

NPS MEDICINEWISE SUBMISSION TO NATIONAL MEDICINES POLICY REVIEW

October 2021

Independent, not-for-profit and evidence based, NPS
MedicineWise enables better decisions about medicines,
medical tests and other health technologies.



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INTRODUCTION

Medicines are the most common intervention used in health care¹. In 2017–18 Australians spent an estimated \$22.3 billion on medicines (including prescribed and over-the-counter medicines)². Used safely and appropriately, medicines can significantly improve lives: treating illness, preventing disease, and relieving symptoms. However, harm from medicines can occur due to error, accident, or communication problems³ and result in emergency presentations, admissions to hospital, and death, at significant cost to the system¹.

The Australian National Medicines Policy (**NMP**) aims to deliver better health outcomes for all Australians with a particular focus on access to, and wise use of, medicines⁴. The NMP is consistent with and aligns to the World Health Organisation's position that national medicines policies are essential in achieving universal health coverage or health care for all – through ensuring access to, and use of, high quality and affordable medicines and health products⁵.

As the national steward for Quality Use of Medicines (**QUM**) in Australia, the NMP has been central to the purpose, mission, and vision of NPS MedicineWise for more than 20 years.

To date, the NMP has made a significant contribution to the safe and equitable access of medicines for all Australians through setting clear objectives and partnership expectations in a complex environment with many players. However, there is undoubtedly a need to review the Policy to reflect significant changes in the medicines (and wider) landscape over this time, and to strengthen associated implementation and monitoring frameworks to ensure activity is well coordinated, resources are used wisely, and impact is maximised.

Going forward, we see the NMP and associated strategies as a critical vehicle to address key environmental changes and challenges, including:

- ▷ Persistence of medication issues where there is risk of harm or waste, including:
 - Medicines safety issues across transitions of care.
 - Antimicrobial resistance.
 - Inappropriate use of high-risk medicines.
- ▷ Increasing prevalence of chronic disease, comorbidities, and associated polypharmacy.
- ▷ Highly specialised, high-cost medicines placing increasing demands on the system.
- ▷ Accelerated market access for medicines and need for real-world data to monitor and review post-market use.
- ▷ An increasing number of healthcare provider groups with prescribing rights in need of competencies/credentialling.
- ▷ Increasing influence of digital systems, digital therapeutics, and smart technologies on prescribing.
- ▷ Development of virtual models of care driven by the COVID-19 pandemic.
- ▷ The rise of misinformation and unethical promotion of medicines as well as an increasing abundance of health information that is highly accessible to the public but not necessarily credible.

We also see significant opportunities to increase the value and impact of the NMP for the benefit of all Australians through placing a greater emphasis on consumers, strengthening governance and

accountability around implementation, and strengthening quality use of medicines as a central tenant of the policy that runs across all policy objectives and activities.

To this end, NPS MedicineWise welcomes the NMP Review and thanks the Expert Advisory Committee for the opportunity to help shape the next iteration of the Policy. This submission makes several comments and recommendations in relation to the Review, highlighting our key priorities below, followed by specific comments and recommendations on the individual terms of reference.

In developing these recommendations, NPS MedicineWise has sought input from, and engaged in discussions with, a number of key partners and other stakeholders, as well as our own staff. We would like to thank all those that have contributed their insights and shaped this response with us.

NPS MedicineWise welcomes the proposal of a stakeholder forum in late 2021 and looks forward to the opportunity for direct engagement with the Expert Advisory Committee.

Subject to the extent of changes to the NMP, it is likely that a review of the National Strategy for Quality Use of Medicines (**NSQUM**) will be necessary to ensure alignment. As the key implementation arm of the NSQUM in Australia, NPS MedicineWise is well positioned to play a central role in assessing the continued effectiveness of this Strategy in the context of a refreshed NMP.

KEY PRIORITIES

As noted above, the NMP has provided important direction for the various organisations involved in ensuring safe and effective access to, and use of, medicines in Australia over the years and remains an essential policy.

There are three key priorities that NPS MedicineWise is strongly advocating for in the context of this Review, in order to achieve a refreshed policy that is agile, impactful and focused on delivering better outcomes for all Australians.

▷ **Increasing Consumer Centricity:**

Consumer engagement and partnerships are key to delivering better health outcomes⁶, and this is certainly true with respect to medicines. The current Policy identifies consumers as partners and recognises their fundamental role but does not articulate this role clearly and is written in a way that is not accessible for most consumers.

We would welcome a refreshed policy that firmly places consumers in the centre, and which:

- Clearly articulates the role of consumers as active and priority partners in the Policy.
- Is explicit in its purpose of improving health outcomes for all Australians and supporting consumers across all care settings
- Recognises diversity and inequity, and explicitly prioritises those at higher risk of harm and where the gaps between current care and optimal care are greatest.
- Supports Improvements in consumer health literacy through all avenues and across all levels of the health system.
- Requires consumer representation at all levels of policy governance.

▷ **Strengthening Governance and Accountability:**

As the NMP itself reflects, there are many players involved in delivering on its objectives, and partnership is a key purpose of the Policy. Whilst the Policy provides a high-level framework through its objectives and principles and all parties contribute to its delivery with good intent, in recent years there has been an absence of governance to support prioritisation and coordination of activity across stakeholders. Further, progress and impact has not been consistently and transparently monitored and reported.

We believe that strengthening governance around policy implementation and clarifying accountabilities around the NMP is an essential step to ensure effective delivery against NMP objectives. This would serve to increase transparency, strengthen partnerships, ensure alignment across the different NMP objectives, and establish consistency and linkages with the broader national health agenda, including national health priorities and other key policies and strategies.

