. The priority areas set out in the GPS include access, timeliness, quality, workforce, and infrastructure to ensure healthcare services are readily accessible to New Zealanders in a prompt and efficient manner. Pharmaceuticals and medicines access were notably absent in the interim GPS (2022-24), so it is pleasing that specific objectives and expectations for improving access to medicines have been set in the 2024-2027 iteration in association with GPS priority areas 1 (Access) and 3 (Quality).

On 16 July 2024, the Hon. David Seymour, Associate Minister of Health (Pharmac), released the Letter of Expectations to the Chair of Pharmac, setting out what Pharmac is expected to focus on during the 2024/25 year. The Minister's letter covers a range of matters, including the need for Pharmac to improve organisational culture, to ensure that lived experience is incorporated into the assessment process, to improve its engagement with consumers, and update its decision-making and evaluation models to include the wider government and societal impacts of funding medicines.

However, for both our organisations, concerns remain that New Zealanders' medicines access is not comparable to that of the populations in our peer nations, including Australia, the United Kingdom, and Canada. Whilst the significant financial investment recently announced by the Government will make inroads into the lengthy medicines' waiting list that the Options for Investment List represents (currently 100 medicines and vaccines as of 2nd September), there will still be many medicines left waiting on the OFI list. The medicines which will remain on the list have already been through Pharmac's assessment processes, so it is known that they are cost-effective investments. The ongoing delay in funding these medicines represent a significant loss of opportunity for New Zealand, because access to these medicines would make an appreciable difference to the health, quality of life, and potentially longevity and productivity of the New Zealanders who need them.

The Government's commitments to reform and modernisation of medicines regulation, and increased medicines access through specific directives in the GPS, are both also very welcome developments. Yet the environment for optimising medicines access in New Zealand needs further enablement, because our current system is so far behind. We think that the key findings of the four workshops held during the Valuing Life – Medicines Access Summit remain as relevant now as they were on the 29 April 2024.

We hope that those of you able to attend the Valuing Life – Medicines Access Summit found it a useful and inspiring event. For those of you only able to experience the summit by reading this report, we hope you will get a sense of the collaborative conversations that took place and the sincere commitment of all present to system change that will result in better outcomes for all New Zealanders. In conclusion, we challenge you to take note of the recommendations for change identified in the workshops and be motivated and guided in translating the key findings of our report into action.

9.0 APPENDICES

9.1 WORKSHOP ONE

Enhancing Health Technology Assessment (HTA) processes in New Zealand

9.2 WORKSHOP TWO

Building a fit-for-purpose Medicines Strategy for New Zealand

9.3 WORKSHOP THREE

Better stakeholder engagement in decision-making processes

9.4 WORKSHOP FOUR

Health innovation optimisation in New Zealand (horizon scanning, precision health and clinical trials)

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9.1 APPENDIX ONE

WORKSHOP ONE WRITE-UP
ENHANCING HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESSES IN NEW ZEALAND

Chair: Sarah Hogan, Deputy Chief Executive (Wellington) and Principal Economist, NZIER

This workshop focussed on potential enhancements that can be made to existing health technology assessment (HTA) processes in New Zealand.

The Chair opened the session, introduced the panel members, and explained that the session was to operate under Chatham House rule. In the workshop opening, the Chair noted that the Summit had highlighted the critical importance of transparency in good health technology assessment (HTA) process and decision making. There was clear support from workshop attendees that transparency was important, but a workshop panellist raised the additional point that timeliness and certainty were also critical for patients - "so people can decide what they are doing in life".

The workshop Chair led an expert panel and workshop attendees through a lively discussion of how transparency, timeliness and certainty, could be delivered for patients and other system stakeholders by focusing on three core questions:

1. What does a good HTA process look like?
2. What adjustments, if any, would be required in New Zealand to achieve this outcome?
3. What actions are needed to start the enhancement processes, and who would be responsible for them?

In the discussion of these questions, the potential for incorporation of societal perspectives and a more holistic approach to accounting for costs and benefits was explored, as was the opportunity for evolving practice overseas to be informative of the New Zealand system. Workshop attendees had been provided with a selection of relevant references as pre-reading materials (see the report references for details on these materials) and a paper which provided a comparative assessment of the incorporation of societal perspective into the HTA guidelines of different countries provoked particularly strident debate.

Importantly, despite the diverse and divergent opinions expressed at times on both the technical and philosophical challenges in New Zealand's current approach to HTA, triangulation of views was feasible. It was possible to identify the current barriers to meaningful change in the HTA process in New Zealand. Through exploration of these barriers, recurrent themes emerged for systemic change to support HTA methodology reform and process enhancement.

- **Adoption of a comprehensive, cohesive, whole-of-system approach to HTA methodology**
  - Genuine consideration of flow-on impacts in the health system.
  - Incorporation of societal perspectives including productivity impacts when appropriate.
  - Pharmac's operations resourced sufficiently to enable their practice to keep pace with the changing treatment environment (horizon scanning of new health technologies.)
  - HTA methodology evolved and refined in step with international best practice and changing societal and patient needs.

- **Multistakeholder approach – and a "user-friendly" system**
  - Patient voice and perspective are front and centre and "lived experience" is accounted for.
  - Recognition of different populations' needs.
  - Multidisciplinary – greater incorporation of health and allied professional perspectives.
  - Openness to different stakeholders' objectives in support of more transparent and collaborative, and less transactional relationships.

- **Greater investment in medicines through a whole of system approach to funding and amendment of Pharmac's statutory objectives:**
  - Increased flexibility of methodological approaches.
  - Remove the legislated budget cap which is unique to Pharmac within the health system and distorting of decision-making.
  - Cohesive and allocatively efficient budget allocation across Vote Health

- **The work of the Independent Pharmac Review must not be wasted, and the recommendations be delivered on through genuine change**

A composite of the detailed notes taken by the two workshop scribes follows. It was notable that although there was significant debate between workshop participants and at times there appeared to be disagreement, when the respective responses to each question were evaluated, common ground could be identified. The discussion in response to each consecutive question built on this common ground. By drilling into the factors that informed participants' initial responses the overlap and saturation of themes for system improvement and change became clearer.

What does a good HTA Process look like?

Triggered by the Chair's opening comments and the first workshop question, a workshop panellist strongly voiced the opinion there is a significant dichotomy between theory and practice in New Zealand's HTA framework for medicines because the aspirations of patients and clinicians for transparency in the system are not fulfilled by Pharmac's current HTA methodology and mode of operation in which "[the] Focus on cost comes up everywhere and the societal perspective seems to be missing".

Following from this, another panellist shared the observation that from a philosophical perspective all stakeholders in the HTA process have the same primary objective of ensuring that patients have access to effective, innovative medicines that will improve health outcomes, but different stakeholders have different secondary motivations and objectives:

- Patients and clinicians need now the clinically effective treatments that they know exist.
- Governments/payers want to manage the costs of funding medicines within overall health system costs.
- Biopharmaceutical companies have commercial imperatives.

