October 2021

Medicines Australia's Submission to the Review of the National Medicines Policy

Achieving Australia's Ambition for Medicines

Medicines Australia

Executive Summary

An historic opportunity to learn from experience so that no Australian patient is left behind

The National Medicines Policy – twenty years on

Medicines Australia is a foundational partner and strong supporter of the NMP, and we welcome the opportunity to contribute to this important review. This is an historic opportunity to build on our experience with the current NMP and aim high for the future.

It has been over twenty years since the NMP was first published. Patient and public expectations of our health system have risen. The rapid development of medicines has led to remarkable advances in human health. Medicines technology has moved beyond traditional chemical compounds to include monoclonal antibodies, companion diagnostics and devices, cell and gene therapies, as well as advanced vaccines technologies, artificial intelligence and digital health solutions. The new NMP must fully address the community's growing expectations and be nimble enough to support exciting new innovations available now and those of the future.

The time is right for change. We have had more than twenty years' experience with the current NMP, and we know what has worked and what could work better. The new Strategic Agreement between Medicines Australia and the Commonwealth offers important direction, including the need to ensure patients have improved involvement in decision making, the need to modernise policies, methodologies and processes to keep pace with innovative technologies, and the need to address the changing international environment. We anticipate the current *House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia* will also offer strong recommendations for reform. The NMP must set the policy context for the future, while these additional initiatives deliver improvements to the associated policies and processes.

A clear vision and governance arrangements are crucial for success

In order to make the best use of all the health, social and economic benefits that the rapidly developing field of medicines can offer, Medicines Australia believes that the NMP requires the following two key reforms. These are crucial to ensuring that no Australian patient is left behind, and that there is a system for driving and measuring the success of the new NMP.

Key Recommendations

The NMP should adopt the following vision

That Australia's National Medicines Policy will deliver the ***World's best outcomes*** *for access and utilisation of medicines, biotherapeutics and vaccines. This requires the ability to make the fastest, most efficient, decisions for safe and effective use of medicines, biotherapeutics and vaccines. Contemporary processes that comprehensively incorporate the patient's views are fundamental. The policy must recognise and facilitate the full realisation of Australia's capacity to research, develop, manufacture and supply new medicines, biotherapeutics and vaccines, from early discovery to the delivery to patients, for the benefit of the community, the economy and broader society*.

The NMP should implement a clear governance and oversight structure

To ensure the achievement of this vision, the revised NMP will include agreed measurement, monitoring, review, reporting and shared oversight of the outcomes to hold all partners to the NMP to account.

Vision and governance will support other important changes

Medicines Australia has undertaken a comprehensive stakeholder consultation and has developed a number of other actions against the terms of reference, and these are shown in the 'Summary of Actions' box below. If a clear vision and governance are implemented, these other changes will naturally follow.

The **four objectives of the current NMP** are a good foundation for medicines policy, however they need to be updated to reflect the changing medicines environment. While all four objectives require updating, there are two which require significant changes. The *Access to Medicines* objective has fallen short of the NMP's goal: we have seen from submissions to the *House of Representatives Inquiry* that Australian patients are waiting too long to access many new medicines. The *Responsible and Viable Medicines Industry* objective should be updated to aim for a 'thriving', rather than a 'viable' industry, as part of a thriving medicines ecosystem which supports employment, investment, exports and the commercialisation of Australian research.

Medicines Australia believes that the *National Medicines Policy* should retain its current title however **the definition of 'medicines' should be expanded** to address the proliferation of new technologies and resolve ambiguities that have arisen over the last twenty years. Likewise, the concept of 'medicines industry' has expanded to include a wide range of new participants and the NMP would benefit from a clear definition of this term.

Patients and carers must have a central role in the NMP. This will require a focus on education, access to information, transparency and close involvement in the various processes under the NMP. This inclusion must reflect the diversity of patients and carers, as well as reflect the needs and perspectives of the Aboriginal and Torres Strait Islander peoples.

Medicines Australia believes that the **benefits of medicines extend well beyond the clinical**, and the NMP should recognise their broader health, social and economic impact. The NMP should also recognise **Australia's place in the global medicines ecosystem**. Research, development, manufacture and supply are conducted globally, and Australia cannot operate in isolation from the rest of the world. All aspects of medicines, from clinical trial investment to pricing, are affected by decisions and influences that lie beyond our borders.