The Policy would be strengthened by a truly national scope that encompasses all areas of accountability with regard to medicine and vaccine access and use (including Pharmaceutical Benefits Scheme (**PBS**) and non-PBS medicines use across all settings), ensuring that consumers have a consistent experience regardless of where they receive care.

NPS MedicineWise supports the establishment of a dedicated NMP governance structure that would provide for:

- Oversight and direction across the aims of the policy and medicine life cycle.
- A coordinated implementation approach and clear accountability for delivery.
- Strategic foresight to enable timely responses to new and emerging issues, such as recommendations from Royal Commissions.
- Monitoring of policy effectiveness through regular, transparent reporting on collective activities against a set of agreed NMP indicators.

To further strengthen governance and accountability, we recommend that the refreshed NMP recognises the need for, and role of, a lead agency for each objective – with these agencies identified in the Policy itself, or in a supporting implementation plan.

▷ **Strengthened Focus on QUM:**

QUM is both a standalone policy objective as well as a central, unifying lens through which successful delivery against the other objectives (and therefore the policy as a whole) can, and in our view, should be assessed. Given the overarching purpose of the Policy is to ensure access to, and use of, quality medicines to benefit outcomes, QUM needs to be strongly reflected across all aspects of the Policy and its implementation.

A refreshed NMP and its governance structure should increase the focus on QUM and incentivise QUM activities through support for:

- Appropriate resourcing to support activities that promote QUM across the full medicine life cycle, and clear leadership and coordination of these activities across the sector.
- Alignment with quality standards, accreditation, and models of care.
- Integration of QUM indicators into related health policies.
- Access to independent, objective, credible, evidence-based, up-to-date Australian health information across the full life cycle of medicine availability.

NPS MedicineWise has been championing the safe, appropriate, and evidence-based use of medicines in the interests of Australian consumers and health practitioners since our inception in 1998. Established explicitly for this purpose, we have built significant expertise and insight in quality use of medicines. As an independent, evidence-based steward, we have significantly improved health outcomes for Australians and contributed to a sustainable health system with savings to government and taxpayers of more than \$1.1 billion. With Australians having access to an ever-expanding array of medicines, the need for strong, independent leadership of QUM is only increasing. As such, we would welcome acknowledgement of NPS MedicineWise as the national steward of QUM within the refreshed policy and supporting implementation frameworks, reflecting responsibility for:

- Leading and coordinating collaborative QUM programs across all parties.
- Ensuring better measurement of QUM through adoption of agreed QUM indicators.
- Providing timely QUM insights that inform strategic planning.
- Supporting improvements in QUM health literacy.
- Demonstrating leadership in engagement of consumers in QUM activities.

TERM OF REFERENCE 1 – NMP OBJECTIVES

Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?

NPS MedicineWise supports the four objectives set out in the existing Policy and considers that these remain relevant (Figure 1). We recommend that these objectives are revised to acknowledge the following:

- ▷ **Access to medicines:** The increasing proportion of medicines that are prescribed and used outside of the PBS.
- ▷ **Quality, safety, and efficacy of medicines:** Medicine safety begins with regulation but is also critical throughout the entire medicine life cycle. Medication safety incidents can result from consumers not receiving or understanding information about their prescription and over-the-counter medicines.
- ▷ **QUM:** Activities to support optimum use of medicines recognise the importance of post-market surveillance of all medicines (not just PBS listed), the increasing need for education to support highly specialised, high-cost medicines, and the role of systems (e.g., clinical information systems) in influencing prescribing.
- ▷ **Viable and responsible pharmaceutical industry:** Industry is required to communicate clearly and directly with consumers and health professionals through:
 - Product information and consumer medicines information (**CMI**) that is up-to-date, accessible, and available for all classes of medicines.
 - Transparency about funding of health professionals and conflicts of interest.
 - Upholding the Medicines Australia Code of Conduct as a standard for ethical marketing and promotion of all medicines in Australia.

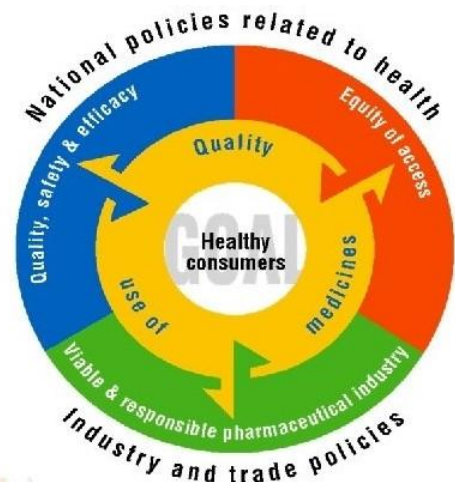


Figure 1: Current NMP Objectives

Are the proposed principles appropriate? With regard to the proposed principles, is anything missing or needing to change?

We welcome the addition of the proposed set of core principles to support coordinated and effective delivery of the NMP objectives. We recommend strengthened wording in both the principles and broader Policy to reflect the following:

- ▷ **Equity:** Acknowledgement of the current inequities in:
 - Health literacy levels within and across communities.
 - Access to medicines, including in public hospital provision across and within jurisdictions).
 - QUM and pharmacovigilance for our most vulnerable populations (e.g., Aboriginal and Torres Strait Islander peoples).
- ▷ **Consumer-centred approach:** Consumer benefits should be central to, and drive, supporting implementation activities. The Policy supports consumers across all care settings regardless of medicine funding and market entry models.