The panellist expressed the view that at a high level a "fit for purpose" medicines assessment and procurement system will recognise that these differing secondary objectives are legitimate, and that all these stakeholders therefore need to have input into the process. The panellist voiced the view that the existence of the Options for Investment (OFI) list demonstrated that there is a disconnect between primary and secondary objectives for stakeholders in the New Zealand HTA process.

The panellist contextualised their opinion by explaining that whilst there is a defined entry point to Pharmac's HTA process, and a degree of transparency around PTAC assessments, medicines can successfully make their way through the assessment process and then languish on the OFI list with no certainty of timely funding. "From a practical perspective, current HTA process in New Zealand works to a point… "[B]ut then the process gets lost".

These perspectives were initially shared by one panellist, but they clearly resonated with most workshop attendees. At a high-level there was agreement that aspirations for change ("what good looks like") would include:

- A fit for purpose medicines HTA process and procurement system that takes account of the different needs and objectives of all stakeholders in the process.
- Greater engagement with stakeholders and less transactional relationships to support timely patient access to innovative medicines that will improve health outcomes.
- Medications which have been assessed and found to be worth funding are funded in a timely manner -i.e., they do not remain "in the OFI black hole" waiting indefinitely for funding. This point was seen as particularly essential to meeting the primary expectations of all stakeholders.

The identification and voicing of these high-level principles for reform of the current approach to HTA in New Zealand then set the scene for a more in-depth discussion of what "good could look like".

Transparency, comprehensiveness, and cohesiveness needed in HTA methodology:
There were a number of views expressed relating to the theme of transparency as a critical driver of fit-for-purpose HTA. It was also seen as important to ensuring a comprehensive and cohesive approach was taken to HTA methodology across the health system, thereby levelling the playing field for medicines assessment.

- Stakeholders should have greater visibility - over not just the overall process but also what is being using in the HTA assessment model and how it is being used – they should be able to discern if there is double-counting or conversely things missed from the process and model that should be included.

- The system needs to be evidence based, but often there will be uncertainty in the evidence available, so there needs to be a proactive and forward-thinking effort to develop robust approaches to dealing with uncertainty.

- The system needs to be unbiased and multidisciplinary – Pharmac's expert Committees include some non-doctors (i.e., pharmacists) but should be further expanded to include representation from the wider health care professions. This would help ensure a better understanding of the health and societal impacts of funding decisions.

- A cross-health system approach should be taken to HTA and there should be greater standardisation across the health system - HTA process should be consistent across all areas of the health system.
    - A panellist expressed the view that the work Pharmac does in cost effectiveness assessment of medicines is likely to be more robust than the approach taken in other areas of the health system! They proposed that potentially the same HTA cost-effectiveness standard should be applied to non-pharmaceutical interventions.

Societal and lived experience perspectives must be included:

There was agreement from many workshop attendees that the societal and lived experience perspectives are missing in the current New Zealand HTA system for medicines.

- The system needs to better recognise the differing impacts of illness on different patient populations (for instance caregiver burden), and the different needs that diverse communities may have.

- Without recognition of "lived experience" as the actual experience of people with a condition early enough in the assessment process, and consideration of the broader implications for society including productivity impacts, HTA assessments are unlikely to recognise the full value of investment in a medicine.

Heated discussion followed as to the "how" of reform of HTA methods for Pharmac to include such perspectives could be possible:

- The tensions between Pharmac's need for evidence to base decision-making on, their resource constraints, and the need to ensure that the distributional effects of decision-making are fair (i.e. serve everyone equitably not just the loudest or best resourced voices) were all acknowledged as potential obstacles to process reform – solutions were proposed to these barriers (see question 2).

- However, there was a majority agreement by attendees that if we are to improve patient outcomes, we have got to be aspirational for the HTA system - as one panellist stated, "Let's not say - it is all too complicated so let's not do it".

The HTA system must be future-looking and user-friendly.

- Incorporation of horizon scanning activities
    - Strong opinions were also voiced that ongoing change was necessary for Pharmac, to give public confidence that we have an HTA system robust enough to deal with the increasing numbers of innovative treatments that are personalised, and that prevent illness and not just treat the symptoms. "Doctors have to go to conferences as part of professional development, but [Pharmac's] specialist advisory committees need to be exposed to that horizon scanning too."

- Straightforward system required.
    - If the system is to be responsive to all stakeholders' needs, then it needs to be straight-forward and accessible - "patients and clinicians can't spend hours putting submissions together, so it needs to be user-friendly"

What adjustments, if any, would be required In New Zealand to achieve this outcome?

Drivers of this change were seen as being:

- A more active rather than passive system – "a system that considers what patients and clinicians need rather than passively waiting for applications";
- A multistakeholder approach - and genuine engagement with those impacted by decisions.

A panellist elaborated on their view that this was important by sharing their impression of the closed nature of the application assessment process despite recent changes by Pharmac.

"In [the] current submission application form, it does ask about societal outcomes and costs, but it is [sic] not included in the economic assessment – there is the grab bag of "Factors for Consideration", but it is not really clear what factors are really being used to make the decision. PTAC minutes give a vague flavour but not the full sense. What factors are impacting on the decisions? Even from PTAC Minutes we can't understand why the decisions were made. More transparency? It feels that the only time we get something is when we push back."

- A system that is flexible and open to new ideas – this was a common refrain from workshop attendees although it was acknowledged that Pharmac is improving in this regard.
- Sufficiently resourced HTA agency – not just funding for medicines but resourcing for Pharmac staff and systems. One panellist noted that in some jurisdictions, HTA agencies charge application fees.
- Consideration and appropriate adoption of new practices and international standards
    - Benchmarking with peer countries to ensure that New Zealand's standard of care and access to medicines is appropriate. "It's embarrassing that Kiwis are having to go to Australia to get drugs - it's time to put the consumer [patient] front and centre."
    - Update of Pharmac's Prescription for Pharmacoeconomic Analysis e.g., including incorporation of broader societal perspectives and productivity benefits (such as the Dutch model).

There was particularly strong discussion of the opportunities, of incorporating societal and productivity perspectives into HTA. It was pointed out that societal perspectives are commonly incorporated in cost: benefit analyses by other Government ministries/agencies in New Zealand, and the question raised as to why Pharmac did not include them.

"The Pharmac model has been there for 30 years, it's not clear whether issues from [the] Pharmac review have been dealt with but probably more fundamental than that – why does Pharmac not have a societal component when everywhere else in government there is?"

Countering this, a panellist raised the challenges of process change and the potential risks, including the potential equity impacts it may have for high-needs patient populations (for example disabled communities).

"Main thing is the budget! Societal benefit won't give a cent more spent on pharmaceuticals, we need to be careful that this doesn't disadvantage those who cannot work and there would need to be public consultation before such a significant change was made"

These concerns were seen as valid but not insurmountable. The appropriate weighting of lived experience, time and opportunity cost were both proposed as means to address equity and distributional fairness concerns that may arise if societal and productivity perspectives are incorporated.

"Could use an opportunity-based approach. It's important to get kids into school not just people into work."

