

# Review of the National Medicines Policy

## NMP Review Committee - Summary Consultation Report and Recommendations

27 May 2022

### Introduction

This report provides a summary of the consultation findings from the Review of Australia's National Medicines Policy (NMP) and the Review's Expert Advisory Committee's (the Committee) commentary on how stakeholder feedback informed the development of the draft 2022 NMP. It identifies the Committee's suggested recommendations to address issues raised that were principally not within the scope of the draft 2022 NMP.

This document should be read in conjunction with the draft 2022 NMP. Further details from the consultation can be read in the full Stakeholder Consultation Report.

### Overview of the Review

In 2019, the Australian Government committed to a Review of the NMP (the Review). This was in recognition of the substantial changes to the health, medicines and medical technology landscape since the Policy was first published in 2000. The Review was scheduled to begin in 2020 however was delayed until August 2021 due to the COVID-19 pandemic.

In August 2021, the Minister for Health and Aged Care, the Hon. Greg Hunt MP established an Expert Advisory Committee (the Committee) to lead the Review for the Department of Health. The Review was chaired by Professor Michael Kidd AM, with Emeritus Professor Lloyd Sansom AO, Mrs Janette Donovan, Dr Sarah Dineen-Griffin and Mr David Herd as Committee Members. The Review's Terms of Reference can be found in Appendix A.

The Committee was supported by a Review Secretariat from the Department of Health.

### Consultation

The Committee undertook extensive stakeholder engagement to ensure that a range of issues and diverse experiences informed the refresh of the NMP, as a high-level policy framework. Public consultation was undertaken in two key phases between 30 August 2021 to 2 March 2022 (Figure 1) including:

- **Phase 1 – Development of an initial consultation draft 2022 NMP (30 August 2021 - 9 December 2021)**

The Review's [Discussion Paper](#) formed the basis for the questions explored through a combination of consultation methods. Over a 12-week public consultation period (30 August 2021 to 17 November 2021), the Committee received 156 written submissions in response to the Review's Discussion Paper. Bilateral interviews and group discussions were conducted virtually with 194 representatives across 135 organisations. The Committee shared its initial reflections on key themes from the stakeholder consultation with 158 participants at a virtual stakeholder forum on 9 December 2021. Stakeholder feedback informed the development of an initial consultation draft 2022 NMP.

- **Phase 2 – Refinement of the initial consultation draft 2022 NMP (2 February 2022 – 2 March 2022)**

Phase 2 sought stakeholder feedback in response to the initial consultation draft 2022 NMP through a consultation survey and webinar. In total, 96 responses were received on the initial consultation draft 2022 NMP and 217 participants attended the virtual stakeholder forum on 9 February 2022.

To analyse stakeholder input, a mixed-methods process was undertaken, predominantly consisting of qualitative thematic analysis. The 156 written submissions were analysed using the qualitative data analysis software, QSR NVivo 12. For analysis, content was grouped into one or more of seven categories (the Review's Terms of Reference, and an 'other' category for feedback not directly related to a Term of Reference). Notes taken during the virtual bilateral interviews and group discussions were synthesised separately to provide a point of comparison and to supplement information throughout the analysis and reporting steps. Emerging key themes were cross checked with the Committee to ensure the full range of stakeholder perspectives had been captured. Comparison of findings from the different data collection methods served to support the validation of findings.

The Committee notes that the draft 2022 NMP prepared for the Minister, by the Committee, has not been released for public consultation.

### ***Committee's Recommendations***

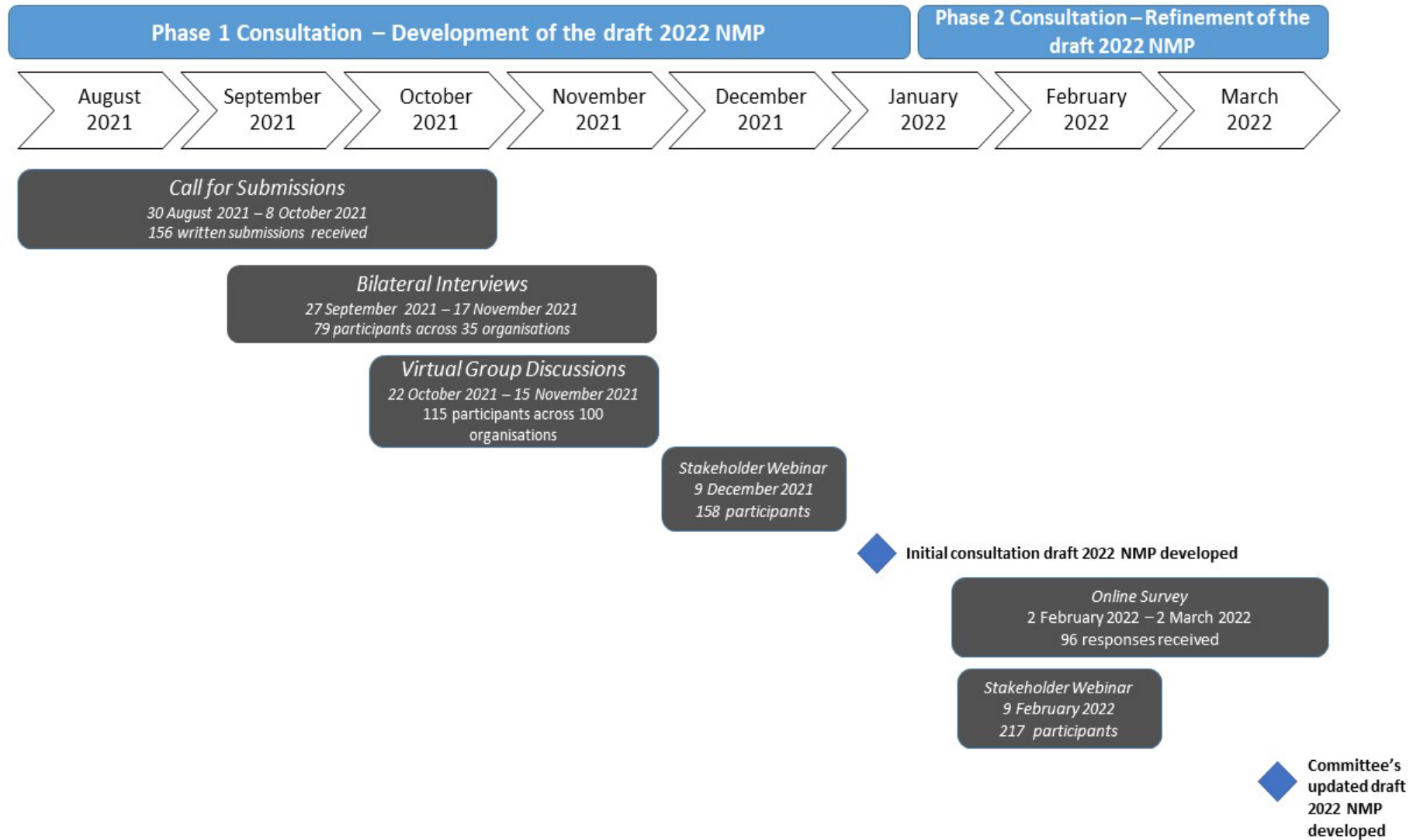
- 1. The Committee recommends that the draft 2022 NMP be released for public consultation.**