- ▷ **Partnership based:** The Policy articulates the key partners and is supported by a framework that defines roles and responsibilities to enable effective and sustainable partnerships and a coordinated approach. Consideration might be given to whether elevating partnerships – and ensuring a cohesive, integrated approach to medicines in Australia – as an explicit, fifth policy objective would strengthen this approach.
- ▷ **Accountability and transparency:** This is consistently applied across all stakeholders, from transparency around funding, funded activities, and conflicts of interest through to publication of patient safety data and provision of accessible, evidence-based CMI.
- ▷ **Stewardship:** Recognition that effective stewardship requires leadership and governance. Without these core elements, there is risk of inefficiencies, ineffectiveness, and lack of engagement from stakeholders.

We also recommend the addition of principles that support:

- ▷ **Systems-based approaches:** This is to ensure embedding QUM and essential medicines access across the sector through key strategies and policies, quality standards and other mechanisms to incentivise practice. This would be an enabler for implementation of the NMP and has the benefit of strengthening alignment between the NMP and the NSQUM.
- ▷ **Best use of best available evidence:** Recognition that decisions around medicines should be based on the best use of the best available evidence, which takes account of evidence of safety, efficacy and effectiveness in real-world conditions.

TERM OF REFERENCE 2 – DEFINITIONS

Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?

NPS MedicineWise considers that there is value for consumers, prescribers and other partners in establishing a clear national definition of medicines and ensuring that this definition is applied consistently. There is also a need to review the definition of medicines to address new and emerging therapies, including vaccines, especially in light of the COVID-19 pandemic.

Medicines use is evolving and will continue to evolve alongside increased use of associated technologies. Consumer and health professional decisions about medicines are often influenced by medical testing and insights from an increasing array of health technologies. Consumers are likely to be better served by a policy framework that encompasses all health technologies, including medical devices, that influence prescribing.

It is our view that expansion of the definition and scope of the NMP should not, come at the expense of a central focus on medicines, but should ensure oversight and influence on health technologies that influence prescribing.

NPS MedicineWise supports:

- ▷ Expanding the NMP definition of medicines, to ensure that the Policy:
 - Accommodates new and emerging technologies including biologics, biosimilars and vaccine technologies.
 - Benefits and protects consumers now and into the future.
- ▷ Consideration of a parallel policy around medical devices/health technologies, which is aligned, in objectives and principles, to the NMP and connected through governance.

It is our view that the definition of medicines should be addressed in the high-level policy framework, as it is central to the policy scope.

Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?

Our view is that the policy title needs to reflect the scope of the Policy, which in turn is connected to the definition of medicines. If the scope is significantly broadened, we suggest that the title should be expanded – otherwise retained as the *National Medicines Policy*.

TERM OF REFERENCE 3 – ADAPTABILITY

How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?

The NMP has maintained its general relevance due to high-level positioning, the strength and enduring nature of its objectives, and by ensuring lead organisations are in place to deliver those objectives, even as the landscape has changed. The Policy's relevance would likely have been enhanced in recent times through a formal governance structure and connections to the broader national health agenda.

How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?

To better address future challenges, the NMP would be well supported by:

- ▷ A **policy scope** that:
 - Is truly national, encompassing all areas of accountability for prescribing and medicines use.
 - Recognises all medicines prescribed and used.
 - Is connected to relevant national health strategies and leverages related policies and plans to deliver on its objectives, including the National Preventive Health Strategy and Primary Health Care 10 Year Plan.
- ▷ A **governance structure** that enables oversight and timely response to priority issues across the arms of the Policy and medicines life cycle: from research and registration to listing, post-market use and surveillance (see response to [Term of Reference 5](#)).
- ▷ An underlying **strategic implementation framework** and appropriate resourcing to:
 - Enable and promote collaborative data sharing (with appropriate privacy safeguards) to identify and understand emerging issues and to continually drive better quality and safety in health care. In particular, signal detection and post-market surveillance of medicines should be enhanced to include PBS and non-PBS medicines, information and incentives provided, to improve reporting of adverse drug reactions and adverse drug events; and post-market surveillance prioritised for high-risk populations (e.g., Aboriginal and Torres Strait Islander people).
 - Drive improvements in health literacy to enable and empower consumers and health professionals to make informed decisions in the presence of changing evidence and new and emerging technologies.
 - Influence health professional behaviours through support for targeted behaviour change programs.

- Allow access to independent, objective, credible, evidence-based, up-to-date Australian health information across the full life cycle of medicine availability. This includes continued support for local, independent, evidence-based sources of information e.g., Australian Medicines Handbook, Therapeutic Guidelines and NPS MedicineWise (including Australian Prescriber). There is also a need to ensure that relevant content is accessible in new formats (e.g., digital and online) in line with health professional and consumer expectations.

TERM OF REFERENCE 4 – CONSUMERS

How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?

The existing NMP has a core focus on healthy consumers (see [Figure 1](#)). NPS MedicineWise strongly supports the principle of consumer centricity and the intent to strengthen the focus on consumers and sees this as essential to an effective policy. We consider that the NMP's focus on consumers can be strengthened in four main ways:

▷ **Consumer centricity:** A refreshed policy should:

- Address consumer expectations of what the policy can and should deliver and articulate the benefits that it provides for consumers in language that all consumers can understand.
- Reflect the role of consumers as active contributors and partners.
- Include consumer representation at all levels of policy governance.
- Include a strategic action framework that requires programs to actively and meaningfully engage consumers.
- Address consumer and health professional health literacy in a coordinated way by:
 - Embedding health literacy into high-level systems and organisational policies and practices⁷.
 - Ensuring that medicines information is clear, focused and useable, and that interpersonal communication is effective⁷.
 - Integrating health literacy into education for consumers and healthcare providers⁷.
 - Supporting improvements in digital literacy as an enabler of health literacy.
 - Supporting national programs addressing health literacy, relating to QUM and health technologies, e.g., Choosing Wisely Australia.
 - Leveraging the development and implementation of a national health literacy strategy.