Overall, the debate on this issue settled at an uneasy equilibrium that can perhaps be summed up by the following opinion from a panellist

"Societal perspective won't work for every disease. Funding, budget this needs to be addressed… Societal perspectives could be a way to convince Treasury to do this".

Critically, the strongest message that came out of the discussion of this question was that the HTA system and process can only work efficiently if it is properly integrated with the rest of the health system:

- Investment in medicines should be driven by principles of allocative efficiency rather than HTA decision-making on medicines funding being arbitrarily hamstrung by a legislatively capped budget
- Other health entities do not have to operate under such a legislated constraint – this is problematic because it distorts decision-making to a high degree
- Pharmac would likely need a change to its statutory objective to be able to appropriately include societal benefit and for the funding of medicines to be better integrated into budgetary decisions across the Vote. A legal assessment and advice, and likely public consultation on this, is important to ensure that any resultant change is beneficial and does not have unintended consequences.

What actions are needed to start the enhancement processes, and who would be responsible for them?

Many of the ideas and opinions expressed in response to questions 1 and 2 were restated in response to question 3 as actions that are needed to be taken. Many attendees in the discussion expressed the view that successful reform of the system will rest upon willingness by the Government and key public officials to acknowledge that the current system doesn't work and to address both the level of funding and the funding model within the health system.

Overarching comments from attendees loosely grouped under three main themes:
1. Greater investment in medicines
2. Consultation, collaboration and communication
3. Revive the Pharmac review and deliver on its recommendations

Responsibility for the actions associated with each of the themes was seen in terms of both leadership (direction setting and financial enablement) by the Government and accountability for delivery by Public Officials (Ministry of Health, Health New Zealand Te Whatu Ora and Pharmac itself).

Greater investment in medicines

There was wide consensus at the workshop that the current Pharmac system of HTA is unable to meet the needs of patient and clinician stakeholders in the system because of the limited budget available to it through the current funding model. System change is unlikely to be successfully implemented unless the approach to setting the agency's budget is also addressed. Comments highlighting these perspectives included:

- "There needs to be acknowledgement that the system doesn't work"
- "Want to see something that is more optimisation focussed and less short-term cost focussed"
- "Budget, is - "what is the clear factor?""
- "Hate the Options for Investment list with a vengeance"

A panellist reiterated the view that the inclusion of the societal perspective/impacts into current HTA process would be an important tool for engagement with the Government on a higher level about why investment in medicines is important and worthwhile:

"Use societal impacts as the case for more budget – Societal benefit isn't just a tool for Pharmac to use to evaluate the funding of a medication but is to be used to give a whole picture for the Government for overall funding"

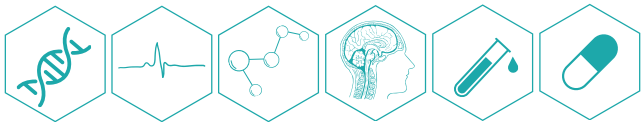
A discussion ensued of using societal perspective as an effective way of increasing the Pharmac budget within the health system– "giving leverage to increase the piece of pie for medicines". It was suggested that there were three core questions that would have to be addressed to make this possible:

- What are the policies?
- What are the methods?
- What are the processes?

The operating budget Pharmac would need to "do this job properly" and answer those questions was also raised and Pharmac's current operational budget limitations were noted by a workshop participant.

"In the health system budgeting space, investment decisions need to look at societal perspective and the impact investment has on other programmes and society itself. There are learnings on how to improve this, but we [NZ/Pharmac/health system] need the resource."

However, these operational limitations were not seen as insurmountable by others in the workshop. The work that the Ministry of Health is leading on the development of a Medicines Strategy was seen as potentially enabling and informative provided Pharmac has appropriate involvement.



Consultation, collaboration and communications (multi-stakeholder and patient-centred approach)

Many of the panellists remarked that it was important that any change be predicated by an understanding of what people want from the system and what trade-offs they are prepared to make to get this.

- Several remarked that public engagement and consultation may be necessary to have this understanding
- It was suggested that it was necessary to find out how New Zealanders think about fairness with respect to medicines access.
- A panellist remarked that internationally, research is happening using public preference discrete choice experiments to answer the same sorts of questions. The work of New Zealand health economics experts/leading academics to understand what people prioritise in terms of funding decisions was also mentioned.
- A workshop attendee remarked that the "Summit was a fantastic example of multi-stakeholder approach, several layers of discussion and review at the higher level".
- The Independent Pharmac Review was also cited as having been an important step in consulting the public about what people want from the system *"What do people want? Timely access to effective medicines"*

Overall, despite the variances in opinions expressed as to how to best answer the question of wants vs trade-offs, it was clear that seeking collaboration and taking a multi-stakeholder and patient-centred approach will be essential. This approach is necessary to the success of any process of reform and improving outcomes at both the macro and micro levels:

- *"Needs to be bigger and broader than just the bureaucrats"*
- *"Understanding what we want the system to do is important, what we care about, this will only come from really collaborative discussions amongst all the stakeholders"*
- *"We have a need to meet with the Ministers etc – to show ground Zero"*
- *"The system needs a review; the world has changed. It might be a co-design process with all stakeholders - patients, academics, industry etc,"*
- *"NZ patients – all things being equal, are likely to think that the severeness of disease is most important, but if we engage them in the funding choices that are most relevant for them, they will be pro-choice and open to trading off"*

Revive the Pharmac review and deliver on its recommendations

It was raised by several workshop participants that there is a need for urgent change because aspects of the current situation are so severe that the system could be considered shameful or broken.

- *"Fewer medicines are coming here. How do we get from the back of the pack to the front of the world? PHARMAC [The system], not the people, are broken. It's embarrassing …"*
- *"The experiences of Emma and Fiona* are absolutely unacceptable – so what should be prioritised in terms of what can be done now?"*

Revisiting the findings of the independent review of Pharmac review was seen as an important step to addressing the question of how to make quick progress for change. "Go back to Pharmac review and look at all the findings and see if they can be genuinely done and what that should look like."

In response to the Workshop Chair calling on attendees to wrap up both question 3 and the overall workshop discussion, the following points were made:

- *"Nothing will change unless the budget does/The loudest thing to come out from today is that the budget missing from access."*
- *New Zealand should not have an "options for investment list" – it is a failing of the current HTA process.*
- *"PHARMAC need to go away and work out what they need operationally to be able to do their job more effectively and responsively."*
- *"It's not impossible to make changes but we need to figure out what we focus on."*

The session closed with the following summation- *"What should be prioritised and how?"*

- Go back to the Independent Review of Pharmac in a detailed way.
- Scope up what change might look like
- And who should do it.

* Emma and Fiona were the patient representatives who spoke in the morning session of the summit

9.2 APPENDIX TWO

WORKSHOP TWO WRITE-UP
BUILDING A FIT-FOR-PURPOSE MEDICINES STRATEGY FOR NEW ZEALAND

Chair: Dr Lee Mathias, Independent Director, former Chair HPA, Medicines New Zealand and Counties Manukau District Health Board

This workshop focussed on establishing core themes and elements for a modernised medicines access strategy that will allow greater certainty for all health sector stakeholders and help future-proof the health system.