Finally, **partnership is key** to the delivery of the NMP's ambitions. There are fewer forums for formal partnership dialogue than previously. A new forum should be established where all NMP partners can engage to achieve the vision of the NMP.

Medicines Australia looks forward to working with all our partners on this historic opportunity. Should the Review Committee have any questions about this submission, please do not hesitate to get in touch. Inquiries can be directed to Anne-Maree Englund (Head of Strategic Policy Implementation) at anne-maree.englund@medicinesaustralia.com.au.

Elizabeth de Somer
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Summary of Actions under each Term of Reference

ToR 1 – Objectives & Principles

1. The NMP should **adopt a vision** t*hat Australia's National Medicines Policy will deliver the World's best outcomes for access and utilisation of medicines, biotherapeutics and vaccines. This requires the ability to make the fastest, most efficient, decisions for safe and effective use of medicines, biotherapeutics and vaccines. Contemporary processes that comprehensively incorporate the patient's views are fundamental. The policy must recognise and facilitate the full realisation of Australia's capacity to research, develop, manufacture and supply new medicines, biotherapeutics and vaccines, from early discovery to the delivery to patients, for the benefit of the community, the economy and broader society.*
2. The NMP should have the aim of providing the **World's fastest access** to the medicines that Australians need, with appropriate reimbursement reflecting the value of the medicine following as soon as possible after registration. This should be achieved through a combination of efficient registration and reimbursement processes, and revised conditional listing arrangements for areas of high unmet need or rare conditions, as foreseen in the new Strategic Agreement.
3. In support of quality, safety and efficacy of medicines, the TGA should continue and increase its **engagement with other national regulators** with a focus on harmonisation and efficiency, and optimal use of use of real world evidence, patient reported outcomes and de-identified health system data.
4. In support of the quality use of medicines, the NMP should recognise industry as the first custodians of our medicines and a **key source of safe and reliable information** for NMP stakeholders including patients, decision makers and the public.
5. The NMP should support a respected, **thriving medicines industry** to secure the health, social and economic well-being of Australians, driven by an ecosystem including world-class medical research, successful commercialisation systems, high-value manufacturing and stable and reliable supply chains.

ToR 2 – Definition of Medicines

1. The **definition of "medicines" should go beyond medicines, biotherapeutics and vaccines** to include: all chemical or biological therapies, designed to be introduced or applied to the human body to achieve a therapeutic effect, including related technologies such as companion diagnostics, devices and software that directly assist in the delivery or outcome of the therapy. The definition should not include other medical devices that do not assist in the delivery of the therapy.
2. The NMP should include a **definition of the "medicines industry"** as: *those organisations that undertake the research, development, manufacture, supply and monitoring of medicines, or contribute to those processes*.

ToR 3 – Utility of the NMP

1. The NMP should explicitly recognise that **investment in medicines is an investment in valuable health, social and economic outcomes**, rather than merely a cost.
2. The NMP should recognise Australia's position in the **global medicines ecosystem** and the consequences for Australia's health outcomes and competitive position.
3. The NMP should recognise the health, social and economic benefits of a world class domestic medicines ecosystem, including the need for greater **harmonisation of Australia's clinical trials** system.

ToR 4 – Consumer Centricity

1. The NMP should make **patient involvement central**, through:
    a. promoting **health literacy** and understanding of the medicines system
    b. **providing information** about current and future medicines
    c. ensuring there is **transparency of information**
    d. including patients in **decision making** in a meaningful way
2. Patient engagement should be done in a way that recognises the diversity of the Australian population.
3. The NMP should recognise the particular needs and perspectives of **Aboriginal and Torres Strait Islander people** to ensure they are benefiting equitably from the policy.