## **Common overarching messages from public consultation**

The common overarching messages heard throughout the public consultation process included:

- The 2000 Policy's objectives have continuing relevance, including the quality use of medicines and medicines safety, and equity, affordability and timeliness of access, particularly for prioritised populations. The importance of a person-centred and partnership-based approach in supporting the Policy's objectives was affirmed.
- The health system and medicines and medical technology environment and broader health landscape is experiencing continuous change. The NMP needs to reflect and respond to the changing nature of this environment and landscape and the pace of scientific and technological innovation. Maintaining flexibility and adaptability within the Policy is important to ensure its sustainability and relevance over time.
- Connections between the 2000 Policy's objectives and their translation into action was not always considered or transparent. Strengthening the Policy's communication, governance, implementation and evaluation processes were seen as critical to bridge this gap, and to build awareness and understanding of the Policy's expected impact. Stakeholders called for the establishment of a transparent and accountable governance structure, detailing the timeframes for future policy reviews, annual reporting of progress against the outcomes of the Policy's objectives, supported by the establishment of agreed key performance indicators.

Figure 1 - Outline of consultation methods used across the Review



## Summary of findings

The following section presents a summary of the consultation findings under five key headings:

- Refreshing the Policy framework
- The Policy's scope
- Direction and intent of the Policy
- Governance and implementation
- Refining the draft 2022 NMP

Each section is accompanied by the Committee's commentary and recommendations.

### Refreshing the Policy framework

Stakeholders universally supported the need for the Review. There was a general sense that the four objectives of the 2000 NMP remained relevant, but that these could be updated or added to, so that the Policy is responsive to change. Increasing the visibility of the NMP as a foundational document within the context of current and emerging health challenges and the evolution of science and technology was suggested. There were consistent calls for the NMP to incorporate a future focus to support continuing relevance and sustainability. The inclusion of a vision statement was recommended by industry stakeholders and some consumer organisations.

Stakeholders also recognised the need for the refreshed policy to balance tensions between different values and interests. It was suggested that this may be assisted by ensuring that the NMP is a principles-based high-level framework that is broad in scope. At the same time, many stakeholders called for clearly defined and articulated objectives, associated roles and responsibilities, measures to monitor progress and to support accountability and transparent communication of the progress and achievements, as a result of actioning the aim of the Policy.

The name of the 'National Medicines Policy' was generally seen as appropriate. Some stakeholders made suggestions to revise the policy name, for example to the 'National Therapeutics Policy'. Such suggestions were reflective of their views to expand the Policy's definition of medicines, or to signal the broad intent of the policy on supporting the achievement of optimal health outcomes, for example the 'National Health Outcomes Policy'.

### ***Committee's Response***

Reflecting the Policy's scope in its title was suggested, with the most frequently referenced terms for inclusion being "therapeutics" and/or "health technologies". Some stakeholders suggested that "therapeutics" was a more encompassing term beyond medicines and reflects the current and future treatment landscape more accurately. However, one stakeholder suggested that the use of the term 'therapeutics' may 'make the policy less consumer friendly' as it was suggested that this term was less well understood in comparison to medicines. Suggested titles included the 'National Medicines and Related Technologies Policy', 'National Therapeutics Policy' or 'National Therapeutics Goods Policy' and the 'National Medicines and Medical Technologies Policy'. The Committee acknowledges that the development of a National Medical Devices Policy would be complementary to the NMP particularly due to the rapidly emerging innovations in the devices area.

The Committee has retained the Policy's title as Australia's 'National Medicines Policy' to ensure continuing global recognition that Australia has an NMP and to reflect the general existing knowledge of the NMP within the Australian health system. This reflects the history of the 2000 NMP's development in response to the World Health Organization's call for member states to develop a National Medicines Policy.

The draft 2022 NMP has been restructured around a high-level vision, aim and four central interconnected pillars to reflect stakeholder feedback. The objectives of the 2000 NMP have been renamed 'Central Pillars' that work together to support the achievement of the Policy's aim. The components of each of the Central Pillars have been clearly articulated in response to calls for increased detail. Each Central Pillar now includes intended outcomes, expanded descriptions to articulate the key concepts of each Pillar, and the inclusion of the key responsible partners and their broad roles and responsibilities to advance each Pillar.