The objective of the session was outlined by the Chair as bringing the relevant stakeholders together for open discussion and to break down barriers to find solutions.

What should a good medicines strategy look like, and have as core elements?

- A panellist identified three essential elements to a good strategy as:
  - Understanding the problem you want to solve.
  - Understanding the choices and trade offs that will need to be made (i.e. talked about finite resources).
  - Identifying the crucial factors.

Attendees noted that a good strategy will help decision makers make trade offs and choices. It was also emphasised that this could be achieved without a strategy, so it is important to be clear what the objective of the strategy is.

It was noted that a good strategy must have a clear vision – for example, New Zealanders having access to the most effective medicines to treat their diseases when they need them.

A good strategy should be patient-centric and contain mechanisms to deliver outcomes for real people in a timely manner to decrease delays in medicines access.

- Those with responsibilities need a 'mission' and that should be to truly achieve access to best practice treatments.

A good strategy should have key values, such as:

- Having an aspiration for best patient outcomes.
- Being proactive.
- Taking responsibility for equity.
- Encompassing innovation - through horizon scanning and transformative technologies.
- This would need to include ethical considerations and avoid genetic discrimination.
- Being connected and collaborative across Government agencies, patients and industry. Multiple panellists agreed that collaboration is fundamental.
- The question of trade offs needs to be considered more holistically not only in health but across agencies.

Other core elements that need to be included are:

- The importance of being efficient and effective. Examples of this include:
  - Implementing global best practice guidelines and drawing upon existing "global wisdom"
    - For instance, there is an international drive to regulatory harmonisation and health economic collaboration so Medsafe and Pharmac could be utilising these approaches rather than repeating the work other countries have done.
- Consideration of the medicines budget to ensure the delivery of the strategy is feasible; it needs to include explicit mention of how sufficient funding will be enabled within the broader health budget.

This element to be incorporated in the strategy led to significant discussion with some strong views expressed, such as:

- New Zealand should be benchmarking to the OECD average medicines budget or higher.
  - The question of why New Zealand has refused to report to the OECD on this since 2007 was raised.
  - It was highlighted New Zealand is missing out on a large number of medicines and without a medicines budget that reflects the OECD average, we cannot be at all ambitious in a Medicines Strategy.

"Even though New Zealand has an income that is around the middle of the OECD it can't afford infrastructure, healthcare, or medicines which leads to the question of where the money is being spent."

- In comparison to other OECD countries, New Zealand's overall health budget as a percentage of GDP is adequate, but the medicines budget is grossly inadequate, by four to five fold.
  - The medicines budget has not kept up with where the best investments are for society and patients.
  - The health budget operates in silos and is disproportionately weighted and needs to be rebalanced towards medicines.

The importance of considering the health system and wider social costs of ill-health were seen as core elements for the strategy to address in consideration of funding for medicines:

- Healthcare needs to be prioritised and medicines need to be seen as a way of generating health and wealth.
  - New Zealand misses out on medical advancements and it was noted that the current suboptimal care people receive affects their ability to return to work and participate in society. However, it is not taken into consideration by Pharmac when assessing medicines.
    - A panellist noted that New Zealanders have grossly inferior outcomes (cancer was used as an example), and that there are also clear examples of inequity as the wealthy can access medicines but the vast majority can not.
- A critical issue is that patients may miss out on innovative treatments and certainty of medicines supply may be compromised if pharmaceutical companies exit New Zealand due to the current limitations on funding.
  - It was raised that people are becoming medical refugees and leaving New Zealand for Australia to receive treatment.
  - The sole supplier Pharmac model is problematic and leads to stock issues, even for standard medications, this needs to be addressed.
- A panel member observed that there is a vital role for medicines to become integrated in the health system to save downstream costs.
  - E.g., during the pandemic community pharmacy really stepped up and we had access to antivirals and vaccines quickly in the community which eased pressure on hospitals. It was raised that if this is what we can do in a time of need, what can we do as "business as usual" around prevention and well being and keeping people out of hospital?
- There was discussion of looking further at public-private streams of funding which may need to be considered in a good Medicines Strategy.
- The best medicines available should be used effectively, and that a potential principle for the strategy should be that the best medicine for the job is used (an example of using a long acting instead of a short acting medicine for patients who struggle with adherence was used).
- There was concern surrounding the narrative *"New Zealand is a poor country and cannot afford the medicines available in other countries."* Attendees noted that this is not true, and that until public perception has changed and the public understands what we are missing out on, driving change will be difficult.
  - This may be something that a good strategy can make clearerand 'set the scene'.
- The strategy should enable the investment required to support public/private system interfacing that could alleviate health system pressures through improved medicines access.
  - Private hospitals and centres are saying they have capacity to clear space in the public system. This is an opportunity for public-private partnership.
  - The panel noted that we need to use the resources that are available to us to improve patients' access to treatments. Whether that is public, private or in-home care.

What adjustments, if any, would be required in New Zealand's existing 2007 Strategy to achieve this outcome?

New Zealand needs a strategy that addresses current problems but is aspirational, as it has been 17 years since the creation of the existing strategy, and a lot has changed in that time.

The following areas were identified by the panellists as missing from the current strategy:

- Horizon scanning of health technology needs to be embedded across the overall health system, (not just at Pharmac) so that the entire health system is aware of new health technologies and can plan for their impacts.
- Guidance from patient reported outcomes and quality of life, alongside hard scientific data.
- Mechanisms for transformation and how to establish pathwaysfor change.
    - The panellists voiced that the actionplan from 2015 associated with the 2007 strategy has not delivered anything of note.
- Milestones with accountability for deliverables.
- Focus on primary prevention and keeping people healthy.
    - The idea that prevention up front in a primary setting leads to less spend later on, for the health system i.e., hospitalisation.

Areas for change in the existing 2007 strategy were also discussed:

- The model (page 3 diagram in existing 2007 Strategy) of the Government at the top provides for a consumer who receives, with 'Pharmaceutical industry' off to the side. It was raised that this diagram, if retained, needs to represent more of a partnership and that consumer needs and inputs should be valued and actively sought rather than just seen as the end-user.
- The strategy needs to be more multi-stakeholder centric than is currently indicated.
    - This needs to be led by good use of data to help break down existing silos in the health system.
    - HQSC has some data but it was noted that it needs to engage with all stakeholders, not just officials, to drive change.
    - That the current Medicines Strategy is in part an aspirational document, but that it is not seen by those working in health and is not embedded in the system.
    - It was discussed that to change this Strategy for the next iteration, there needs to be strong collaboration and a government that will stand behind it and provide the necessary funds to operationalise the Strategy and the strategic goals.
- Industry needs to be recognised as a key stakeholder, and as a country New Zealand needs to aim for industry to thrive and be part of the system.
    - This requires clear line of sight on certainty of investment into medicines by Government, but is accompanied by a spill over benefits to country and patients and public health system, such as access to clinical trials and compassionate access
- It was raised that the Medicines Strategy should centre on patient pathways i.e. focus on the patient and prescriber and be built around them to make it as easy as possible for them to navigate and operate in the health system specifically around medicines.
- It was raised that the system is driving inequity as people are paying out of pocket and that a lot of New Zealand's inequity is driven by how Pharmac is set up.
    - Panel noted that whatever Medicines Strategy is developed, structures need to not drive inequity.
- Prevention in the context of New Zealand's ageing population needs to be considered. For instance, immunisations- and this needs to be part of the Medicines Strategy.
    - A panel member noted that using medicines at the right time and not at the wrong time is important, another member highlighted the importance of optimisation and making sure the medicines used are right for the stage of life.
- It was noted it would be good to see the strategy outline what the clinical pathway looks like for specific groups- for instance oncology- from prevention, through to primary, secondary and tertiary services.