ToR 5 – Governance

1. A dedicated **NMP governance committee** should be established to champion the implementation of the NMP and review its progress towards achieving the vision.
2. The committee should produce a public **annual report** on the progress of the NMP implementation against jointly agreed metrics.
3. A set of **metrics** should be developed to measure progress in key areas, for example:
    a. **health outcomes** e.g. diseases specific outcome measures such as 5-year cancer survival rates and immunisation coverage
    b. **patient centricity** e.g. feedback from patients on inclusion
    c. **access to medicines** e.g. global comparative time from registration to reimbursement
    d. **vibrant industry** e.g. number of clinical trials, investment in R&D, number of research collaborations
4. The NMP should be **reviewed every five years** to ensure it remains fit-for-purpose.

ToR 6 – Partners & Accountability

1. The NMP should include a **forum for discussion between NMP partners**, focused on collaboration and resolution of differences, in alignment with the vision for the NMP.
2. The forum should work through each partners' barriers to **providing greater transparency** in the interests of all partners, while ensuring each parties' interests are appropriately safeguarded.

ToR 1 - Objectives & Principles

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.

A vision for the NMP

Medicines Australia believes that the NMP requires an aspirational and clearly articulated vision, which sits above the proposed principles and the revised objectives. The health, social and economic opportunities associated the use of medicines have become more significant over the last twenty years. The promise of better health through better treatments, preventions and now cures, even for the rarest diseases, is coupled with growing economic opportunities driven by translating academic research into medicines, investment in high-value manufacturing and increased employment. However, experience with the NMP has demonstrated that, on its own, the goal to 'optimise health outcomes' has not been sufficient to deliver these benefits in full. Australia is one of the wealthiest countries in the World with great health infrastructure, an outstanding health workforce and highly regarded academic and research institutions. Yet compared to similar countries, patients face delays in accessing the latest treatments, and the commercialisation of great Australian ideas lags.

A new vision is required. Given the capacities and resources Australia continues to enjoy, that medicines vision should be bold. This has already recognised by many stakeholders. The Australia Government's *Long Term National Health Plan* provides: "Our goal: to make Australia's health system the world's number one." The Australian Medical Association's ambition is for Australia to become "the healthiest community on Earth".

The vision in our medicines policy should clearly align with these broader aspirations as well address the additional social and economic opportunities that come from medicines. We recommend that the new NMP should have at its heart the vision that: "*Australia's National Medicines Policy will deliver the World's best outcomes for access and utilisation of medicines, biotherapeutics and vaccines. This requires the ability to make the fastest, most efficient, decisions for safe and effective use of medicines, biotherapeutics and vaccines. Contemporary processes that comprehensively incorporate the patient's views are fundamental. The policy must recognise and facilitate the full realisation of Australia's capacity to research, develop, manufacture and supply new medicines, biotherapeutics and vaccines, from early discovery to the delivery to patients, for the benefit of the community, the economy and broader society.*"

Proposed principles are appropriate

Medicines Australia fully supports the proposed principles. We view them as a continuation of the spirit of the current NMP.

Objectives are a good foundation but require updating

We support the four objectives in the current NMP however they need to be updated to reflect the changing medicines environment.

Objective 1 – Access to Medicines

We believe the current access pillar has fallen short of its objective. Access is not always timely, and the health technology system is not always adaptable, as we have seen from the evidence provided by many parties to the *House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia*. This evidence, including from Medicines Australia, details the many issues in relation to timeliness and adaptability. The Strategic Agreement re-states the priority of timely access and the need for adaptability, and also adds: "keeping Australia a global priority for the launch of new and innovative medical treatments".

To better support the objective of 'timely access' in alignment with the proposed vision, we believe that this objective should be more specific with respect to timely access. The NMP should have the aim of "*providing world's fastest access to the medicines that Australians need, with appropriate reimbursement reflecting the value of the medicine following as soon as possible after registration. This should be achieved through a combination of efficient registration and reimbursement processes and revised conditional listing arrangements for areas of high unmet need or rare conditions, as foreseen in the new Strategic Agreement".*

Achievement of this objective will be greatly strengthened by the independent HTA review of methods and policies that is one of the key deliverables of the Strategic Agreement.

Objective 2 – Quality, Safety & Efficacy

Medicines Australia fully supports the safeguarding of quality, safety and efficacy (QSE) as a fundamental element of the NMP. Our proposed vision for the new NMP to be 'World's best' should apply to all aspects of the NMP, including QSE. Currently the standard is 'equal to that of comparable countries'.

