NATIONAL MEDICINES POLICY REVIEW

Australian Patient Advocacy Alliance Submission

OVERVIEW

The review of the National Medicines Policy (NMP) represents an important opportunity to drive reform of the 20-year-old policy, and ensure it enables all Australians to receive the therapeutics they need at the right time.

Since 1999, the NMP has served as the guiding framework underpinning all policy decisions related to access and reimbursement of medicines, safety and quality of medicines, medicine management, and industry policy. The goal of the NMP is to "optimise health outcomes for all Australians through a collaborative partnership with key stakeholders, focusing especially on people's access to, and wise use of, medicines." Whilst this goal remains relevant, the Department of Health discussion paper recognises that twenty years after the development of the NMP the health landscape has changed; patient voices are better informed, Australians are living longer, often with multiple chronic conditions and healthcare delivery is being transformed by digital advances.

Ongoing use of an outdated NMP in a rapidly changing health technology environment has resulted in piecemeal policies and confounding regulatory processes. This context, coupled with inconsistent implementation of the outlined principles across medicine policy and decision making plus cost saving measures, contributes to significant inequities in consumers' health outcomes. As such, a review of the NMP must modernise the system and ensure it is fit for purpose, now and into the future.

It is noted that there is significant work already underway, including the House of Representatives Standing Committee inquiry in to HTA process. We are pleased that the NMP Expert Advisory Committee will consider the findings of this work in the context of the NMP review. It is envisaged that a refreshed NMP will provide a framework to underpin policy change across the breadth of this work enabling an integrated approach to a more contemporary patient treatment landscape.

A key factor attributed to the success and longevity of the current NMP was the considerable stakeholder consultation undertaken to inform the policy. We applaud the outlined current process that includes significant opportunities for stakeholder input. The APAA stands firm in our belief that consumers must be consistently consulted at each stage of the review as a true measure of co-creation, essential to ensuring we will achieve a NMP that advances health outcomes for all Australians, including those living with chronic and complex disease.

To develop an initial APAA perspective in relation to this review, all members were invited to take part in four workshops in 2020 to inform a position for APAA representatives to champion throughout this review. This early work has now been further informed and expanded in line with the Department of Health Discussion Paper.

OUR VISION

A National Medicines Policy framework that guides and empowers a system to ensure all Australians receive the therapeutics they need at the right time to deliver better health outcomes. A system that enhances consumer participation, is flexible and adapts to advances in technology, and is transparent with established measures to evaluate the success of how it is delivered.

The following discussion points are aligned to the NMP review Committee *Terms of Reference (1-6)*

1. Evaluate the current NMP objectives and determine whether these should be modified or additional objectives included. This includes consideration of the proposed Principles to be included within the NMP.

Australians must be able to access the therapeutics they need no matter how much they earn or where they live. Recognising that the NMP is an overarching framework, we want the programs which are underpinned by the Policy to address the inherent and systematic issues leading to inequity and lack of access.

Central to the NMP is its role in ensuring patients' access to medicines, in line with the proposed principles. Today, Australians face disparity in their access to therapeutics, particularly innovative therapies. Once therapeutics are funded, decisions on what is available are too often restricted based on the state/territory where they live or even down to local Primary Health Networks they are seen in and leads to considerable disparities. A review must work with state and territory governments to strengthen the availability of therapies once a drug is funded and ensure equity of access is guaranteed for all Australians no matter where they live.

Additionally, the NMP must consider the economic burden on patients, which too often is a barrier to patient access, particularly those living with chronic or complex conditions, often with co-morbidities and multiple treatments. While we acknowledge access to therapeutics must come at a cost the community can afford, we believe there is an opportunity to update the determinants of medicine effectiveness and cost-effectiveness to better reflect environmental and market change to improve the equity of treatment for all patients.

Proposed Principles of the NMP

Consideration must be given to future proofing the revised policy, which could be achieved using a principles-based approach, clearly articulating the policy's appropriate and comprehensive overarching principles. This can then be used to guide the programs which sit within the policy framework to ensure they remain adaptable, contemporary and effective.

Objectives of the NMP

While the current NMP objectives remain relevant, admirable and fundamental, we could question as to whether they have been achieved for all Australians and, if not, why not? It is vital that these objectives are brought to life and do not remain as words within a policy. We need a plan to operationalise these objectives to ensure they achieve their intent.

i. Timely access to the medicines that Australians need, at a cost that individuals and the community can afford.