What actions are needed to start the enhancement processes, and who would be responsible for them?

- **Things not in the current strategy that are needed were discussed as follows:**
  - Having a vision which reflects what the settings needs to be : Stating what position New Zealand wants to hold- i.e. Just average? Or the desire to be a world leader or a fast follower in terms of comparative medicines access. This needs to be established and stated in the strategy.
  - Embedding horizon scanning and role of medicine innovation in strategy that focuses on impact and embedding of innovation in the health system.
  - End to end delivery where all government departments/agencies/ministries can see how they align which aids in breaking down the silos.
  - Mechanisms to join forces and collaborate more closely domestically must be explicitly stated in strategy which aids in breaking down the silos between and within public health system and officials.
  - Look at opportunities to collaborate internationally around innovation- New Zealand does not need to start from scratch (e.g. the genetic oncology and clinical trials program in Australia was used as an example here),so include collaboration as part of the strategy if and where appropriate.

Ministers responsible for Health and medicines strategy need to take responsibility for changing the settings in existing strategy so that the above is enabled.

- It was proposed that we need to build an inclusive and collaborative multi-stakeholder Medicines Working group to update the medicines system including the strategy.

Ministers of Health, including those accountable for medicines strategy would be responsible to initiate this multi-stakeholder working group, with stakeholders in the group being multi- stakeholder representatives (i.e. patients, officials, health practitioners (pharmacists, doctors, nurses) and industry).

- Need to have that Working Group agree on vision, mission, values, and objectives for strategy then identify actions needed to achieve mission and assign responsibility for each of these actions.

The working group would take responsibility for this while consulting stakeholders through this process for strategy and informing the Minister(s).

NB: Suggested that the multi-stakeholder Medicines Working Group become permanent to ensure ongoing multi-stakeholder collaboration and interactions, and to advise the Ministers.

- Need to include a medicines strategy in the Pae Ora (Healthy Futures) Act was raised in relation to creating greater accountability. A panel member noted this would be time-consuming and they would advise against it, but many other panel members held the opposing view and noted how quickly legislative change has occurred this political term.

Minister of Health and Associate Minister of Health (Pharmac. Medicines Strategy) to take responsibility for this change to Pae Ora (Healthy Futures) .

- It was noted that commissioning/procurement and reviewing of medicine is not intrinsically linked to the Government Policy Statement (GPS) for Health , and this needs to be altered now. This would be done by including statements around medicines commissioning procurement within the GPS by the Government. This would then allow it to be part of prioritised planning i.e. into the National Health Plan (NHP) and then into policies and actions in the health system therefore all stakeholders would be engaged and accountable.

Minister of Health and Associate Minister of Health (Pharmac. Medicines Strategy) to take responsibility for this change to Pae Ora (Healthy Futures) .

- Capped budget in Pae Ora (Healthy Futures) Act for Pharmac also a problem and a need to alter the statutory objective so that focus is on best health outcomes that are reasonably achievable i.e. remove phrase "from within the amount of funding provided". That way the health system, including Pharmac, focuses on patients and the ability to measure health outcomes.

Minister of Health and Associate Minister of Health (Pharmac) Medicines Strategy to take responsibility for this change to Pae Ora (Healthy Futures) .

- Discussion on the need for suitable investment setting and a need to articulate this in an updated strategy as highlighted earlier. A panellist noted that there was some difficulty in moving money within the health budget (VOTE Health), and so needed to look at new investment coming in if looking at pharmaceutical funding to be OECD benchmarked i.e. increased. This reprioritisation of money within the Health budget would be difficult. However most members of the panel and audience did not agree with this perspective, and felt that it came down to allocative efficiency as with many budget matters.

Associate Minister of Health (Pharmac) to take lead on investment setting , supported by Health officials.

- There was discussion about the limitations Pharmac has in examining cost utility and that a wider view using broader measurements such as societal impacts (indirect costs) and a social investment approach to show that medicines are the best investment needs to be taken. This allows for better allocative efficiency cases to be made around medicines in the overall health system and productivity setting for the country.

Associate Minister of Health (Pharmac) responsible for working with Pharmac to update assessment tools to include broader societal impacts, supported by Health officials.

- A panel member noted that if all consumers speak with one voice, politicians will listen and that creating one consumer-led Medicines Strategy is the best way to achieve policy change. Certainly the role of consumers in any multi-stakeholder developed strategy will be vital.

Patient Voice [Aotearoa] to be responsible for ensuring suitable consumer representation in any Medicines Working Group established.

General discussion points raised during the workshop

- The question was raised as to how we enable the preparedness and awareness of the entire health system to the new Medicines Strategy (given lack of knowledge about the 2007 version)
  - It was noted that once formulated the Medicines Strategy needs to clearly communicate to all stakeholders which would play a role for all stakeholders involved in its development.
  -
- It was asked how important the gathering of evidence has been overseas e.g. Australia to demonstrate cost effectiveness.
  - It was noted that drugs that have come forward in 50 plus markets are safe and effective and that is clear. The uncertainty issue is something that needs to be managed but the issue is not a lack of data or evidence.
  - It was suggested by a panel member that uncertainty is used as an excuse for rationing, while another noted that there are 140 medicines in Pharmac's waitlist (Options for Investment) that are recommended so the issue is funding not uncertainty.
  - It was raised by a panel member that the funding for those medicines are sitting in bed days in hospital and lack of productivity, so a sunk cost and better investment in the medicines to avoid downstream issues in hospitals.

9.3 APPENDIX THREE

WORKSHOP THREE - WRITE UP
BETTER STAKEHOLDER ENGAGEMENT IN DECISION-MAKING PROCESSES

Chair: Sue Chetwin, Chair, Independent Pharmac Review

The Chair opened the workshop by introducing the panellists and explaining the workshop was under Chatham House rule and giving the disclaimer that the panellists' views do not reflect the views of PVA and MNZ. The Chair then outlined the three questions that were going to be asked of the panellists and attendees.

1. What does a good consumer engagement in decision-making processes around medicines look like?
2. What adjustments, if any, would be required in New Zealand to achieve this outcome?
3. What actions are needed to start the enhancement processes, and who would be responsible for them?