The strong emphasis in the current NMP on close collaboration is vital, evidenced by the current high level of cooperation between industry and the TGA. We believe increased emphasis on continuous improvement should be included in the new NMP. We welcome the recent recognition by the Commonwealth in the Strategic Agreement that 'continuous system improvements are needed to ensure access'.

Objectives 3 – Quality Use of Medicines

Medicines Australia fully supports the quality use of medicines (QUM) as a fundamental element of the NMP. Broad stakeholder support for QUM has delivered gains in reducing preventable harm and optimal use, but there is an opportunity to do even better. Over the last twenty years communications, digitisation, data storage, artificial intelligence and data analytics technologies have progressed in remarkable ways. This leads to two key opportunities: education, and monitoring and analysis (leading to improved utilisation).

Digital media, including social media, facilitates the provision of convenient, as-needed, when-needed information at very low cost. This is both a threat and an opportunity. The spread of misinformation during the COVID-19 pandemic, where unofficial 'news' travelled digitally, while official information travelled mostly by traditional media, has the potential to cause enormous harm to human health. QUM is a shared responsibility which extends to education about safe practices and improved decision making. Properly delivered, QUM as an activity can overcome and potentially replace misinformation. It is important to recognise the strengths of each NMP stakeholder. The medicines industry is the first and best custodian of safe, reliable information about our medicines. We are ready to play our full role, together with other NMP stakeholders, in educating about medicines, optimising outcomes and saving lives.

The technological capacity for closer monitoring and analysis of medicines use continues to grow rapidly. This has the potential to improve Australia's performance in preventing harm and optimising outcomes. Real time monitoring of powerful medicines, interventional research, greater use of real-world evidence to inform decision making, and enhanced post market surveillance are all possible. Currently however, Australian health data systems are limited, dispersed, siloed or lack common reference points. They also lack linkages to broader social and economic data sets which would help drive further improvements.

We acknowledge the need to respect privacy and the resource constraints facing all NMP stakeholders in the face of technological change. The NMP already contains a commitment for all NMP stakeholders on '*ensuring the exchange of relevant information*'. We recommend this commitment be expanded to: 'ensuring appropriate resourcing to collect, manage and share de-identified health system data between NMP stakeholders to better drive the reduction in preventable harm and the optimisation of use of medicines'.

Objective 4 – Maintaining a responsible and viable medicines industry

In addition to providing access to medicines, the medicines Industry in Australia is a significant source of employment, investment, exports, tax revenue and commercial translation of Australian research. The pharmaceuticals sector provides significant manufactured exports, employs more than 14,000 Australians and underwrites substantial investment in great Australian ideas, all the while helping to

secure the health, social and economic well-being of Australians. A 'World's best' vision for the NMP should apply to all aspects of medicines, hence we recommend replacing 'viable' with 'thriving'.

We also recommend removal of the term 'responsible' in relation to this objective. The medicines industry operates with a high degree of integrity, undertakes publicly reportable, transparent interactions with other NMP stakeholders, maintains a rigorous Code of Conduct and is subject to oversight by the TGA. Under the proposed principles, every NMP stakeholder is responsible as a steward of the health system.

During the COVID-19 pandemic the innovative medicines industry delivered on the values of the NMP. Supply of innovative medicines was maintained, despite unprecedented circumstances, and the development and supply of crucial new medicines (COVID-19 vaccines and therapeutics) was facilitated in a truly remarkable timeframe. The medicines industry was a cooperative and engaged partner with all stakeholders and remains committed to achieving the World's best health outcomes for Australia.

ToR 1 Actions

1. The NMP should **adopt a vision** t*hat Australia's National Medicines Policy will deliver the World's best outcomes for access and utilisation of medicines, biotherapeutics and vaccines. This requires the ability to make the fastest, most efficient, decisions for safe and effective use of medicines, biotherapeutics and vaccines. Contemporary processes that comprehensively incorporate the patient's views are fundamental. The policy must recognise and facilitate the full realisation of Australia's capacity to research, develop, manufacture and supply new medicines, biotherapeutics and vaccines, from early discovery to the delivery to patients, for the benefit of the community, the economy and broader society.*
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5. The NMP should support a respected, **thriving medicines industry** to secure the health, social and economic well-being of Australians, driven by an ecosystem including world-class medical research, successful commercialisation systems, high-value manufacturing and stable and reliable supply chains.