▷ **Diversity and equity:**

The Discussion paper notes consumer diversity and the need to reflect this, which we also strongly support. As an organisation with over 20 years of experience in supporting QUM, we know that there are many population segments in Australia at risk of poor health literacy and sub-optimal medicines use, and that there is inequity within consumer groups around health literacy and understanding of medicines and other technologies. This is important because QUM is heavily dependent on consumer health literacy. Without a focus on diversity, the NMP risks contributing to further inequalities in health outcomes for vulnerable populations. It is important that the refreshed policy is not just consumer centric, but actively acknowledges and focuses on those at higher risk of harm and where the gaps between current care and optimal care are greatest.

Research undertaken by Consumers Health Forum of Australia (**CHF**) and NPS MedicineWise has identified four key populations requiring focus⁸:

- Older people (65 years and over).

- Aboriginal and Torres Strait Islander people.
- Culturally and linguistically diverse consumers.
- Consumers with low literacy and/or low health literacy.

Lessons learned from the COVID-19 pandemic can inform how an NMP might more effectively engage with all consumers. All key consumer agencies (including COTA Australia, Older Persons Advocacy Network, Federation of Ethnic Communities' Councils of Australia, National Aboriginal Community Controlled Health Organisation, Carers Australia and CHF) should be engaged to provide leadership and advice on policy, research and practice, to improve access and equity with respect to medicines and medicines use and achieve better health outcomes for these Australians.

▷ **Accountability and transparency:**

There is a need to build consumer and health professional trust in the NMP and the delivery of its objectives through:

- Increased transparency of risks and benefits by ensuring availability of accessible CMIs (including for complementary medicines).
- Improved transparency regarding out-of-pocket costs for medicines.
- Appropriate consumer protections for rapid-market-entry medicines.
- Transparency and consistency regarding access to, and availability of, medicines across public hospitals.
- Increased accountability for medicines sponsors to provide safety data.
- Consistent reporting of conflicts of interest of NMP partners.

▷ **Monitoring:**

Developing an agreed set of indicators on medicines-related health literacy and QUM that provides a consistent way of measuring and monitoring across the sector would add significant value. CHF and NPS MedicineWise have recently undertaken research in this area and have included indicators in Appendix 1, which could be adopted for this purpose.

TERM OF REFERENCE 5 – GOVERNANCE

What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?

▷ **Strengthening the NMP governance:**

As noted earlier, NPS MedicineWise sees strengthening governance arrangements for the NMP as a key priority, and perhaps the most significant opportunity in this review. NPS MedicineWise would like to see an overarching governance structure for the NMP that facilitates:

- A clear, coordinated strategic action framework and implementation approach.
- Clear responsibilities and accountability for delivery, including lead agencies for each objective.
- Regular and open communication between parties.
- Prioritisation of activities and resources.
- Regular monitoring of progress against the policy objectives.

The NMP review is an ideal opportunity to amplify policy governance and, in turn, provide clarity and coordination to increase efficiency and effectiveness in policy implementation and use of resources, reduce duplication, and increase alignment of activities. This in turn would provide a platform for stronger partner engagement.

In addition to increasing focus and improving communication and transparency, an effective governance structure would provide useful advice to both federal and state governments and ensure alignment across NMP objectives, health technologies policies, and the broader health agenda. It would provide a central focus for medicines issues, a mechanism to engage consumers at the strategic level and an opportunity for better monitoring and assessment of policy impact.

We envisage the governance structure would enable effective cross-agency responses to complex and priority medicines-related issues. These may range from medication management issues at transitions of care to responses to specific inquiries, such as the Royal Commission recommendations in response to medication-related harms in the aged-care and disability sectors.

In addressing governance, consideration should be given to ensuring:

- Consumer representation at all levels.
- Oversight, engagement and accountability with commonwealth, state, and territory governments.
- Representation from lead agencies required for delivery of objectives, including industry.
- Strategic alignment of separate policies related to medicines and health technologies, enabling review and monitoring of co-dependent technologies, and the use of new and emerging technologies such as digital therapeutics (for example National Preventive Health Strategy, Primary Health Care 10 Year Plan, Digital Health Strategy).

When determining the NMP governance structure, we recommend considering a similar approach to the structure that was recently established to support Australia's National Antimicrobial Resistance Strategy. Like the NMP, this strategy requires significant co-ordination across parties, industries and jurisdictions and it may provide a template for effective governance of the NMP that is both coordinated and responsive. Based on this strategy, the Expert Advisory Committee may wish to consider the following governance groups in support of NMP objectives:

- NMP Governance Group – responsible for overall governance of the Policy, with representation of consumers, senior executives from government and key delivery agencies. Consider reporting to Health Chief Executives Forum to ensure truly national oversight.
- Strategic and Technical Advisory Group (**STAG**) that advises the Governance Group. STAG would consist of a small, core group of members appointed on an individual basis from across all NMP objectives.
- Consultative Group – a broader group that would include representation from lead agencies responsible for delivery/stewardship across all NMP objectives, as well as other NMP stakeholders. This group would support STAG in the development of advice.
- Time-limited Technical Working Groups – established on specific issues, as needed. Membership of the Technical Working Groups may include representatives from the Consultative Group, as well as representatives from outside of the Consultative Group where required.