What does good consumer engagement in decision-making processes around medicines look like?

- **Vital role of patients, citizens, and consumers**
  - Patients, citizens, and consumers are essential to HTA processes.
  - Engagement is supported by substantial research and evidence, with organisations like PCIG promoting this involvement.
  - Effective HTA cannot exist without patient input.

- **Components of effective consumer engagement**
  - Patient collected evidence: gathering quantitative data directly from patients.
  - Patient storytelling: qualitative insights through personal stories, which are compelling and provide context.

- **Importance of early engagement**
  - Consumer engagement should begin at the start of clinical trials.
  - Early involvement ensures that the right questions are asked, reflecting patient priorities and outcomes beyond clinical data.

- **Financial support for patient groups**
  - Advocacy groups often lack funding.
  - Research grants should allocate 10% specifically for patient groups to support their participation in HTA.

- **Outcomes of improved engagement**
  - Enhances the relevance and transparency of decision-making processes.
  - Focuses on unmet health needs and the suitability of products, particularly for marginalised communities.
  - Leads to better accountability and consistency in HTA outcomes.

- **Collaboration and transparency**
  - Stakeholders must work together to gather comprehensive and relevant information.
  - Parallel assessments of patient voice and standard HTA should be integrated at the end of the process.
  - Transparent processes where feedback and submissions are publicly accessible.

- **Learning from international examples**
  - Australia: co-design assessment process with 19 tasks, of which New Zealand is good on 6, needs improvement on 8, and lacks action on the rest.
  - Canada: CADTH model with early and broad stakeholder engagement, consumer input, and transparent online submissions and feedback.

- **Challenges with current systems**
  - Mathematical approaches like QALYs dominate but may not reflect the full value of treatments.
  - Need to balance local cultural considerations, especially for Māori and Pacific communities, with international data.

- **Global collaboration**
  - Engaging international experts can provide valuable perspectives.
  - Sharing data and processes across countries can prevent duplication of efforts and leverage stringent international assessments.

- **Equity and inclusion**
  - Inclusion of older demographics and other marginalised groups is crucial.
  - All lives are equally valuable, and input from diverse age groups enhances the richness of consumer engagement.

There was a question from the attendees *"Do you think there are opportunities to collaborate between countries"*. It was noted that bringing in experts from overseas could ease pressure on patient advocates, as those experts would be able to provide a patient perspective if they have treated them. Given clinical data already comes from overseas, it wouldn't then be unusual to also collect lived data from overseas as well. New Zealand is the last cab off the rank, so let's invite in the global experts and value what they say.

A panellist noted that New Zealand is not the rest of the world (in relation to our focus on Māori and Pacific communities), countries like Australia can hold their own due to their size, but smaller APAC countries, like New Zealand can get left behind. There is no opportunity to get the data and the analysis to show the challenges in the smaller countries and there is a massive need to look at this differently. If a medicine has passed all the 'tests' in another country, why do we need to do it all again here?

Another panellist asked if consumer data or stories were presented to Pharmac, how would that be assessed? It was noted again that much of the data currently used is from overseas, so it wouldn't be unusual to look at the consumer data, however there isn't currently a framework for doing so, but we would be remiss to ignore local consumer data.

An attendee asked *"Does Australia cut people off after a certain age"* [in terms of funded access to a medicine/vaccine] using the shingles vaccine [in New Zealand] as an example.

A panellist answered, saying that it was similar in Australia [for that specific example] and that after a certain age, to get the vaccine you would have to pay for it, but for something like Cancer medicines, it wasn't thought that there were age restrictions.

An attendee asked, *"How valuable is an older person's voice in terms of 'consumer voice'?"* The panel answered, 'A life is a life is a life, everyone is equally valuable'. It was noted that a study conducted in Australia, thought that the results would be that younger people value their lives more, that wasn't the case. It was also noted that Pharmac's CAC do hear from those in an older demographic but also younger demographics.

What adjustments, if any, would be required in New Zealand to ensure a better outcome?

- **Consumer input and benchmarking:**
  - Consumer role: It's crucial to maintain consumer input, but the driving force in New Zealand is the availability of medicines overseas. Currently, Pharmac does not monitor international developments or incorporate these comparisons into their processes.
  - Benchmarking: mandating continuous benchmarking against international standards would address many consumer concerns about Pharmac. This comparison can help New Zealand keep pace with global advancements and improve the local pharmaceutical landscape.

- **Medicines as investment:**
  - Investment perspective: medicines should be perceived as investments, not costs. Discussions involving patients, industry representatives, and Pharmac could benefit from Treasury's input, which would provide a balanced view of the long-term economic impacts, such as reduced hospitalisations and broader societal benefits.

- **Alignment for positive outcomes:**
  - Unified goal: All stakeholders, including patients, industry, and Pharmac, share the common goal of improving patient well-being. Alignment in strategies and collaborative efforts are essential to achieve positive outcomes.

- **Strengthening assessment and incorporating equity:**
  - Enhanced assessment processes: strengthening the assessment processes to include patient voices and an equity measure is essential. This can ensure more comprehensive and fair evaluations of medicines.
  - Equity in HTA: Equity must feature prominently in the Health Technology Assessment (HTA) process, ensuring decisions benefit all communities equitably. Addressing perceived inequities, such as those in the Keytruda decision, is vital.
  - Equity measure: implementing an equity measure to address disparities in access to medicines for Māori and Pacific communities is necessary for fairer healthcare outcomes.

- **Process improvements:**
  - Comprehensive changes: both significant and incremental improvements should be considered. Small adjustments can make a substantial difference over time.
  - Predictable timelines: establishing more predictable timelines for the assessment process can improve efficiency and transparency.
  - Transparency and resources: enhancing transparency in decision-making and addressing resource shortages to clear assessment backlogs is critical. This involves better planning and allocation of resources.
  - Workforce utilisation: leveraging the existing workforce to conduct societal perspective assessments could expedite processes and provide a more holistic view of the benefits of new medicines.

- **Broad health and societal costs:**
  - Comprehensive cost consideration: expanding the assessment of costs to include societal perspectives, in addition to health system costs, can provide a more complete understanding of the value of medicines. This broader view can help justify investments in new treatments.

Adjustments required for better outcomes in New Zealand

- Mandate benchmarking: implement a mandatory benchmarking process to compare New Zealand's pharmaceutical offerings with international standards, ensuring continuous improvement and alignment with global advancements.
- Shift to investment mindset: encourage a shift in perception from viewing medicines as costs to seeing them as investments. This includes integrating Treasury input to balance economic and health benefits.
- Enhance equity measures: strengthen the HTA process by incorporating explicit equity measures to ensure fair access to medicines for all communities, particularly marginalised groups.
- Improve process efficiency: address resource shortages and improve planning to clear assessment backlogs. Establish more predictable timelines and enhance transparency in the decision-making process.
- Leverage workforce: utilise the existing workforce more effectively to conduct comprehensive societal perspective assessments, speeding up the evaluation process.
- Consider societal costs: broaden the cost assessment to include societal impacts, providing a more comprehensive justification for investments in new medicines.
-

An attendee asked, *"How does consumer voice make a difference?"*
Pharmac has a backlog of assessments, these processes need to be improved so that they are more focussed, planned and more predictable. So that consumers can understand the processes, and so that Pharmac can provide clarity. Once processes are improved, Pharmac can ask for input early and look across conditions, doing it once and doing it right.