ToR 2: Definition of Medicines

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

Definition of "medicines" should be expanded

The NMP is intended to be the overarching policy in Australia that addresses every aspect of what are considered to be medicines. Since the NMP was published we have seen the rapid development of medicines, biotherapeutics and vaccines. There has been a proliferation of technologies beyond the traditional chemical compounds to include monoclonal antibodies, companion diagnostics and devices, cell and gene therapies, as well as advanced vaccines technologies, artificial intelligence and digital health solutions. The NMP must fully address these developments to ensure that it will continue to be the policy that encompasses every aspect of what are considered to be medicines. Given contemporary rapid scientific development, there is also a need to ensure capacity for the definition of medicines to include future technologies.

Re-defining "medicine"

The definition of "medicines" should go beyond medicines, biotherapeutics and vaccines to include: all chemical or biological therapies, designed to be introduced or applied to the human body to achieve a therapeutic effect, including related technologies such as companion diagnostics, devices and software that directly assist in the delivery or outcome of the therapy. The definition should not include other medical devices that do not assist in the delivery of the therapy.

The aim is not, necessarily, to expose every medicine and/or related technology to exactly the same detailed processes, but to ensure that all the key principles within a new NMP would apply (e.g. QUM, QSE, valuation etc).

Definition of "industry" should be introduced

There has been a related rapid expansion in the concept of the 'medicines Industry', adding to the traditional conception of stand-alone entities undertaking research, development and manufacturing to include a broad range of commercial partners from biotechnology start-ups through data analytics companies to software developers.

Increasingly, the delivery of new medicines is reliant on multiple industry participants. This has long been the case where there are multiple brands, but today the delivery of a health intervention might involve multiple industry contributors for a single medicine. Some examples are co-dependent technologies, combinations of medicines and health interventions consisting of a diagnostic device, a medicine and/or an outcomes assessment tool. A positive example to illustrate the broader definition

of “industry” is that several entities are involved in the research and development, manufacture, supply and delivery of advanced therapy medicinal products (ATMPs). Although a single “intervention” reaches the patient, there are multiple industry contributors along the way. All these entities are “industry” and essential in delivery of a world-class medicines ecosystem.

There is also a broader role of partner organisations such as clinical research organisations, contract home infusion teams, digital health providers, registry or real-world data providers and other services. The role of such organisations is critical to the efficiency, effectiveness, and success of operationalising the NMP. The NMP should equally support such organisations, recognise their role in aiding traditionally defined industry and other participants to deliver on the NMP goals.

The NMP should include a **definition of the “medicines industry”** as: *those organisations that undertake the research, development, manufacture, supply and monitoring of medicines, or contribute to those processes*. This will ensure that the principles of the NMP will apply to all organisations that contribute to medicines activities.

“National Medicines Policy” as a title

Medicines Australia believes that the current title is appropriate, provided the definition of ‘medicines’ is expanded to address the proliferation of new technologies, as recommended below.

ToR 2 Actions

1. The **definition of “medicines” should go beyond medicines, biotherapeutics and vaccines** to include: all chemical or biological therapies, designed to be introduced or applied to the human body to achieve a therapeutic effect, including related technologies such as companion diagnostics, devices and software that directly assist in the delivery or outcome of the therapy. The definition should not include other medical devices that do not assist in the delivery of the therapy.
2. The NMP should include a **definition of the “medicines industry”** as: *those organisations that undertake the research, development, manufacture, supply and monitoring of medicines, or contribute to those processes*.

ToR 3: Utility of the NMP

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

The NMP is a highly useful overarching policy statement, setting out key goals and objectives and the relationships between the stakeholders. The suggestions below would further enhance its utility.