This objective relies on rigorous and adaptable HTA processes including the Pharmaceutical Benefits Scheme and Life Saving Drugs Program.

It is noted that there is strong linkage here, specifically in relation to timely access, with the House of Representatives Standing Committee inquiry into HTA processes. However, we question how well this objective is achieved in different contexts such as rural and remote locations.

ii. Medicines meeting appropriate standards of quality, safety and efficacy

The TGA thorough procedures ensure the required standards of safety, quality and efficacy. Process improvements, such as were highlighted in the HTA review, should be evaluated to determine whether the recommendations achieved the anticipated improvements to the timely review of medicines by the TGA, to understand (if not) why not, and to implement corrective actions.

iii. Quality use of medicines

Medicines are one of the most common treatments used in health care, and there are growing numbers of people with multiple chronic conditions, that are prescribed multiple medications.

The premise of quality use of medicines is: Right patient, right medicine, right time.

There are several partners, including patient support groups, that contribute to the mechanisms, such as monitoring usage, that ensure optimal quality use of medicines. The role of these partners should be recognised for the integral role that they play and articulated in the NMP.

We note that the NMP discussion paper outlines some consultative mechanisms of the NMP. However, it is notable that there is a lack of mechanisms for ongoing consumer consultation. This should be highlighted and remedied.

iv. Maintaining a responsible and viable medicines industry

The NMP commits all parties to a coordinated and aligned approach between health and industry, to maintain a consistent and supportive environment. This is increasingly relevant as the treatment context steps outside of medicine alone.

2. Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

The term medicines no longer captures the extent of the therapeutics used to improve patient outcomes. We must broaden the definition to ensure new treatments, diagnostics and medical devices don't fall through the gaps.

The World Health Organization defines health technology as the '*application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life*'[1]. This breadth of this definition demonstrates the inter-relationship of the therapeutic landscape.

There is a rationale to consider interventions which serve to prevent, treat or cure disease within one framework of "effectors", while tools that determine the risk, diagnosis or ongoing status of disease may need to be considered separately as "enablers". Approaches that tie one treatment with one diagnostic tool and/or one monitoring tool risks a proliferation of combinations and permutations leading to overly complicated bureaucracy and evaluation with the potential to delay approvals. This would be contrary to the principle of timely access to treatment.

The NMP is only as effective as the principles and definitions that it sets out and the advent of innovative treatments, such as 3D printing. We support the broadening out of a definition used in the policy to ensure advances in treatments, diagnostics, and medical devices are considered and incorporated to lead to better patient outcomes for all. Most logically, this would also lead to a

change in the title of the NMP, for example the National Therapeutics Policy, to demonstrate the breadth of the policy encompassing all treatments.

3. *Assess the NMP's utility in the context of rapidly evolving treatments options, population changes, interconnected relationships and system-wide capacities.*

We want a NMP that provides a framework that is fit for purpose and enables processes that are flexible to adapt to advances in constantly evolving technology to ensure timely access for all.

Changes in technology and the health landscape are outpacing our system's capacity to evaluate and fund innovative treatments and interventions.

We acknowledge the important step taken in implementing the House of Representative Standing Committee review of Australia's HTA process. We look forward to the recommendations of this review anticipating they will lead to improvements in the process enabling better access to treatments, improve equity of care for all Australians, and a mechanism to regain the trust of all involved.

The NMP review must work alongside the HTA review and other initiatives, in seeking improvements to ensure the system is flexible and agile. This will create a system that can respond to technological advancements, standards and sources of evidence necessary to support funding applications including global, and real-world data, and assess the basis and consideration of risk that is currently used.

We are pleased that the Medicines Australia Agreement 2022–2027 serves in part to address the funding of innovative treatments and interventions.

Health Policy Landscape

Expansion of available treatment options has arisen out of the advent of advanced therapies such as gene therapies, cell therapies and tissue engineered medicines. Simultaneously, we are seeing national reform of the health system and changes in policy frameworks. This is anticipated to lead to a health system that is more person centred, influenced by digital solutions in health service delivery, that should result in improving value and efficiency in the health system. These changes must be reflected in the framework of the NMP.