Overarching principles have been added to address the calls for the Policy to be flexible and responsive. Following stakeholder feedback, the principles have been refined, additional principles have been added, and increased detail on what the principles mean in action has been included. In addition, Enablers have been added to the Policy as a guide for all partners to provide consistent support and alignment across the implementation process supporting each of the Central Pillars and the execution and delivery of the intended outcomes.

### **Committee's Recommendations**

- 2. The Committee recommends that the Commonwealth Government consider the development of a 'National Medical Devices Policy'.**

### **The Policy's scope**

Stakeholders called for clarity about the NMP's purpose and its relationship to aligned policies, strategies, programs, initiatives and other relevant national policies. This was commonly supported by calls for more communication on the Policy to define it within the context of the broader health environment.

Overall, stakeholders suggested that the NMP's definition of medicines should include biologics and vaccines. There were mixed views on the inclusion of medical technologies, and a general sense that medical devices should be excluded as expansion may dilute the Policy's focus on medicines. Stakeholders highlighted the need to acknowledge that the achievement of the aim of the NMP relies on supportive medicines-related services, structures, and processes. One example provided was the provision of medication management review services in supporting the quality use of medicines and medicines safety.

### **Committee's Response**

The scope of the draft 2022 NMP has been expanded to cover a broad range of products that are used to prevent, treat, monitor, or cure a disease or health condition. The definition of medicines contained within the draft 2022 NMP encompasses "*prescription medicines, including biologic and non-biologic medicines, gene therapies, cell and tissue engineered medicines and vaccines, non-prescription products, complementary medicines, and traditional medicines, including Aboriginal and Torres Strait Islander traditional medicines*".

Devices used to administer and to monitor the outcomes of medicine use have also been included in the draft 2022 NMP scope. The Committee has referred to 'medicines-related services', as being in scope of the NMP. The term refers to "*services and programs that support the quality use of medicines and medicines safety*", with medication review and diagnostic services referenced as examples. This broad approach seeks to ensure that the NMP can adapt and respond to new and emerging treatments and technologies (including diagnostics), personalised medicines and medicines-related services.

The inter-relationship between the NMP and other relevant health policies, including Closing the Gap, Australia's Primary Health Care 10 Year Plan and the National Preventative Health Strategy, has been considered within the draft 2022 NMP. The Policy acknowledges that "*close*

alignment with key areas of health reform in Australia and action through a whole-of-government approach” is required to achieve the Policy’s aim.

### **Committee’s Recommendations**

- 3. The Committee recommends that a document be prepared by the Department of Health to explain how the NMP aligns with other policies, strategies and agreements. Specific examples that overlap with the NMP include the National Preventive Health Strategy, the National Digital Health Strategy, the National Strategic Action Plan for Rare Diseases, the Primary Health Care 10 Year Plan, Closing the Gap and the National Health Reform Agreement.**

### **Direction and intent of the Policy**

Five themes emerged from the stakeholder consultations on the Policy’s direction and intent, including:

- access;
- person-centredness;
- using medicines appropriately;
- shared endeavour; and
- a policy fit for the future.

### **Access**

The opportunity for all Australians to have access to medicines when required (in a timely manner) was widely considered as an important dimension of equity of access. Several stakeholders, particularly the pharmaceutical industry and stakeholders representing those with high unmet clinical needs, highlighted timeliness as an important issue. Many stakeholders called for an explicit and clear definition of ‘timeliness’.

Affordability and reliability of access to medicines and medicines-related services were elements of equity emphasised by stakeholders. Challenges to access and equity included medicines shortages and supply chain issues. This was important in relation to specific access challenges facing priority populations including Aboriginal and Torres Strait Islander communities and those living in rural and remote areas.

Equity of access was not limited to a description focused on access to medicines, but also incorporated broader influences on access, such as obtaining health professional expertise and appropriate health information. Stakeholders suggested that equity of access could be embedded in the NMP by ensuring that the needs of Australians of all backgrounds and circumstances are considered in the Policy. Many stakeholders called for a recognition in the Policy of the systemic, socio-economic and geographic drivers of inequity. Examples of these included geographical access disparities, medicine shortages and supply challenges. Some stakeholders highlighted that the lack of reported outcomes and key measurement data as contributing to ongoing disparities, particularly for Aboriginal and Torres Strait Islander people. Emphasising the responsibility of the NMP partners to address and proactively work for greater equity, was also suggested.

### **Committee’s Response**

The draft 2022 NMP specifically identifies key priority groups, including Aboriginal and Torres Strait Islander people, people from culturally and linguistically diverse backgrounds, people with a

disability, and other priority groups. The draft 2022 NMP specifically refers to and includes the need for a greater emphasis on 'health literacy', as an enabler. The following paragraphs from the draft 2022 NMP demonstrate how access has been described in terms of equity, timeliness and affordability.

*The NMP's focus is on delivering positive ways to eliminate health inequities that are experienced by priority groups within the community. These groups include Aboriginal and Torres Strait Islander people; people from culturally and linguistically diverse backgrounds; children and older people; people with disability; people living in rural and remote areas; people of low socioeconomic status; people living with rare and under-recognised diseases; people with mental illness; lesbian, gay, bisexual, transgender, queer or questioning, intersex and/or other sexuality and gender diverse people (LGBTQI+); and other priority groups. People may identify as belonging to one or more of these priority population groups, and as such, may have compounding health and wellbeing experiences that must be considered.*

### Equity

*Irrespective of diversity, background, age, disability, location or personal circumstance, all Australians should have equitable access to safe, effective and high-quality medicines, culturally appropriate medicines-related services, and medicines information. This pillar focuses on eliminating health inequities that may be experienced by priority groups, as outlined in the principle of 'Equity and access'. Specific examples of issues experienced by priority populations which need to be considered and addressed by partners include:*