Value should consider health, social and economic impact

A healthy society is a critical component of a healthy economy. Ill health directly affects social and economic participation. The Australian Government Productivity Commission estimated that a healthier population would benefit the nation by over $8.5 billion over 5 years.[1]

Medicines can help ensure our population remains healthy and productive into their later years.[2] While innovative medicines require upfront investment to treat conditions with an unmet need, returns are seen in health and reduced mortality over the lifecycle of the treatment.[3] A lack of investment in important medicines can impact health outcomes and have flow-on impacts to the workforce, economy, and wider society. The impact of the COVID-19 pandemic has clearly demonstrated the importance of investing in medicines to achieve not only immediate health benefits, but also secondary productivity benefits (such as enabling people to return to work) and savings to other areas of the health system (such as keeping people out of hospital) [4].

The current NMP's language about 'new high-cost medicines' is problematic. In the era of precision medicine, new medicines are used by smaller populations, and though their cost per dose can be higher than for older medicines due to their higher efficacy, there are fewer patients that benefit from them. Over the past decade, the pharmaceutical government spend is declining for branded medicines (i.e. newer, patented medicines), and growing for older, off-patent medicines[5].

The valuation and financing processes should consider health, social and economic impacts. Only the first of these is truly considered within the current valuation process. Value and valuation are strong tenets of the NMP. We believe that appropriate valuation should be reviewed and updated to

[1] https://www.pc.gov.au/inquiries/completed/productivity-review/report/productivity-review.pdf
[2] The McKell Institute (2018) '*Our Health Our Wealth, The Impact of Ill Health on Retirement Savings in Australia'*
[3] Frank R. Lichtenberg 2019, *The impact of pharmaceutical innovation on premature mortality and hospitalisation in Australia, 1998-2018*
[4] Ibid
[5] IQVIA 2020, *Understanding Medicine Spending in Australia – Trends and dynamics in healthcare and medicines spending*, IQVIA Institute for Human Data Science

properly view individual medicine contributions, while also considering the impact of medicines overall on social, economic contributions. To not do so under-represents the value of medicines and the value of the NMP.

There are validated methodologies for assessing many of the key determinants of social impact, used often in other areas of health and social research.[6] Countries such as Germany, Netherlands and Spain explicitly account for 'social productivity' as an evaluation criterion for reimbursement.[7] While these methodologies can increase the complexity of submissions and evaluations, Australia could lead the way in more efficiently valuing the impact of medicines on social wellbeing and economic impacts on consumers through public-private collaboration on this topic.

Australia as part of the global medicines ecosystem

Medicines research, development, manufacture and supply is conducted globally. Australia cannot operate in isolation from the rest of the world. Australia is impacted by global trends and policies: actions taken elsewhere have consequence and may occur with little control or degree of influence from Australia. Awareness of these trends will help us prepare leverage emerging opportunities as well as mitigate for negative consequences.

One example of potential global impact relates to the pricing of medicines. International reference pricing is a pricing mechanism whereby a government considers the price of a medicine in other countries to inform or establish the price in its own country. The United States has signalled its intention to introduce international reference pricing, using Australia as a reference country. This could carry significant risks to access for Australia patients. Changes to Australia's HTA processes are critical to ensure Australia remains a first-wave launch country. This will help avoid delays, prioritise innovation in health, and ensure preparedness for future pandemics.

There are already encouraging examples of efficiencies in Australian assessment processes that have been achieved by applying a global lens, such as global regulatory harmonisation initiatives.

Australia has many strengths including its competitiveness in clinical trials, high quality basic research, and a relatively stable economic and democratic environment. It also has some key areas for improvement, notably in medicines access, and commercialisation of local research and manufacturing. Various papers have been written about the sectors' competitiveness[8], various metrics have been collated and disseminated, and yet competitiveness has not improved.

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[6] https://pubmed.ncbi.nlm.nih.gov/33230613/

[7] A. Angelis, A. Lange and P. Kanavos, *Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries*. Eur J Health Econ, vol. 19, no. 1, pp. 123-152, 2018.

[8] https://www.mtpconnect.org.au/reports/SCP

This is largely because other countries have not stayed still. Using clinical trials as an example, other markets have sought to gain a greater share of the global clinical trials sector, as this benefits patients, the health system and the local economy. Australia has successfully implemented some initiatives to attract a higher numbers of trials, but there remains work to do, particularly in the area of harmonising clinical trials approval processes across the different local jurisdictions. At times, there are confusing juxtapositions of policies and initiatives aimed at supporting clinical trials on one hand, and diminishing Australia's competitiveness on another. The constant policy reviews for R&D tax provisions may be a case in point.