▷ **Strengthening NMP implementation:**

Beyond establishing formal governance structures, NPS MedicineWise would welcome the strengthening of policy implementation and use of incentives to deliver on NMP objectives by:

- Ensuring consistency of QUM messaging in clinical guidelines and clinical care standards for medicines use across the health system.
- Ensuring consistency and accountability in medicines governance across jurisdictions, i.e., supporting equity of access to medicines in public hospitals.
- Establishing standardised decision-making across jurisdictions through national-level health technology assessment (including public hospitals).
- Embedding QUM indicators within all key health strategies (and related policies) to incentivise safe use of medicines for consumers at all points of care within the health system e.g., hospitals, primary care, aged care, community.
- Embedding system supports to ensure supply and access to essential medicines.

▷ **Monitoring and evaluation of the NMP:**

To date, beyond program-level evaluation of QUM activities⁹ evaluation of the policy impact has been limited. We recommend implementing an NMP indicator framework that can be used to assess the impact of the NMP and support decision on priorities and activities.

In consultation with key partners, NPS MedicineWise has developed a QUM Indicator framework to measure the collective impact of QUM activities in Australia [Appendix 2. Informed by the NSQUM, the framework includes key measures relevant to the NMP objectives and proposed principles, covering:

- Minimising harms from medicine use for consumers.
- Optimising the benefits of medicine use for consumers.
- Improving consumer and health professional health literacy related to medicines.
- Evidence of sustainable partnerships with shared goals of supporting QUM.

NPS MedicineWise recommends adopting QUM collective impact indicators, as part of a standardised set of indicators, to monitor progress of the NMP. Implementing the indicator framework through a strategic action framework would support delivery on NMP objectives and provide accountability and transparency to consumers.

When considering NMP effectiveness, the increasing complexity of the environment should be considered. This includes changes in population demographics and longevity; prevalence of chronic disease and comorbidity; availability and types of medicines; how health services are funded and delivered; who can prescribe; and how consumers engage with the health system, health information and manage their own health.

To support alignment across the health system, we recommend:

- Integration of relevant indicators into other indicator sets e.g., Practice Incentives Program Quality Improvement measures.
- Leveraging alignment with hospital, primary and community care accreditation standards to drive implementation and evaluation.
- Data sharing and linkage across the sector and the leverage of all available data sets to report impact against indicators (including MedicineInsight).

How can communication about the NMP be enhanced or improved? What would be effective mechanisms to support communication about the policy?

▷ **Strengthening communication about the NMP:**

In many ways, the NMP is very visible to the Australian public. Consumers expect that the medicines they use are of high quality and affordable. Community interest in medical data and information has also increased as a result of the pandemic.

To strengthen understanding of the NMP and its role, we recommend:

- Reviewing the language of the current Policy to ensure it is consumer-friendly and the benefits to consumers are clear.
- An associated communication strategy that states the benefits of the Policy in a way that is meaningful to consumers, using personal case studies that people can relate to.
- Transparent reporting of progress towards objectives, for example through a reporting dashboard that is publicly available.
- Providing progress updates against key QUM indicators in communications to consumers, health professionals and key stakeholders.
- Timely communication to the sector on high-risk areas and current priorities.
- Increased use of data to raise awareness of new and emerging issues in the sector.

NPS MedicineWise can play an important role in leading communication on QUM issues, priorities and impacts through publication of QUM formative research reports, distribution of MedicineInsight data insights and reports [Appendix 3] and reporting progress of QUM objectives.

TERM OF REFERENCE 6 – PARTNERSHIPS

How should the NMP's 'partnership-based' approach be defined? How could the NMP be refreshed to support greater accountability among NMP partners? How could the partnership approach be improved? How are conflicts of interest among NMP partners currently managed and should more be done to address this? What approaches could be taken?

In its opening paragraphs, the NMP identifies partnerships as critical in enacting the Policy, and this remains essential. The Policy could be strengthened by actively supporting the key elements necessary for effective partnering. Specifically:

- Direction (i.e., an overarching strategic framework).
- Governance (i.e., to ensure delivery of the strategic plan).
- Leadership (i.e., backbone organisation(s) responsible for facilitating multifaceted collaborations that drive implementation of the strategy).

Central to successful collaboration is a common goal that is identified and measurable. A number of opportunities currently exist to unite NMP partners around a shared goal. These include QUM and medication safety as a national health priority; significant medication safety issues identified from Royal Commissions into the aged-care and disability sectors, and the COVID-19 pandemic response.

NPS MedicineWise is advocating for the adoption of a collaborative partnering model based on a collective impact approach¹⁰. NPS MedicineWise has adapted this model to support network-based collaborations to deliver programs and services on QUM under the existing NMP [Appendix 4]. Central to success has been the support of a lead or backbone organisation (in this case NPS MedicineWise), which:

- Provides overall strategic direction for an agreed QUM activity.
- Facilitates dialogue between partners.
- Manages data collection and analysis.
- Handles communications.
- Mobilises funding (where relevant).

NPS MedicineWise partnering models could be considered as exemplars to inform a broader NMP partnering model [Appendix 5].

To further strengthen partnerships, define expectations, and increase accountability, NPS MedicineWise recommends that:

- The policy outlines the partners, partnering objectives and expectations.
- Roles and responsibilities towards shared goals for the benefit of consumers are clearly outlined.
- Partnership priorities are identified in the policy and/or its underpinning implementation frameworks, addressing key issues such as transitions of care, high-risk/cost medicines, QUM evidence and information.
- The policy recognises the need for lead agencies on each objective and formalises their role within it.
- Adequate and transparent funding is provided to support implementation activities.
- Governance structures ensure:

- Organisational commitments to NMP objectives are formalised and published, and structures bringing key stakeholders together to drive collaboration (through leadership and governance) are embedded.
- Strengthened requirements for transparency regarding conflicts of interest.
- Strengthened transparency regarding funded activities to ensure opportunities for alignment and collaboration are maximised and duplication is minimised.
- Partners coordinate their actions and share lessons learned.
- Data-driven decision-making that is central to evaluating the effectiveness of partnerships.