- Aboriginal and Torres Strait Islander leadership and self-determination is needed in all partnerships to enable shared decision-making in identifying priorities and to drive solutions given the substantial barriers Aboriginal and Torres Strait Islander people experience.*
- People from culturally and linguistically diverse backgrounds are included in partnerships to co-design solutions to increase access to medicines, culturally appropriate medicines information and medicines-related services.*
- People living with disability may face specific challenges including accessing the required medicines formulations and medicine reviews, communicating with health professionals, and accessing easy to read written information about their medicines.*
- People from rural and remote communities face specific and ongoing barriers associated with the cost, supply and distance to access medicines and health services.*
- People, including children, living with rare and under-recognised diseases often face inequities due to the scientific and technical complexities of generating data and its collection, and the absence of evidence for the evaluation and subsidisation of treatments for rare conditions.*

*The location of care delivery should not impact access to medicines whether in different states and territories, in hospital or community health care settings or in environments such as disability care settings, residential aged care settings and correctional settings. Health systems can support this by recognising these barriers and addressing them through innovative approaches in meeting health literacy needs, providing continuous education to improve the skills of the workforce and increasing access to internet and telehealth services.*

### Timeliness

*All Australians, regardless of where they live, who they are and the health condition they have, will have timely and reliable access to safe and effective medicines and medicines-related services to maintain their health and wellbeing. Appropriate and efficient processes must exist for the evaluation of risk-benefit, value and subsidisation to ensure*



*timely access. This includes the ability to rapidly respond to emerging and disruptive technologies, including innovative and highly specialised medicines and services, especially in circumstances where individuals have high unmet clinical needs or in response to public health emergencies or natural disasters. These processes and their outcomes need to be effectively communicated to all stakeholders, including to the public, to build and maintain community understanding and confidence. Further, processes finalising the financing, price, economic and supply arrangements of medicines must be efficient to secure access in a timely manner. Timeliness has several other contexts and barriers for consumers, including not being able to access medicines and medicines-related services due to shortages or supply challenges, particularly for those in rural and remote communities. This requires an open and transparent commitment by all partners to work together to minimise the impact of shortages and supply challenges of essential medicines.*

### Affordability

*It is critical that all Australians can afford the medicines and medicines-related services they need. This is particularly important for people with multiple health conditions taking multiple medicines, people with low incomes, or families experiencing high health care costs. A robust and transparent mechanism for determining the value of a medicine by governments and other payers is essential for the coordinated, fair and efficient supply and use of medicines. The value of a medicine includes benefits to the health and wellbeing of the individual, the social and economic benefits to the individual, carers, and families, as well as to the broader society. Initial and continued investment decisions should be informed by rigorous health technology evaluation, including the consideration of incorporating real-world evidence and patient reported outcomes, where appropriate.*

### **Committee's Recommendations**

- 4. The Committee recommends that equity, timeliness and affordability be continually monitored, and transparently reported on, by all partners to ensure all Australians, especially from priority populations, can access the medicines they need.**
- 5. The Committee recommends that all policies, programs, systems and processes aligned with the NMP be reviewed by stakeholders to ensure they have the ability to rapidly respond to emerging and disruptive technologies including innovative and highly specialised therapies and services, especially in circumstances where individuals have high unmet clinical needs or in response to public health emergencies or natural disasters.**

### **Person-centredness**

Person-centredness was considered important by stakeholders to ensure that people who are current or potential users of medicines are at the centre of decision-making, from registration and funding decisions to individual treatment decisions. Suggestions to embed person-centredness included reframing consumers as active contributors and partners to the NMP. Enhancing health literacy and shared decision-making was acknowledged by stakeholders, as was the inclusion and consideration of consumer expertise, as an enabler of person-centred medicines decision-making. Consumer stakeholders viewed clear communication about medicines to be the responsibility of those providing medicines-related services. Ensuring access to trustworthy sources of information (including responsible media reporting and online information) was also considered as an enabler of a person-centred medicines environment. A preference for inclusive terminology, such as 'people or persons or consumers' (to refer to individuals, carers and families) was expressed by some, and the need for the Policy to 'speak' to all Australians



regardless of their culture and language, health condition and/or belief, accessibility, disability, identity or circumstance, was emphasised.

### **Committee's Response**

Person-centredness has been maintained as a key part of the draft 2022 NMP and as a fundamental Principle. Diverse consumer representation in all elements of the Policy and the involvement of the individual and/or carer in their health care, have been highlighted. The draft 2022 NMP states that:

*Consumers will be supported and enabled to be informed and active participants in all decision-making, acknowledging their aspirations, diversity and lived experience. This includes developing and building health literacy, so that individuals, carers and families, and the broader community are informed and active participants in decision-making. Consumers will be supported to be involved at all levels of the NMP, including in the co-design and development, implementation and evaluation of its related policies, strategies, programs and initiatives.*

### **Committee's Recommendations**

- 6. The Committee recommends diverse consumer representation and active consumer involvement in all aspects of the NMP, including in the co-design and development, implementation and evaluation of related policies, strategies, programs and initiatives to achieve the aim of the NMP.**
- 7. The Committee recommends that the Commonwealth Government and responsible partners invest in the co-design and development with consumers of specific programs including developing culturally appropriate medicines information to promote and build the health literacy of consumers to help people participate in shared decision-making about their medicines and health.**
- 8. The Committee recommends that the Commonwealth Government and responsible partners invest in training programs for health professionals to deliver culturally appropriate person-centred care and shared decision-making, particularly for priority populations.**

### **Using medicines appropriately**

Universal support for retaining and strengthening the objective supporting the quality use of medicines (QUM) was received. QUM was described as a whole-of-system issue, requiring effort and input from all NMP partners to maximise health outcomes and minimise harm. The changing demographic profile, disease burden and related complexities and issues relating to the delivery of healthcare in Australia, particularly in rural and remote areas, were factors commonly mentioned by stakeholders as influencing the current and future achievement of QUM. Important and evolving issues for the appropriate use of medicines and medicines safety included:

- appropriate use of antibiotics to reduce antimicrobial resistance.
- monitoring and responding to inappropriate polypharmacy (the use of multiple drugs) and the need for pharmacovigilance.
- deprescribing (removing) unnecessary medicines.
- reducing harm from high-risk medicines.
- improving medication safety at transitions of care and in all settings.