ToR 3 Actions

1. The NMP should explicitly recognise that **investment in medicines is an investment in valuable health, social and economic outcomes**, rather than merely a cost.
2. The NMP should recognise Australia's position in the **global medicines ecosystem** and the consequences for Australia's health outcomes and competitive position.
3. The NMP should recognise the health, social and economic benefits of a world class domestic medicines ecosystem, including the need for greater **harmonisation of Australia's clinical trials** system.

ToR 4: Consumer Centricity

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

Patients at the centre

Patients and their carers should be absolutely central to the NMP, as they are the ultimate 'users' of medicines. They are at the heart of Medicines Australia's vision to 'make a real difference to the health of Australians by ensuring they have access to world-class medicines when they need them'. The NMP recognises the 'fundamental role consumers have in reaching these [NMP] objectives'. However, it is clear from the many patient submissions to the *House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia,* that more work needs to be done to include patients and carers in medicines policy.

Medicines Australia strongly support efforts to increase the patient and carer voice within the NMP to better understand and incorporate their needs. The development of an *Enhanced Consumer*

Engagement Process as part of the new Strategic Agreement is a welcome initiative. Though this will be focused on the PBAC process, there needs to be patient input at all touchpoints in the medicines life cycle, from research and development, to clinical trial design, through to regulatory and reimbursement decision making and real world use.

Patients have greater expectations with respect to medicines than they did twenty years ago, and these need to be considered in the new NMP in several areas.

Health literacy: There must be appropriate provision of education so that patients and their carers can make informed decisions about medicines. This includes education about medicines themselves but also education about medicines policies and processes, so that patients are aware of opportunities to be involved.

Provisions of information: While reliance on clinicians remains strong, patients also seek information from other sources. There has been a massive increase in digital communication which can result the dissemination of unapproved, or unsanctioned, internet-based information. This concern does not apply to clinicians, since Medicines Australia has effectively constrained its member companies by requiring adherence to its Code of Conduct. Medicines Australia does not propose to alter this, but believes that the system of information flow does not meet patients' expectations for immediate and direct access to information to guide their own individual decisions.

Transparency of information: Decision-makers require and deserve to have access to the latest information upon which to make robust decisions, and that information ought ideally to be available to all. However, changes in this area have been difficult, due to the real concerns about the role of confidentiality of data, the extent to which that information is used in decision-making, and transparency in communicating decisions.

Involvement in decision making: There has been good progress in this area in recent years, with the involvement of consumer representatives on key decision-making bodies such as the PBAC, and efforts to include consumer and community representation on community health boards and ethics review committees. The development of the *Enhanced Consumer Engagement Process* will be crucial in further improving patient involvement.

Reflecting diversity

In making patients central to the NMP, ways must be found to ensure that the diversity of the Australian population is considered. This includes cultural and socio-economic diversity, urban and rural populations, as well as populations suffering from rare diseases.

In particular, the NMP should recognise the particular needs and perspectives of Aboriginal and Torres Strait Islander people to ensure they are benefitting equitably from the policy. The inequality of health outcomes compared to other Australians is well documented, and there are issues respecting the small sizes of sub-populations requiring treatments, and lack of epidemiological and HTA-relevant health data.

ToR 4 Actions

In order to improve the consumer centricity within the NMP, Medicines Australia recommends the following:

1. The NMP should make **patient involvement central**, through:
    a. promoting **health literacy** and understanding of the medicines system
    b. **providing information** about current and future medicines
    c. ensuring there is **transparency of information**
    d. including patients in **decision making** in a meaningful way
2. Patient engagement should be done in such a way that recognises the diversity of the Australian population.
3. The NMP should recognise the particular needs and perspectives of **Aboriginal and Torres Strait Islander people** to ensure they are benefiting equitably from the policy.