Precision Medicine

The fields of genomics, biotechnology and medical science have seen advancements that enable new ways of identifying, preventing and treating disease. Precision medicine considers the variability of an individual's genes, environment and lifestyle enabling a tailored and targeted approach to preventing, managing and treating disease.

Currently MSAC considers genetic and genomic tests for public funding through the MBS. The National Medicines Policy must recognise that therapeutics has a wide definition that includes, but is not limited to, medicines.

Clinical trials and Medicines Access Programs

Access to clinical trials and medicines access programs are not discussed in the current NMP despite the obvious implications for patient treatment options. It is our recommendation that these are explicitly included int eh refreshed NMP.

Health Literacy

Quality use of medicines is not only about safe and effective delivery but also about supporting and empowering consumers to build their understanding and knowledge of medicines use, leading to improved engagement with treatment and enhanced outcomes.

Health literacy is a fundamental enabler for patient-centred care, and we know that higher levels of health literacy are associated with increased patient involvement in shared decision making. Advances in treatments and therapies, whilst welcome, create further challenges for consumer health literacy.

Health literacy must be explicitly included in the NMP framework and support must be provided to consumers to find, evaluate and use health information effectively and the system must support health professionals in delivering health-literacy responsive services.

Equity and Sustainability

Many novel medicines have been associated with high upfront costs including investment in the establishment of system infrastructure and workforce to support treatment delivery, which comes in addition to the cost of the treatment itself. This may lead to limited options available, particularly for people living in rural and remote locations.

Real world evidence

The use of real-world evidence has the potential to address current evidence gaps. At present this does form part of the decision-making process with reimbursement programs such as the Managed Access Program providing funding access to new medicines based on preliminary evidence. However, the use is limited and expansion presents an opportunity.

Drug Repurposing

Equity of access to existing medicines outside their approved use has been an issue. We note that the new Medicines Australia Agreement contains commitments to addressing barriers to the use of repurposed drugs to enable faster and fairer access, supported by innovative technologies.

Digital Health

Convenience and safety in treatment can be enhanced through effective use of digital technology such as the My Health Record and e-Prescibing and integration of these policy areas with the NMP will be an important recognition of this.

4. Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

Patients must be at the core of the NMP with a policy that empowers informed patient participation, closing the gap between patients and decisions.

Consumer involvement in Australia's therapeutics policy is not a desired principle; it is, and should be, a core fundamental of the NMP and applied to each and every program, policy and service.

Decisions happen at arms-length of the patients who will benefit from them. We must reduce this gap and put the patient at the centre of the NMP by increasing understanding of the NMP, transforming patient co-design and involvement in policy into the standard and expectation, and strengthening health literacy to ensure the effective use of therapeutics. While some Australians are more informed than ever about their health, overall health literacy remains too low. Improvements can, and must be made, now and into the future.

The 2020-25 Nationally Cohesive Health Technology Assessment provides a commitment by all governments to work together on long-term system wide reforms to provide patient-centred care in the most appropriate setting. The standard will be set through this review process with a comprehensive consultation process required to ensure patient views are heard, reflected on, and placed at the core of the NMP.

Whilst the NMP articulates the central role of patients in their healthcare, there is little acknowledgement of the diversity of consumers and their specific needs.

It is recognised that considerable work has been done to date to increase the inclusion of the consumer voice. However, more can and should be done to strengthen this, evidenced by the contributions heard at the recent House of Representatives Standing Committee inquiry into HTA processes, specifically looking at the need for inclusion of consumer in the early stages of policy discussion and in providing **greater transparency in the decision-making processes**.

5. Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

Effective and clear communication will contribute to increased transparency in the process and improved engagement by consumers. Additionally, evaluation and performance measures must be established in the NMP to ensure it is working where it matters.

It is vital that we ensure all relevant policies are effectively delivering on the principles outlined in the NMP. To ensure this, the NMP must include performance measures that are evaluated on a regular basis.

Additionally, regular reviews of the NMP, potentially every 5 years, built into the policy, would ensure the system remains fit for purpose into the future as technology continues to advance. A multi-stakeholder committee to monitor the implementation of the NMP may be an effective way to deliver this in practice and ensure the patient voice is at the centre of decisions.