- prescribing practice and communication between health care providers (including live prescription monitoring systems).
- participation of consumers and clinicians in shared decision-making about treatment options (including deprescribing).

Many stakeholders pointed out that QUM is not just about the medicines themselves, but about the way medicines are used in the context of a broad range of interventions and supports. One common suggestion to strengthen the emphasis on QUM in the NMP was to highlight the importance of consumer access to accurate, independent, appropriate and up-to-date information about the safety and efficacy of medicines, including complementary and traditional medicines. Another prominent suggestion was to provide more support to health professionals to achieve QUM and providing adequate funding and resourcing for targeted QUM improvement initiatives.

The implications of any expanded definition of medicines to include vaccines and/or devices was also considered important for QUM. Furthermore, many stakeholders commented on the need for the refreshed NMP to broaden and explicitly define what is considered as evidence to support claims of quality, safety and efficacy. The consideration of real-world evidence and strengthening data collection were suggestions to support this.

### **Committee's Response**

Central Pillar 3 specifically relates to quality use of medicines and medicines safety. The draft 2022 NMP notes that *'the quality use of medicines and medicines safety is a National Health Priority Area'*.

The draft 2022 NMP states that the quality use of medicines includes:

- **Selecting treatment options** – *medicines may be chosen to manage health conditions and treat illnesses, but they may not always be the best option. When required, self-care, prevention and other management options will be considered and be accessible.*
- **Choosing suitable medicines** – *in selecting, prescribing or deprescribing a medicine, the clinical and non-clinical factors, patient experiences and preferences, potential benefits and harms, and the out-of-pocket cost of access, will be considered.*
- **Using medicines safely and effectively** – *getting the best possible results means monitoring outcomes, minimising misuse, overuse and underuse, and empowering and supporting people to make decisions to use medicines safely and effectively.*

The importance of all partners working collaboratively, cooperatively and transparently in achieving the quality use of medicines and medicines safety is repeatedly highlighted throughout the draft 2022 NMP. The draft 2022 NMP identifies the critical importance of addressing the need to deliver *'culturally appropriate, person-centred services, including health and medicines information and support'* to ensure that the needs of Australia's diverse population are met. Furthermore, an intended outcome of the Central Pillar highlights that *'health professionals are trained and proactively supported to implement programs and initiatives to achieve the quality use of medicines and medicines safety'*.

### **Committee's Recommendations**

**9. The Committee recommends that the Commonwealth and State/Territory Governments continue to invest in programs and initiatives to achieve QUM and medicines safety for consumers, and training programs for health professionals to deliver these programs and initiatives, particularly for priority populations.**

**10. The Committee recommends that the Minister initiates an update of the National Indicators for QUM to enable the monitoring of QUM in the community.**

- 11. The Committee recommends that the Commonwealth and State/Territory Governments continue to promote the interoperability of technologies, particularly IT systems, across health settings to enhance the safety and quality of services and QUM for consumers, carers, families and communities.**
- 12. The Committee recommends the Commonwealth Government considers the establishment of a medication advisory service for rural and remote Australians and that this service be explored with rural and remote service providers, consumers, carers and families.**

### Shared endeavour

Viewing the achievement of the NMP's objectives as a shared endeavour was commonly highlighted by all stakeholder groups. Stakeholders stressed the importance of collective and collaborative efforts by partners to achieve the aim of the NMP. Valuing each partner's specific expertise was highlighted as a key component of this shared endeavour.

The relationship between a partnership-based approach and accountability and transparency was frequently emphasised, including the responsibility of all partners, including Commonwealth and State/Territory Governments, to be transparent and accountable. Accountability was associated with the delivery of outcomes and the transparency of effective and interoperable processes. Mixed views on the proposed principle of stewardship were heard, with suggestions that this term required further definition and explanation.

Calls were also made to clearly articulate partners' roles and responsibilities in relation to the NMP, to support accountability and transparency in the future. Articulation of a governance framework for the NMP was supported by stakeholders to enable clarity in relation to the roles and responsibilities of each partner.

### *Committee's Response*

The draft 2022 NMP repeatedly identifies the need for active dialogue, collaboration and cooperation between all stakeholders to achieve the aims of the NMP. 'Partnership and shared responsibility' is specifically identified as a fundamental Principle within the draft 2022 NMP. Under each Central Pillar, partners and their broad responsibilities and functions are identified to achieve the intended outcomes of each Pillar.

### *Committee's Recommendations*

- 13. The Committee recommends that the Commonwealth and State/Territory Governments continue to pursue consistency across jurisdictions on issues relating to medicines and medicines-related services, including ensuring interoperability of systems, policies and procedures and clinical trial governance.**
- 14. The Committee recommends that all partners map areas where they believe they can contribute to the achievement of the aim of the NMP and intended outcomes.**

### Fit for the future

Stakeholders viewed the Review as an opportunity to future-proof the policy. Updating the NMP to respond to changes in the health and medicines environment was considered important. There were calls to consider how the NMP can create a flexible, responsive and sustainable policy environment that is conducive to innovation, promotes continuous improvement and is resilient and responsive to current and future challenges.

Suggestions to promote a resilient medicines environment included an emphasis on the importance of a thriving research sector and medicines industry, accompanied by best-practice regulatory approaches. Harnessing the benefits of digital technologies and strengthening the collection and use of data were also considered important enablers of a policy that is fit for the future.

Many submissions mentioned the COVID-19 pandemic as an example, when considering the sustainability and resilience of the medicine's environment. Ensuring the reliability of supply chains and the possibility of expedited yet robust regulatory processes were highlighted. Feedback was also heard about long-term sustainability, including maximising the use of limited resources, and reducing the broader climate and environmental impact of medicines manufacture, use and disposal.