A panellist asked, *"Has anyone thought to use the [OFI] list to do societal costs, for Pharmac to push what they need?" and "is there an appetite to do the work, then go to the Government and say, 'this is what we need'?"*

It was noted that Pharmac already looks at the health cost/saving to the system when considering applications.

What actions are needed to start the enhancement processes, and who would be responsible for them?

- **Breaking down silos and fostering collaboration:**
  - Collaborative approach: Pharmac should not operate in isolation. It's essential to breakdown silos within the government and across sectors, ensuring that all relevant stakeholders are involved in discussions.
  - Inclusive conversations: engage the right people, in sufficient numbers, for honest and open conversations. Ensure that everyone brings and shares pertinent data, fostering a collaborative environment.

- **Addressing lived experience and application processes:**
  - Streamlining processes: the current application process for Pharmac is lengthy and complex, making it difficult for the general public to navigate. Simplifying and streamlining this process is necessary.
  - Leveraging data: incorporate lived experiences and organised data, such as Official Information Act (OIA) requests and international care standards, to support applications and improve decision-making.

- **Government role and breaking down silos:**
  - Government involvement: the government must actively participate in breaking down silos to accelerate Pharmac's initiatives. This involves promoting a more integrated approach to investment and decision-making.
  - Regulatory framework: review and potentially revise laws and regulations that govern Pharmac to facilitate a more flexible and collaborative operational environment.

- **Ensuring clear and measurable data:**
  - Data-driven decisions: clear, measurable data is crucial for making informed decisions. This data should be used to demonstrate social and economic impacts and to justify investments in healthcare.
  - Treasury's role: for Treasury to be effectively involved, it needs access to clear and actionable data. This ensures that economic evaluations and budgetary decisions are based on solid evidence.

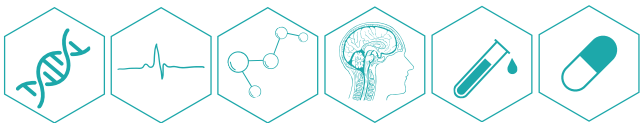
- **Economic consequences and benefits:**
  - Comprehensive discussions: There needs to be a broad conversation about the economic consequences and benefits of Pharmac's decisions. This includes evaluating the long-term impacts on the health system and society.
  - Investment perspective: Shift the focus from viewing medicines as costs to seeing them as investments that can yield significant societal benefits, such as reduced hospitalisations and improved public health outcomes.

Responsible parties for enhancement actions:

- **Pharmac:**
  - Collaborative initiatives: lead efforts to foster collaboration and break down internal and external silos.
  - Streamline Processes: Simplify the application process and make it more accessible to the public.

- **Government (including Health Ministry and Treasury):**
  - Policy and regulation: review and amend laws and regulations to support a more collaborative and flexible Pharmac.
  - Integration and support: facilitate integration across departments and provide necessary support to accelerate Pharmac's initiatives.
  - Economic evaluation: Treasury should use clear, measurable data to evaluate the economic impact of healthcare investments.

- **Stakeholders (Patients, Industry, Healthcare Providers):**
  - Data contribution: provide comprehensive data and lived experiences to support decision-making.
  - Active participation: engage in discussions and collaborations with Pharmac and government bodies.



Steps to initiate enhancement processes:

- Form collaborative working groups: establish working groups with representatives from Pharmac, government departments, healthcare providers, patient advocacy groups, and industry.
- Organise stakeholder meetings: conduct regular meetings to discuss ongoing issues, share data, and develop strategies collaboratively.
- Review and amend regulations: task the government with reviewing existing laws and regulations to identify areas needing change to support collaborative efforts.
- Develop clear data standards: create standards for data collection and reporting to ensure consistency and clarity in the information used for decision-making.
- Public awareness campaigns: inform the public about changes to the application process and provide guidance on how to navigate it effectively.
- Monitor and evaluate progress: implement mechanisms to monitor the effectiveness of changes and adjust as needed based on feedback and outcomes.

Closing notes on Workshop Three

- **Inclusive collaboration and patient engagement:**
  - Holistic inclusion: it's essential to bring all relevant stakeholders, including patients, government representatives, healthcare providers, and industry experts, into the discussion. Simply including patients without the rest will not lead to meaningful progress.
  - Diversity and mutual respect: ensure diversity and the presence of the right people in discussions. Mutual respect among all parties is crucial from the outset to facilitate effective collaboration.

- **Commitment to ongoing progress:**
  - Stage one commitment: this is just the beginning. There must be a commitment to continue meeting and progressing beyond this initial stage. Without follow-up, initial efforts will be in vain.
  - Long-term vision: acknowledge that there is a long way to go. With the will and collaborative efforts with global organisations, there is potential to achieve significant improvements.

- **Funding and government support:**
  - Increased funding: patient engagement and speed of access are critical, but substantial improvement requires more funding from the New Zealand government and Treasury for Pharmac. This will help create more certainty and improve access to medicines.
  - Breaking down silos: the government needs to break down silos within the health system, changing the mindset to support collaborative and integrated healthcare delivery.

- **Data generation and use:**
  - Collaborative data projects: initiate collaborative pilot projects to generate and bridge data gaps. Accurate and comprehensive data is vital for informed decision-making and improving healthcare outcomes.
  - Data-driven decisions: ensure that all discussions and decisions are based on clear, measurable data, which helps in proving and measuring progress.

- **Equity and access:**
  - Equal access: there is no reason New Zealand cannot provide access to medicines equal to or better than other countries. Funding and systemic changes are key to achieving this.
  - Preventing inequity: while funding medicines, it's essential to ensure that these decisions do not exacerbate health inequities. Equity should be a core consideration in all funding and policy decisions.

- **Final thoughts:**
  - Global collaboration: continue to engage with organisations worldwide to learn and adopt best practices.
  - Stage two preparation: prepare for the next stage by ensuring any commitments made in stage one are met and building on the foundations laid. This includes continuous engagement, increasing funding, generating data, and maintaining diversity and inclusion in all processes.

9.4 APPENDIX FOUR

WORKSHOP FOUR WRITE-UP
HEALTH INNOVATION OPTIMISATION IN NEW ZEALAND
(HORIZON SCANNING, PRECISION HEALTH AND CLINICAL TRIALS)

Chair: Dr Christian Schwabe, CEO and Senior Research Physician, New Zealand Clinical Research

The Chair opened the workshop by explaining the workshop was being run under Chatham House and the disclaimer the panellist views do not reflect the views of MNZ &PVA. The Chair along with the panel introduce themselves to the workshop attendees.