Communication and Engagement

The discussion paper noted that improved communications, including clear links between policies and initiatives associated with the NMP will minimise fragmentation, improve transparency and improve consumer engagement. This is welcomed by the APAA.

6. Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

End-to-end transparency must be a core principle of the NMP to ensure trust in the system that supports access to the medicines Australians need.

A lack of transparency in the way the NMP policy comes to life is a considerable barrier to the trust that patients and other stakeholders have in the NMP. Working together with industry, government and other stakeholders, we must shine a light at every step – whether it is policy development, registration, HTA assessment or post-market review – to better understand how decisions are made and why, and at what cost. Transparency must be the rule, not the exception.

Additionally, there is a need for a structured, transparent and accountable evaluation process to monitor and improve on delivery of the objectives of the NMP.

The importance of partnership is a key theme in the overarching NMP framework. We note that the lessons learned from the pandemic have resulted in negotiated strategies to facilitate a guaranteed supply chain which is greatly welcomed and reflects the importance of partnership. Implementation

of the policy framework is reliant on partners and we note that this can present challenges in delivering an integrated approach. There is recognition that the need to address replication and gaps in the current NMP will contribute to greater transparency and accountability for all partners.

SUMMARY

The review of the NMP is welcome and timely in a context of a rapidly evolving health system. We are seeking a refreshed NMP that will provide a framework to underpin policy change enabling an integrated approach to a more contemporary patient treatment landscape.

The APAA seeks a NMP that will:

- Ensure Australians can access the therapeutics they need no matter how much they earn or where they live. The NMP must provide a framework that enables program delivery to address the inherent and systematic issues leading to inequity and lack of access.
- Broaden the definition to ensure advanced therapies such as new treatments, diagnostics and medical devices are recognised as part of the therapeutics landscape.
- Provide a framework that is fit for purpose and enables processes that are flexible to adapt to advances in constantly evolving technology to ensure timely access for all.
- Place patients at the core with a policy that empowers informed patient participation, closing the gap between patients and decisions
- Prioritise effective and clear communication to enable increased transparency in the process leading to improved engagement by consumers. Additionally, evaluation and performance measures must be established in the NMP to ensure it is working where it matters.
- Embed end-to-end transparency as a core principle to ensure trust in the system that supports access to the medicines Australians need.

Aligned with this submission is consideration of the key elements of the Medicines Australia 2022–2027 Strategic Agreement that includes:

a) A commitment towards an independent HTA review
b) Enhanced consumer engagement with the PBAC
c) Earlier access to treatment via conditional listings
d) Securing the New Medicines Funding Guarantee; and
e) Removing of the Cost Offset Policy.

These changes are welcome and it is hoped that this will, in part, address some of the concerns. At this stage there remain significant concerns regarding the funding of therapeutics and the decisions that have originated from successive governments' desire to rein in spending on new therapeutics. We are pleased with the policy shift that removes the Cost Offset Policy so that the Government is no longer required to find an equivalent saving elsewhere in the portfolio, anticipating that this will enable increased speed of funding.

We ask the Government to consider a model that ensures the sustainability of therapeutic funding in a way that supports access to innovative treatments, is transparent, and ensures trust in the system to fund new therapeutics. This is essential to build an environment that encourages confidence amongst industry, strengthens their commitment to bring timely access to new therapeutics, and ultimately, improves patient health outcomes. In this way, a policy should also reference the commitment to medical research, R&D, and clinical trials that enhances Australia's attractiveness to industry.

The **Australian Patient Advocacy Alliance** (APAA) brings together peak health advocacy organisations representing more than 12 million people living with chronic and complex health conditions, with the purpose of providing a coordinated and cohesive approach to government. Our aim is to create efficiency for government and our members and to ensure meaningful and informed contribution by the patient voice in health strategy and decision making.

On behalf of our members, the APAA monitors the views and activities of the government, the opposition, the health department and the external context with a patient lens to identify opportunities to advocate for policy change with a specific focus on ensuring:

- Health policy reflects the needs of the breadth of the Australian population by strengthening the voice of patients living with complex or chronic disease in the policy making process.
- Health performance measures drive better clinical practice and improved patient outcomes.
- Health expenditure is seen as an investment in a healthy Australia.

[1] World Health Organization. Europe Office. Health Technology Assessment. < https://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/policy-areas/health-technology-assessment ,