### **Committee's Response**

Central Pillar 4 specifically relates to the importance of having and supporting the innovative research and industry sectors. Innovation and sustainability have been specifically identified within the draft 2022 NMP as fundamental Principles to address the future health needs for all Australians. Furthermore, the draft 2022 NMP identifies technology as an enabler:

*Technology – to embrace and adopt digital information and technologies, and methods that are validated and interoperable to drive improvements in access, quality, safety, and efficiencies for all Australians across their health journey and use of medicines.*

The Committee acknowledges that the medicines industry and research sectors require support by appropriate strategic investment and effective industry and education policies of governments, driving strong partnerships between academia, government science organisations, industry, health services and consumers. The Committee recognises that the Australian industry and the research sectors must be able to operate with confidence in a global environment to further enhance international competitiveness.

The Committee also acknowledges the critical need that *'all partners will work to reduce the impact on the natural environment from the research, development, manufacture and supply of medicines. This includes the safe collection and appropriate disposal of expired or unwanted medicines, devices and medicines packaging'*. 'Sustainability' is identified as a fundamental Principle in the draft 2022 NMP.

### **Committee's Recommendations**

- 15. The Committee recommends that innovation be recognised as adding value to the Australian society and that it be supported for its contribution to continuous improvement and the opportunity to respond to current and future health challenges.**
- 16. The Committee recommends that the Commonwealth Government ensures appropriate horizon scanning mechanisms are in place to identify and act proactively on the opportunity of future scientific and technological innovation.**

## **Governance and implementation**

Suggestions to strengthen the policy's implementation, governance, communications, and evaluation were heard from all stakeholders. A strong theme heard in stakeholder feedback was the call to build upon existing mechanisms, and minimise the duplication of efforts, for the purposes of achieving the intended outcomes of the NMP.

## Strengthening accountability and reporting

There were consistent calls for greater clarity on the Policy's governance arrangements. This included calls for clear descriptions of policy ownership and the roles and responsibilities of each of the Policy's partners. The re-introduction of a governance committee, comprised of multi-stakeholder representation, was the most common suggestion to strengthen the Policy's governance. Consistent feedback was also heard about the need for governance mechanisms to remain relevant and flexible in recognition of the evolving health and policy landscape.

Stakeholders viewed the functions of governance mechanisms to be oversight and the monitoring of the Policy's implementation and progress towards the delivery of its aim; the facilitation of ongoing collaboration and consultation between the Policy's partners; and the management of the evaluation, monitoring, review and reporting of progress against the Policy's intended outcomes. Stakeholders consistently emphasised the importance of identifying and managing conflicts of interest and to strengthen transparency.

Establishment of a monitoring and evaluation framework, with process and outcome metrics, was also emphasised. This was seen as an important foundation for strengthening accountability, promoting continuous quality improvement, and supporting periodic review of the impact and effectiveness of the NMP. There was general agreement that any measures should be aligned with the Policy's aim, Central Pillars, intended outcomes and Principles.

### *Committee's Response*

The Policy's aim will be achieved through a governance structure that will be the bridge between the Policy, its programs and outcomes. The governance structure should ensure strong accountability, responsibility and transparency and the coordination of aligned policies, strategies, programs and initiatives. The governance structure should work with the Commonwealth Government to facilitate and encourage collaboration between partners including diverse consumer partners to achieve the aim of the NMP.

The Committee supports the creation of a governance structure which we believe will assist in the achievement of the intended outcomes of the Central Pillars. The Committee has not made recommendations with respect to the structure or composition of this governance structure within the draft 2022 NMP, as this was considered to be outside its Terms of Reference. However, it is recommended that the governance structure work cooperatively with and advise the Commonwealth Government on progress towards achieving the aim of the NMP and to identify barriers and enablers for the implementation of the NMP.

### *Committee's Recommendations*

- 17. The Committee recommends that the Commonwealth Government considers the appropriate mechanisms and processes to ensure the participation of all partners, including diverse consumer partners, and to enhance transparency and accountability in overseeing the implementation, evaluation and communication of the NMP**
- 18. The Committee recommends that the National Medicines Policy is reviewed and refreshed every 5 years to ensure it remains relevant and responsive to the future health environment.**

## Strengthening communication and engagement

To support an increase in the NMP's reach and impact, stakeholders suggested a greater focus on the communication of the Policy's purpose and objectives. Existing awareness of the NMP and its purpose was considered low by some stakeholders, particularly consumer organisations.

Promoting visibility of the policy was suggested to support the engagement of partners and the public with its implementation. Improving health literacy and the communication skills of health professionals was commonly referenced as a key enabler of communication.

Suggestions to improve dissemination of information about the NMP, and about medicines more broadly, included providing access to sources of trustworthy information, and learning lessons from the misinformation spread during the COVID-19 pandemic. Improvements in two-way or multilateral communication, including appropriate opportunities for diverse consumer involvement, were also considered important areas of focus.

### ***Committee's Response***

The Committee has incorporated stakeholders' feedback regarding strengthening the principles and expectations of accountability and transparency that underpin effective policy governance, implementation and evaluation. High-level guidance, inclusive of broad expectations and parameters for these sections of the policy, is included in the draft 2022 NMP. This reflects the NMP's status as a high-level policy framework, which articulates the direction and desired outcomes of medicines-related activity in the health system. This also responds to stakeholder feedback on the need for flexibility to be built into the Policy to support its ongoing relevance.

The draft 2022 NMP includes a list of partners and provides guidance on their roles and responsibilities, that reflects the broad categories suggested by stakeholders. The draft 2022 NMP also includes consistent references on the need for the Policy's partners to communicate alignment of their programs, initiatives or activities with the NMP, including how they have put the principles into action, including promoting areas where collaboration and cooperation between partners has shown to make a significant contribution to the NMP. This responds to stakeholder feedback for greater clarity about the connection between the NMP itself and the implementation mechanisms for translating it into practice. The draft 2022 NMP emphasises that this information should be made publicly available and meaningfully communicated for all audiences.