What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?

The Policy would benefit from inclusion of researchers as partners across the NMP to drive advances in evidence-based practice. The Policy should also include mechanisms to enhance partnerships between state and federal health departments in order to capture the full breadth of medicines access and use and assist in addressing significant QUM issues relating to transitions of care and other issues that span care settings.

ABOUT NPS MEDICINEWISE

NPS MedicineWise is the national steward for QUM in Australia and a key implementation arm of the NSQUM. Independent, evidence based and nationally scaled, our work is underpinned by QUM principles. With funding from the Australian Government Department of Health, NPS MedicineWise has supported and promoted QUM and medical tests for over 20 years. We are a trusted source of independent, evidence-based information and education programs, with an established network of partners. We have extensive reach with prescribers, dispensers and consumers, and a proven track record supporting improved health outcomes for consumers, as well as a sustainable PBS and Medicare Benefits Schedule (**MBS**). Since we were established in 1998, NPS MedicineWise has delivered over \$1.1 billion in savings to the PBS and MBS¹¹. Annual evaluations show positive changes in knowledge, attitudes, and prescribing and test ordering behaviours, as well as improvements in health outcomes¹¹.

NPS MedicineWise has continued to respond to new and emerging challenges through:

- ▷ QUM programs that support high-volume medicines used in primary and aged care, as well as highly specialised and high-cost medicines, including biologics and biosimilars, prescribed by specialist physicians.
- ▷ Programs that support the quality use of diagnostic tests.
- ▷ Programs that address the needs of health professional and consumer audiences, using interventions designed for impact based on identified barriers and enablers.
- ▷ Multi-faceted digital delivery of QUM education and information, and the use of digital applications to reach consumers.
- ▷ QUM program delivery where need is greatest, with delivery of national educational programs targeting primary care, aged care, and specialist physicians.
- ▷ Increased support for post-market surveillance of medicines through provision of MedicineInsight data.
- ▷ Timely responses to priority issues, e.g., responding to the COVID-19 pandemic with evidence-based information for health professionals and consumers including support for COVID-19 vaccine adverse events reporting.

NPS MedicineWise is committed to supporting a refreshed NMP through:

- ▷ Stewardship – leading and facilitating collaborative QUM programs that address priority issues across settings in line with an agreed strategic framework.
- ▷ Providing strategic advice within a refreshed governance structure alongside other lead agencies responsible for delivery/stewardship across all NMP objectives.
- ▷ Driving the introduction and uptake of QUM indicators through measurement and reporting.
- ▷ Demonstrable leadership of consumer involvement in planning, delivering, and evaluating activities.
- ▷ Contributing to strategic planning through provision of formative research and stakeholder insights.
- ▷ Maximising MedicineInsight data insights to support the NMP across all stages of the medicine life cycle.
- ▷ Development and dissemination of independent, evidence-based, Australian content on QUM for health professionals and consumers.

REFERENCES

1. The Pharmaceutical Society of Australia (2019) *Medicine Safety: Take Care*, Canberra
2. Australian Institute of Health and Welfare (AIHW) (2019) *Health expenditure Australia 2017–18*, Cat. no. HWE 077, Canberra
3. Australian Commission on Safety and Quality in Health Care (2019) *Medication without harm – WHO Global Patient Safety Challenge*, Sydney
4. Australian Government Department of Health (2000) *National Medicines Policy*, Canberra
5. World Health Organisation: *Promoting National medicines policies* <https://www.who.int/activities/promoting-national-medicines-policies>, accessed October 2021
6. Australian Commission on Safety and Quality in Health Care (2011) *National Safety and Quality Health Service Standards*, Sydney
7. Australian Commission on Safety and Quality in Health Care (2014) *Health literacy: Taking action to improve safety and quality*, Sydney
8. Consumers Health Forum of Australia (2020) *Consumer Health Literacy Segmentation and Activation Research Project. Final Report*, Canberra
9. NPS MedicineWise: *Evaluation Reports* <https://www.nps.org.au/about-us/reports-evaluation>, accessed October 2021
10. Hanleybrown, F., Kania, J., Kramer, M. (2012) *Channeling Change: Making Collective Impact Work*, Stanford Social Innovation Review, Stanford
11. Lynn Maria Weekes, L.M., Blogg, S., Jackson, S., Hosking, K. (2018) *NPS MedicineWise: 20 years of change*, Journal of Pharmaceutical Policy and Practice (vol. 11, issue. 19), Sydney

APPENDIX 1: QUM HEALTH LITERACY INDICATORS

Key health literacy QUM indicators identified through the Consumer Segmentation Research undertaken by Consumers Health Forum and NPS MedicineWise⁸. These indicators may be used to track impact on health literacy and awareness of QUM annually as part of a larger indicator set that assesses impact of a refreshed NMP.

