# Medicines Australia submission to the Department of Health and Aged Care's consultation on the '**Development of the new National Genomics Policy Framework'**

21 October 2024

## Introduction

Medicines Australia had the opportunity to respond to the Department of Health and Aged Care's consultation on the '**Development of the new National Genomics Policy Framework'** via virtual interview on 15 October 2024. The interview was conducted by consultants from KordaMentha, and attended by Medicines Australia's Chief Executive Officer, Head of Strategic Policy, Senior Manager of Policy and Manager of Policy. This paper provides a summary of the feedback presented during the interview. Additional information is also included in this summary to provide further clarity around the issues raised.

**How does your organisation/the constituents you represent currently engage with Health Genomics?**

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture the medicines that are the foundation of a healthy and prosperous society, including prescription pharmaceutical products, biotherapeutic products and vaccines. Our members invest in Australian medical research and take local discoveries and developments to the world.

Genomic technology is driving a shift from a "one-size-fits-all" approach to a more personalised, effective form of medicine, making treatments more targeted and reducing the risk of adverse effects. It is also improving diagnostics, enabling early interventions, and opening the door to potential cures for genetic diseases.

Genomic technology is revolutionising medicine in several key ways:

1. **Personalised Medicine**: Treatments are tailored to an individual's genetic profile, improving efficacy and reducing trial and error in finding the right drug.
2. **Drug Development**: Genomics helps create targeted therapies by understanding diseases at a molecular level, making treatments more effective and precise.
3. **Pharmacogenomics**: It helps doctors predict how patients will respond to medications, allowing for customised prescriptions based on genetic makeup.
4. **Early Detection and Prevention**: Genetic screening identifies predispositions to diseases, enabling earlier interventions and preventive care.
5. **Improved Diagnostics**: Genomic sequencing provides accurate diagnoses for rare and complex conditions.
6. **Gene Therapy**: These technologies can modify or correct defective genes, offering potential cures for genetic disorders.

7. **Companion Diagnostics**: Genomics guides the use of targeted therapies, especially in cancer, by matching treatments to a patient's genetic profile.
8. **Population Health**: Genomic studies help identify genetic variations linked to diseases, aiding in public health strategies and vaccine development.

In short, genomics is driving a shift towards more personalised, precise, and effective healthcare.

**What do you see as the major priorities for embedding Health Genomics in Australia, currently and in the future?**

In developing the new National Policy Genomics Framework, it is vital that recommendations from recent Australian Government reviews are embedded into the framework. These are:

- The House of Representatives Standing Committee on Health, Aged Care and Sport *Parliamentary Inquiry into the approval processes for new drugs and novel medical technologies in Australia* (*Parliamentary Inquiry)* determined that reform is urgently needed to enable timely access to innovative medicines and vaccines.[1]
- The Health Technology Assessment (HTA) Review Reference Committee's report *Accelerating Access to the Best Medicines for Australians Now and into the Future. A review of Australia's health technology assessment policies and methods for the Australian Government.*[2]

Many of the major priorities for genomic technology in Australia identified below were also identified in these two major reviews.

Industry partnership and engagement

As our members discover and supply innovative pharmaceutical products, biotherapeutic products and vaccines that benefit Australians, we are well positioned to work in partnership with government and other stakeholders in ensuring Australians' appropriate access to genomic technology. For example, The HTA Review report recommended expediting the implementation of Schedule C of the National Health Reform Agreement (NHRA) Addendum. We note that these reforms are currently underway via the 'Framework for the assessment, funding and implementation of high cost, highly specialised therapies and services'. There has been no engagement with industry or transparency of the implementation of these reforms to date. Lack of information on such reforms may contribute to concerns by our members on the viability of the Australian market for innovative genomic technology.

[1] Parliament of the Commonwealth of Australia. House of Representatives Standing Committee on Health, Aged Care and Sport. (2021). T*he New Frontier – Delivering better health for all Australians. Inquiry into approval processes for new drugs and novel medical technologies in Australia.*

[2] HTA Review Final report collection (2024) https://www.health.gov.au/resources/collections/hta-review-final-report-collection

Market access

*The Medical Services Advisory Committee (MSAC) process creates delays in access to genomics technologies:*

- The MSAC process is long and complex for genomic applications, which does not match the evolution of clinical practice.
- Both federal and state governments are responsible for funding genomics and have different pathways creating ambiguity and opportunities for funding delays
- MSAC evidentiary requirements are difficult to meet and the HTA process struggles to cope with some genomics applications (e.g. large panel applications).
- There is a lack of transparency around MSAC decision making and ongoing reforms in the MSAC process.
- Lack of opportunities for patient engagement and representation in HTA process
- MSAC adopts a narrow definition of value which inhibits the adoption of new genomic technologies.
- A paradigm shift in clinical practice is required to harness the benefits of genomics, whereas MSAC deals with incremental change.
- There is no requirement for the government to act on MSAC recommendations.

Furthermore, in order for successful implementation of genomics in Australia, we must address the disparity between genetic testing regulation via the Therapeutic Goods Administration (TGA), funding of genomic tests through the Medical Services Advisory Committee (MSAC) and what happens in clinical practice. For example, there is a gap where certain Next-Generation Sequencing (NGS tests) are funded and used in clinical settings (via the Medicare Benefits Schedule), but these tests have not gone through full regulatory approval by the TGA. This lack of regulation creates challenges in ensuring the quality, safety, and efficacy of NGS tests in clinical practice because the technology currently available doesn't meet the regulatory framework required by the TGA.