### ***Committee's Recommendations***

**19. The Committee recommends that a shorter plain English version of the Policy be developed by the Department of Health to ensure it is both accessible and easily understood by all Australians.**

#### **Creating a conducive context for implementation and evaluation**

Stakeholders commented on how policy, legislative and financial levers could be better aligned to create an environment conducive to successful implementation and evaluation of the NMP. Alignment of policy, legislation, and regulatory frameworks between different levels of government (Commonwealth and State/Territory) and between different government agencies was considered important. Better alignment of funding considerations to the Policy's objectives was also called for, especially in terms of the need to overcome financial barriers to access. Consumer experiences of high out-of-pocket costs were described as a barrier to access and the quality use of medicines for those unable to afford medicines.

The development of guidance documentation, such as an action plan, describing the roles and responsibilities in relation to the NMP's intended outcomes supported by high-level performance indicators, was commonly suggested. The development of such documents to implement the Policy were seen as enabling greater coordination to drive transparency and accountability.

A monitoring and evaluation framework, with process and outcome metrics, was seen by many respondents as an important foundation for strengthening accountability, promoting continuous quality improvement, and supporting periodic review of the impact and effectiveness of the NMP.



## **Committee's Response**

The Committee believes that better alignment between policy, legislation and regulatory frameworks across different levels of government is essential to ensure equity of access for all Australians. The Committee believes that the evaluation of policies, strategies, programs and initiatives is essential for quality improvement interventions. High-level performance indicators should be defined and considered as part of this process.

In relation to overcoming financial barriers the draft 2022 NMP states:

*It is critical that all Australians can afford the medicines and medicines related services they need. This is particularly important for people with multiple health conditions taking multiple medicines, people with low incomes and families experiencing high health costs.*

## **Committee's Recommendations**

- 20. The Committee recommends that the co-design and development, implementation and evaluation of the NMP's related policies, strategies, programs and initiatives should be linked with the Policy's aim, Central Pillars, intended outcomes and Principles.**
- 21. The Committee recommends that each partner with accountability and responsibility for processes and systems that support the delivery of the NMP, review their current outcome measures, to ensure they are consistent with the Policy's aim, Central Pillars, intended outcomes and Principles.**
- 22. The Committee recommends that any policies, programs and initiatives relating to medicines and medicines-related services should facilitate collaboration and co-operation between partners including consumer partners and be transparent.**
- 23. The Committee recommends that all partners responsible for policies, strategies, programs and initiatives aligned with the NMP regularly evaluate each element to ensure they are contributing optimally to the aim of the Policy.**

## **Strengthening partnerships**

Establishing and maintaining strong partnerships and collaboration between all stakeholders for successful implementation of the NMP, and its associated programs, was commonly highlighted. Suggestions to achieve this included providing clarification on partners' roles and responsibilities; enhancing transparency between partners and the broader community; and improved use of communication and engagement tools and evaluating these. Effective partnerships were described as going beyond transactional relationships towards respectful collaboration. Stakeholders identified the need for accountability and transparency between the partners and with the community to show that progress is being made towards the NMP's intended outcomes. The Policy's partnership-based approach was often framed as the foundation of the Policy's governance.

## **Committee's Response**

The importance of collaboration and cooperation between all partners, focusing on the wellbeing of the individual is a fundamental component of the draft 2022 NMP. Throughout the document, the role of partners in contributing to the intended outcomes of the Central Pillars is repeatedly emphasised. Partnership and shared responsibility and accountability are included as two of the fundamental Principles within the draft 2022 NMP. Only by partners working together will the aim

of the Policy be achieved. Collaboration must be respectful and recognise the contribution each partner makes to the health, social and economic outcomes for all Australians.

## Refining the draft 2022 NMP

Respondents indicated broad levels of agreement for most components of the initial consultation draft 2022 NMP. Over half of the respondents 'strongly agreed' or 'agreed' with the draft aim (66 per cent), scope (70 per cent), principles (over 80 per cent for each principle), enablers (over 83 per cent for each enabler) and central pillars (Pillar 1 – 67 per cent, Pillar 2 – 79 per cent, Pillar 3 – 77 per cent, Pillar 4 – 74 per cent). Respondents also provided suggestions to inform the Policy's refinement. This was broadly focused on the language, logical flow and level of detail contained in the initial consultation draft 2022 NMP. Feedback on the initial consultation draft 2022 NMP has been summarised to:

- Ensure consistency in the language and phrasing used to strengthen readability. This included suggestions to increase the use of person-centred language, and to use clearer language to support the understanding of each of the Policy's components. This was commonly suggested for the Policy's aim, and the descriptions of the Policy's Principles and Central Pillars.
- Increase specificity and detail throughout the Policy. This was commonly suggested with reference to the Central Pillars, with calls for greater detail on how the pillars would be implemented, and the roles and responsibilities of all partners.
- Provide more explicit linkage between the NMP's components. As an example, it was suggested that there be more explicit linkage between the Policy's principles with the Central Pillars, governance and evaluation components (including reporting mechanisms).

Less than half of the respondents indicated agreement with the consultation draft Policy's governance (44 per cent), implementation (44 per cent) and evaluation (41 per cent) components. Suggestions included the development of an implementation plan, clear timelines for review and reporting, the creation of an oversight or governing body and the inclusion of key performance indicators or metrics within the Policy.

Overall, 28 respondents (30%) also called for a delay to the Review to undertake further consultation. This call was primarily from the medicines industry, as well as from some peak health professional and consumer organisations. Calls to delay the Review were primarily associated with an argument to further develop details relating to the Policy's governance, implementation and evaluation. An extension to the NMP's consultation period was also requested by five consumer organisations to allow for broader feedback to be received from across their organisational membership which would allow for a more considered response.