Dimension	Indicator
Individual health literacy relating to QUM	Proportion of consumers who feel confident asking doctor, pharmacist, or nurse questions when more information is needed to understand what is being explained.
	Proportion of consumers that search for information about health and medicines.
	Proportion of consumers that find the information provided by a doctor, pharmacist, or nurse hard to follow or confusing.
	Proportion of consumers that are happy to take any medicine their doctor prescribes to them.
	Proportion of consumers who discuss complimentary and over-the-counter medicines they are taking with their doctor.
Understanding of QUM	Proportion of consumers that understand that some medicines can be addictive.
	Proportion of consumers that, when they start taking a new medicine, ensure they understand how it could interact with other medicines or things they eat and drink.
	Proportion of consumers that know how their medicine(s) needs to be stored.
	Proportion of consumers that have taken out-of-date medicines.
	Proportion of consumers who sometimes take medicines that were prescribed for someone else.
Attitude towards health professionals' role in QUM	Proportion of consumers that ask their doctor or a pharmacist questions about their medicines.
	Proportion of consumers that talk to their doctor or pharmacist before they start taking a new medicine.
	Proportion of consumers who have one consistent doctor or pharmacist to talk to about their medicines.

<p>Reading information on medicines</p>	<p>Frequency with which consumers read the following information on a medicine:</p> <ul style="list-style-type: none"> - Pharmacist instructions or directions for use. - The active ingredients in the medicine. - The description of what the medication is used for. - Warning or allergy information. - Storage information. - Information on possible side effects. - Consumer medicine information leaflet. - The dosage of the medicine.
<p>Information sources on medicines</p>	<p>Rating of information sources about medicines:</p> <ul style="list-style-type: none"> - Doctor - Pharmacist - Medicine information leaflet - Internet search - Allied health professional - Trusted online resources - Nurse - Friends and/or family - Telephone information service - Online forum and/or support group - Social media

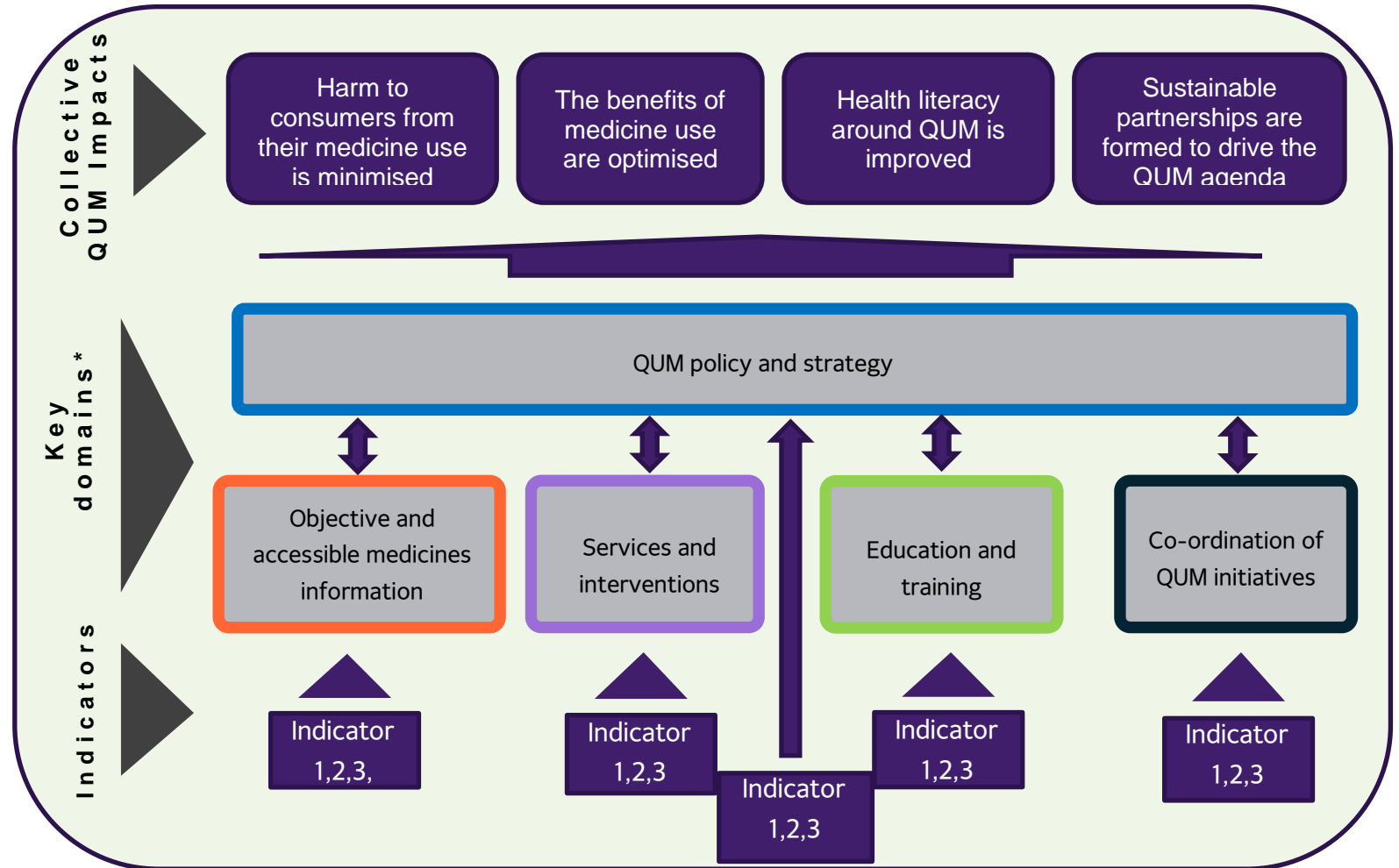
APPENDIX 2: CONCEPTUAL MODEL OF PROPOSED QUM INDICATOR FRAMEWORK

NPS MedicineWise recommends adopting QUM Collective impact indicators, as part of a standardised set of indicators, to monitor progress of the NMP.