The workshop outline was read out, "to determine what the critical success factors are to optimise implementation of three key health research and innovation platforms in New Zealand:

- a "1 stop shop " for human pharmaceutical clinical trials;
- a unified health technology horizon scanning system, and;
- a precision medicines/health platform.

The workshop discussion was prompted by the following three questions:

1. What are the critical success factors for best practice Health Innovation Optimisation in clinical trials, precision medicines and horizon scanning?
2. What adjustments, if any, would be required in New Zealand to achieve this outcome in each area (clinical trials, precision health/medicines and Horizon scanning)?
3. What actions are needed to start the enhancement processes in each of the 3 areas (clinical trials, precision health/medicines and Horizon scanning), and who would be responsible for them?

The workshop started with the panel discussing horizon scanning. The pre-read for horizon scanning, "Horizon scanning in the New Zealand system" was produced in consultation with multiple stakeholders and lists the key recommendations for horizon scanning to work in New Zealand. It was suggested that the Government use the report as guidance for horizon scanning.

- Lots of other countries (UK, Canada, and Singapore) are doing more horizon scanning, so New Zealand can look at other regulators to see what they are filtering and prioritising.
- Horizon scanning should also encompass prevention and early intervention, thinking more broadly not just around technologies such as diagnostics and medical.
- To help structure the health system for the future, there needs to be planning around the health needs of the population.
- Also need to think about the impacts on the health budget.
- There was debate on the period of horizon scanning should take, whether it should be a 5–10-year period or longer.
- It has been indicated work has started in the Ministry of Health (MoH) on Horizon Scanning, with collaboration from Health New Zealand.
- Along with a team consisting of personnel from Health New Zealand, Pharmac and MoH working on Health technology assessment.
- Horizon scanning is operational as well as both temporal and spatial.

It was mentioned long-term insights briefing was published by the Ministry of Health focussing on precision health and artificial intelligence.

It was brought to the attention by a panel member, the speed at which patients are now able to access information, both misinformation and true information, so it is critical that horizon scanning is available for the public.

- Patients having access to the internet
- Patents are going overseas to seek treatment
- Patients are making their own decisions to undertake treatment

There are 3 building blocks which are required to ensure the success of health innovation in New Zealand.

- A medicines strategy that encompasses horizon scanning and draws the path to making new health innovations accessible to patients.
- Regulatory framework to ensure patients are able to access and to become productive in society
- Funding process, which is up to par with other countries, utilising a collaborative approach and taking in the industry's perspective.

The following comments were made by attendees:

- *Having a stable ground (the now) before looking at the horizon.*
- *Horizon scanning is helpful but to not forget about looking back, the links to whakapapa and data sovereignty.*
- *The process of developing regulations means the legalisation is fuzzy to ensure it would be future proof. Therefore, legalisation needs to be broad enough where new technologies are able to be introduced while still being detailed.*
- *Need to find the balance and have dialogue with industry to the find the common ground when developing regulations and legislation.*
- *Include participation from NGOs in Horizon scanning as well as utilising private partnerships.*
- *The public seems to have lost trust in the public agencies and institutions to be able to move quickly.*

Industry is able to accommodate timelines and a lot of other things but there needs to be constant dialogue and communication between the government and the industry.

The German model was raised as an example New Zealand could follow, there is commitment from the German government, so industry is able to invest.

Precision Health

Precision health encompasses more than just precision medicines and it also has a role to play in prevention and education. Examples of the HIV and Covid response were brought up, both these problems were solved and taking the experience taken for Covid but there is a need to think broader than cancer.

- Initial focus on genomics, in particular precision oncology as a landmark template to provide "proof of concept"
    - Creating confidence and a pathway to roll out to other therapeutic areas

Omico, an Australian organisation working in the precision oncology area, was able to secure funding from the Australian Government. When looking at funding from the Government to think about other budgets, not just health but MBIE.

- Suggested a company be formed, separate from the industry or the Government (consider innovative structures and contracts)
    - Contribution from both the industry and the Government
    - This ensures the company goal and commitment will present even when the people are not
    - Appropriate management of risk and uncertainty for all parties involved
    - Can't be a subsidiary of Omico but taking the Australian model and adapting it to the New Zealand environment
- Precision health regulatory environment is already there, so not starting at zero
- There is a need to build on the structural infrastructure, so talent is retained in New Zealand
- Better access to critical treatments is required, patients and HCPs can't rely on clinical trials
- Industry is looking for a clear pathway for drug approval and funding

What needs to happen now?

- A commitment, purpose, and strong leadership
- Including clinical trials – public clinical trials have been dropping off and the industry is taking off
- Need models that work for Māori and Pasifika (MBIE has done data sovereignty)
- Be able to provide optimal care for patients

The solutions include long term commitment, as the industry deals with long timelines and there is a need for certainty and committed timelines by the Government.

- It was mentioned the Government is ready for discussion around precision health.
- There is urgency to continue dialogue with Government, local & regional experts, and industry

Clinical Trials

"1 stop shop" clinical trials hub has potential to create critical efficiencies making it an attractive proposition and there is a need to create more competent sites by providing access to information, quality systems (SOPs), tools and resources.

- Clinical trials have a big role to play in supporting a successful long-term health innovation strategy.
- It has been shown health outcomes improve when health research is being conducted.

The New Zealand Health Research Strategy 2017-2027 set a 10-year strategic direction for the health research system.

- Halfway through the 10-year plan but no positive outcomes seen from it.
- Sector not impressed with the strategy.

As historically New Zealand is good for clinical trials but with the unified system of Te Whatu Ora and no tax incentives in New Zealand makes it less attractive than Australia.

- New Zealand has a positive track record with speed, data quality and expertise.
- But the ability of public health providers to support clinical trials has decreased significantly over recent years.

The Middlemore clinical trials unit was used as an example of what a national approach could take.

- Funding is cycled through the unit, i.e. re-invested back into clinical trials instead of the funding being moved elsewhere.

The building blocks and enablers are already there, but there is a need for a holistic plan and a long-term commitment for the country.

- Many countries have dialogues very early on in regard to CT, to know the likelihood of being able to bring the medicines to the patients.
- Looking at the benefit of the (CT) medicine compared to the current standard of care, and the benefits to the patient.

To improve clinical trials environment in New Zealand:

- Need a national centre where SOPs are needed for each site.
- There is a need for a unified system for clinical trials.
- A supportive regulatory environment is critical; one which is robust, consistent, pragmatic and speedy.
- By providing a better environment and infrastructure this would help attract more global players.
- Awareness that there is strong global competition for clinical trials.
- Inclusion of commercial clinical trial units in consultation, strategy development and delivery.
- A clear pathway for drug approval and funding at the end of the clinical trial process.
- This will help mitigate the risk for sponsor of a long, unpredictable compassionate drug access.
- Consider changes to the R&D tax incentive scheme.

Closing comment from the Chair, recognised that due to the complexity of each the three key health research and innovation areas allocated for this workshop discussion was limited due to the time restriction.

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