### ***Committee's Response***

As previously articulated in the section 'Strengthening accountability and reporting', the Committee supports the creation of a governance structure which we believe will assist in the achievement of the intended outcomes of the Central Pillars. The Committee has not made recommendations with respect to the structure or composition of this governance structure within the draft 2022 NMP, as this was considered to be outside its Terms of Reference.

Notwithstanding, the strong opinion of most respondents suggested that a comprehensive framework was needed to promote ownership of the NMP by stakeholders particularly consumer stakeholders and to facilitate partner engagement in order to achieve the aim of the Policy.

## Recommendations from the Review Committee

1. The Committee recommends that the draft 2022 NMP be released for public consultation.

### *Refreshing the Policy Framework*

2. The Committee recommends that the Commonwealth Government consider the development of a 'National Medical Devices Policy'.

### *The Policy's scope*

3. The Committee recommends that a document be prepared by the Department of Health to explain how the NMP aligns with other policies, strategies and agreements. Specific examples that overlap with the NMP include the National Preventive Health Strategy, the National Digital Health Strategy, the National Strategic Action Plan for Rare Diseases, the Primary Health Care 10 Year Plan, Closing the Gap and the National Health Reform Agreement.

### *Direction and intent of the Policy – Access*

4. The Committee recommends that equity, timeliness and affordability be continually monitored, and transparently reported on, by all partners to ensure all Australians, especially from priority populations, can access the medicines they need.
5. The Committee recommends that all policies, programs, systems and processes aligned with the NMP be reviewed by stakeholders to ensure they have the ability to rapidly respond to emerging and disruptive technologies including innovative and highly specialised therapies and services, especially in circumstances where individuals have high unmet clinical needs or in response to public health emergencies or natural disasters.

### *Direction and intent of the Policy – Person-centredness*

6. The Committee recommends diverse consumer representation and active consumer involvement in all aspects of the NMP, including in the co-design and development, implementation and evaluation of related policies, strategies, programs and initiatives to achieve the aim of the NMP.
7. The Committee recommends that the Commonwealth Government and responsible partners invest in the co-design and development with consumers of specific programs including developing culturally appropriate medicines information to promote and build the health literacy of consumers to help people participate in shared decision-making about their medicines and health.
8. The Committee recommends that the Commonwealth Government and responsible partners invest in training programs for health professionals to deliver culturally appropriate person-centred care and shared decision-making, particularly for priority populations.

***Direction and intent of the Policy – Using medicines appropriately***

- 9. The Committee recommends that the Commonwealth and State/Territory Governments continue to invest in programs and initiatives to achieve QUM and medicines safety for consumers, and training programs for health professionals to deliver these programs and initiatives, particularly for priority populations.**
- 10. The Committee recommends that the Minister initiates an update of the National Indicators for QUM to enable the monitoring of QUM in the community.**
- 11. The Committee recommends that the Commonwealth and State/Territory Governments continue to promote the interoperability of technologies, particularly IT systems, across health settings to enhance the safety and quality of services and QUM for consumers, carers, families and communities.**
- 12. The Committee recommends the Commonwealth Government considers the establishment of a medication advisory service for rural and remote Australians and that this service be explored with rural and remote service providers, consumers, carers and families.**

***Direction and intent of the Policy – Shared endeavour***

- 13. The Committee recommends that the Commonwealth and State/Territory Governments continue to pursue consistency across jurisdictions on issues relating to medicines and medicines-related services, including ensuring interoperability of systems, policies and procedures and clinical trial governance.**
- 14. The Committee recommends that all partners map areas where they believe they can contribute to the achievement of the aim of the NMP and intended outcomes.**

***Direction and intent of the Policy – Fit for the future***

- 15. The Committee recommends that innovation be recognised as adding value to the Australian society and that it be supported for its contribution to continuous improvement and the opportunity to respond to current and future health challenges.**
- 16. The Committee recommends that the Commonwealth Government ensures appropriate horizon scanning mechanisms are in place to identify and act proactively on the opportunity of future scientific and technological innovation.**

***Governance and implementation – Strengthening accountability and reporting***

- 17. The Committee recommends that the Commonwealth Government considers the appropriate mechanisms and processes to ensure the participation of all partners, including diverse consumer partners, and to enhance transparency and accountability in overseeing the implementation, evaluation and communication of the NMP**
- 18. The Committee recommends that the National Medicines Policy is reviewed and refreshed every 5 years to ensure it remains relevant and responsive to the future health environment.**

***Governance and implementation – Strengthening communication and engagement***

19. The Committee recommends that a shorter plain English version of the Policy be developed by the Department of Health to ensure it is both accessible and easily understood by all Australians.

***Governance and implementation – Creating a conducive context for implementation and evaluation***

20. The Committee recommends that the co-design and development, implementation and evaluation of the NMP's related policies, strategies, programs and initiatives should be linked with the Policy's aim, Central Pillars, intended outcomes and Principles.
21. The Committee recommends that each partner with accountability and responsibility for processes and systems that support the delivery of the NMP, review their current outcome measures, to ensure they are consistent with the Policy's aim, Central Pillars, intended outcomes and Principles.
22. The Committee recommends that any policies, programs and initiatives relating to medicines and medicines-related services should facilitate collaboration and co-operation between partners including consumer partners and be transparent.
23. The Committee recommends that all partners responsible for policies, strategies, programs and initiatives aligned with the NMP regularly evaluate each element to ensure they are contributing optimally to the aim of the Policy.

## Appendix A - Terms of Reference

This is a review aimed at identifying any gaps in the NMP's objectives, partnership approach and accountabilities. The Review of the NMP will:

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.
2. Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.
3. Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.
4. Consider the centrality of the consumer within the NMP and whether it captures the diversity of consumers, and their needs and expectations.
5. Identify options to improve the NMP's governance, communications, implementation (including enablers) and evaluation.
6. Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.