Co-dependant test/therapy submissions and single gene test method reviews by MSAC are a significant barrier to Australian patients receiving proven testing methods. We propose the adoption of UK national genomic test directory for rare and inherited diseases[3]. That is, Australia should adopt the same tests that have been robustly evaluated by the UK National Health Service (NHS) as each test would equate to hundreds of hours of HTA evaluation time/cost. The focus for Australia should be on implementation of internationally reviewed/adopted tests. Australia can learn from the implementation of approved genomic tests overseas, as implementation requires engagement with experts that perform the test, validate the test and understand the patient journey and services utilised in supporting patients. HTA of genetic tests which have been carried out and approved in other comparable HTA markets around the world should also be fast-tracked for access in Australia.

[3] https://www.england.nhs.uk/publication/national-genomic-test-directories/)

Genomic testing can provide prognostic, predictive, diagnostic and therapeutic outcomes. The current model of funding is mostly based on diagnostic or companion diagnostic outcomes for patients, often linked to a therapy. We must recognise value of testing for other outcomes also.

Review of funding mechanisms, including consistent federal and state funding of clinical genomics

Whilst MSAC assesses funding of new tests for the entire population, in practice State powers over funding of public hospitals means that public pathology services may not be able to claim the MBS.

Genomic testing is an expensive and rapidly growing part of a pathology service's offering, and we are observing that some hospital budgets are not accounting for this expanding area of cost.

This has the potential to lead to inequity of access for public patients where budgets are exhausted, and will continue to get worse if not addressed. This could extend to:

- Promoting improved, equitable access to genomic services across all regions of Australia, including rural and underserved populations.
- Funding for widespread infrastructure and training in these regions to support equity in care and quality of life for impacted patients.

Infrastructure:

Private pathology providers must have adequate funding to deliver genetic testing capabilities as they have vast logistics networks into regional and rural communities therefore reducing access barriers for genetic testing.

Workforce

With increased testing rates, particularly for inherited genetic diseases, it is anticipated that there will be a far greater requirement for genetic counsellors. There will need to be more jobs created and funded to support this increase. In the long term there is a need for all health care workers to have a base level of genomic literacy, however, access to specialist support will still be required to support complex cases and primary care providers who are the contact point for patients with rare and less common conditions.

Universal access to Comprehensive Genomic Profiling (CGP) at the point of diagnosis is needed

We believe that equitable access to CGP will significantly reduce barriers to biomarker testing and access to precision oncology medicines in Australia.

Our current HTA system evaluates medicines and their associated tests in parallel, which results in significant delays for both the medicines and tests to receive reimbursement.

With universal CGP, we envisage that access to treatments will be expedited, as patients access a test de-linked from a reimbursement submission for a medicine.

In the lab, CGP will improve efficiencies by removing multiple small panels on different instruments; and lastly, a single CGP assay will reduce the risk of test failures and avoid the need for multiple genetic tests which exhaust tumour DNA - therefore increasing the patient's likelihood of finding a matched treatment for their diagnosis.

There needs to be a transition plan of national projects such as Zero Childhood Cancers and PrOSPeCT into the MBS.

Reimbursement of this testing requires an understanding of CGP being a multi-indication predictive and prognostic tool that doesn't fit easily into MSAC's current assessment framework. This will also rely on:

a) Integration of CGP and genomics into routine clinical care, standardisation of funding and frameworks to incorporate genetic information (metro/regional) i.e. supporting standardisation for genetic testing and counselling pathways nationally.

b) enhanced education and training support for registrars/HCPs regarding genomics and driving community awareness.

**Ensuring priorities of the existing Policy Framework are evaluated, and determine if they should continue**

We note that many of the strategic priorities of the existing Policy Framework remain very relevant, and this includes:

- Delivering high-quality care for people through a person-centred approach to integrating genomics into health care.
- Building a skilled workforce that is literate in genomics.
- Ensuring sustainable and strategic investment in cost-effective genomics.
- Maximising quality, safety, and clinical utility of genomics in health care.
- Responsible collection, storage, use and management of genomic data.

It is unclear from this consultation if the previous Framework has been evaluated to determine the progress and the current status of the strategic priorities, and whether there are specific priorities which need to be carried forward into the next Framework. The implementation plan has many actions which are labelled as 'long-term' which suggests that they may be ongoing, so it would be ideal to have clarification about whether or not they are going to be carried forward.

**Updates to be considered in an updated Framework**

Since the previous Framework was published, there has been an evolution in this space from a pharmaceutical perspective, In particular:

- Personalised medicine: There are now a greater number of biomarker driven treatments and panel testing (particularly for cancer treatment). Currently, whole genome sequencing is only being conducted in research settings in Australia, but in other comparable counties this is the standard of care.
- Medicines to treat genetic disorders: The growing number of advanced therapies that can treat genetic disorders has been expanding, and this has been transformative for patients and has additional benefits to the community. To enable treatment for genetic conditions, accurate and timely access to genetic testing becomes critical. On top of this there is a need to develop

nationally consistent models of care for advanced therapy delivery to ensure that there is equality across Australia.

- For example, it has been suggested by Australian clinicians that paediatric tertiary hospitals will need dedicated infrastructure and highly skilled personnel to cater for the complexity of precision medicine[4] The model of care for advanced therapies may need to be different for different disease types, such as rare diseases or oncology.

[4] https://www.mja.com.au/journal/2024/220/3/providing-australian-children-and-adolescents-equitable-access-new-and-emerging).