ToR 5: Governance

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

Metrics are key to implementation

The NMP sets out the aims for medicines access, regulation and delivery in Australia. Assessment of the impact of the policy is currently difficult as there is a lack of measurable standards. While the current policy refers to achieving 'optimal health outcomes' and 'economic objectives', the optimal results are not defined. Increasingly, government policies have been subject to transparent measurement and reporting regarding delivery to expectations – the NMP does not currently meet these expectations.

Medicines Australia proposes that the review of the NMP must include a thorough review of the governance framework. An NMP governance committee should be formed, consisting of representatives of all NMP partners. The committee should develop a set of metrics to measure progress towards the vision. Having an agreed set of metrics will also promote joint accountability between all partners. The metrics should be publicly reported in an annual report which would assess how well the NMP is delivering on expectations, and which areas require more focus. The NMP itself should be reviewed every five years for currency.

Australia's Long term National Health Plan outlines the Australian Government's desire to be a world-leader in healthcare delivery, including access to new medicines and medical technologies. The NMP should be a key driver in achieving this goal.

ToR 5 Actions

To improve the NMP's governance, Medicines Australia recommends the following:

1. A dedicated **NMP governance committee** should be established to champion the implementation of the NMP and review its progress towards achieving the vision.
2. The committee should produce a public **annual report** on the progress of the NMP implementation against jointly agreed metrics.
3. A set of **metrics** should be developed to measure progress in key areas, for example:
    a. **health outcomes** e.g. disease-specific outcome measures such as 5-year cancer survival rates and immunisation coverage
    b. **patient centricity** e.g. feedback from patients on inclusion
    c. **access to medicines** e.g. global comparative time from registration to reimbursement
    d. **vibrant industry** e.g. number of clinical trials, investment in R&D, number of research collaborations
4. The NMP should be **reviewed every five years** to ensure it remains fit-for-purpose.

ToR 6: Partners & Accountability

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

An opportunity to renew partnership dialogue

The NMP is described as a partnership for better health outcomes. Medicines Australia, as a foundational partner, strongly supports the view that partnership and collaboration is essential to the full delivery of the benefits that medicines can bring to Australia. We recognise that all the

stakeholders in the medicines ecosystem have a part to play in this goal, and that the interdependence and integration of these stakeholders is vital. Even though there are areas of potential difference between the partners to the NMP – not least the tension between breadth of access and cost – the existence of these areas of difference underscores the importance of a partnership approach.

Opportunities to discuss and debate differences lies at the heart of an effective partnership. Dialogue is vital to developing trust and understanding. Over time we have seen a decline in the opportunities for formal partnership dialogue. Some such previous opportunities have been:

- the Australian Pharmaceutical Advisory Council
- the Pharmaceutical Industry Working Group, which aimed to improve discussions between industry and government across the health and industry portfolios.
- more regular discussions between industry and PBAC.

Medicines Australia would like to propose that a new discussion forum be established, including representatives of all NMP partners, to continue and enlarge the work done by these previous groups.

Managing conflicts of interest through the Code

Medicines Australia's Code of Conduct ensures that its members can continue to innovate and do business in Australia while having the best interests of patient communities at heart. The Code provides a principles-based framework for appropriate and ethical decision making by Companies when promoting prescription products and interacting with healthcare professionals, health consumer organisations and the general public. In addition to having mechanisms for dealing with conflicts of interest, it also requires all members to transparently report on transfers of value to Australian healthcare professionals who are engaged in patient care, to third party organisations conducting educational activities, and to health consumer organisations. Medicines Australia believes there should be a similar level of transparency between all NMP partners.

ToR 6 Actions

To promote greater accountability for all NMP partners, Medicines Australia recommends the following:

- The NMP should include a **forum for discussion between NMP partners**, focused on collaboration and resolution of differences, in alignment with the vision for the NMP.
- The forum should work through each partners' barriers to **providing greater transparency** in the interests of all partners, while ensuring each parties' interests are appropriately safeguarded.

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Medicines Australia's members play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately $9 billion to the Australian economy in 2016-17; employ, directly and indirectly, over 23,000 Australians; invest over $1 billion into research and development annually to help 33,000 Australians get early access to emerging innovative therapies. In 2017-18, our industry exported $1.6 billion worth of medicinal products. None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

Pharmaceutical companies represented by Medicines Australia have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.