NPS MedicineWise has developed a draft QUM indicator framework to demonstrate the impact of NPS MedicineWise QUM programs, as well as collective impact activities against QUM objectives.

The conceptual model depicts the major components of the proposed QUM Indicator Framework and the relationships between them.

Draft indicators have been developed for the top line Collective QUM Impacts and the key domains (which are aligned to the 'Building Blocks' of the National QUM Strategy).



APPENDIX 3: MEDICINEINSIGHT FOR POST-MARKET SURVEILLANCE

MedicineInsight is a quality improvement program developed and managed by NPS MedicineWise with funding from the Australian Government Department of Health. It supports quality improvement in Australian primary care and the post-market surveillance of medicines. The following reports are examples of how MedicineInsight is being used to provide data insights that support all stages of the medicine life cycle. Such information can inform the NMP in priority setting, monitoring and the assessment of policy impact.

Medicine life cycle	Opportunity	Example
Pre-market listing	Contextual information on: <ul style="list-style-type: none"> No. of patients with condition of interest in primary care. Snapshot of current management (prior to listing of a new medicine). 	<ul style="list-style-type: none"> General Practice Insights Report (condition prevalence) 2018/19, 2017/18 Inflammatory Bowel Disease prevalence Hyperkalaemia in patients taking renin-angiotensin aldosterone system inhibitors (RAASis)
Post-listing (0-12 months)	<ul style="list-style-type: none"> Provide early data on uptake of new medicines in primary care. 	<ul style="list-style-type: none"> Factors influencing oral anticoagulant use in patients newly diagnosed with atrial fibrillation (uptake of DOACs)
Risk management plans (0-24 months post-registration)	<ul style="list-style-type: none"> Provide early data on uptake of new medicines in primary care. Concordance with indications for use, contraindications, and drug interactions. Assess whether regulatory requirements (e.g., pathology testing) have been implemented. 	<ul style="list-style-type: none"> Trends in potential drug interactions with direct-acting oral anticoagulants SGLT2 inhibitors and risk of UTIs/genital infections
Safety signal detection (throughout life cycle)	<ul style="list-style-type: none"> Non-targeted safety signal detection unlikely to be possible, as it requires monitoring of many different conditions for many different medicines. 	<ul style="list-style-type: none"> MedicineInsight is not yet used to support signal detection, which relies on near real-time data on adverse events and requires extensive data mining

<p>Safety signal validation (throughout life cycle)</p>	<ul style="list-style-type: none"> • Support regulators by providing Australian data on the expected baseline prevalence/incidence of a condition which is a suspected adverse event to compare with the actual rates being reported. • Test hypotheses about signals that have been detected through spontaneous reports (would be enhanced via linkage with hospital/death data). 	<ul style="list-style-type: none"> • Mental illness in young people report with regards to antidepressants and suicidal/self-harm behaviour: Report to DUSC. (Not yet public) • <u>SGLT2 inhibitors and risk of UTIs/ genital infections.</u> • <u>Safety of the herpes zoster vaccine</u>
<p>Investigate impact of regulatory or other environmental changes</p>	<ul style="list-style-type: none"> • Investigate impact of regulatory or other environmental change. 	<ul style="list-style-type: none"> • General Practice Insights Report (COVID analyses – released Nov) • <u>Codeine up-scheduling</u> • <u>General Practice Insights Report 2017–18</u> • <u>Hydroxychloroquine regulatory change</u>
<p>Other post-market surveillance to support QUM</p>	<ul style="list-style-type: none"> • Utilisation studies. • Non-PBS (private) prescribing. • Snapshot of current management. • Concordance with guidelines. 	<ul style="list-style-type: none"> • <u>AURA report (antimicrobial use and resistance in Australia)</u> • <u>Use of direct-acting antiviral medicines for the treatment of chronic hepatitis C</u> • <u>Real-world patterns of pregabalin prescribing (indications for use and co-prescribing)</u> • <u>Real-world patterns of opioid prescribing (including private prescriptions)</u> • <u>Trends in the prescription of drugs used for insomnia</u> • <u>QUM in patients with chronic kidney disease</u> • <u>Osteoporosis management</u>

APPENDIX 4: QUM COLLECTIVE IMPACT FRAMEWORK

This framework has been developed to support the engagement and commitment of multiple organisations to a set of shared goals and collaborative action. Informed by a collective impact, collaborative partnering model¹⁰, NPS MedicineWise is employing this framework in its role as QUM steward to drive collaborative activities addressing priority QUM issues. We would advocate the adoption by lead agencies of this model, or elements thereof, in supporting collaborative activities that support NMP objectives more broadly.

Key elements	Phase 1: Initiation	Phase 2: Creating alignment	Phase 3: Sustaining action and impact
Governance and infrastructure	<ul style="list-style-type: none"> Identify 'champions' to lead engagement. Establish key cross-sector stakeholder group and associated 'champions' for ongoing collaboration. Establish governance process for engagement with key stakeholders 	<ul style="list-style-type: none"> Establish supporting infrastructure and processes (includes strategic direction, transparent communications, facilitated dialogue between key stakeholders and the broader sector, processes for data collection and analysis, sector outreach, and mobilisation of resources. 	<ul style="list-style-type: none"> Ongoing facilitation and refinement as needed. Refinement of governance processes and approach based on progress reports.
Strategic planning	<ul style="list-style-type: none"> Understand existing QUM landscape of key players and relevant work already underway. Engage sector around common goals and imperative to change. 	<ul style="list-style-type: none"> Create common agenda (goals and strategy). Strategic action framework that includes: <ul style="list-style-type: none"> a clearly and strongly articulated problem and clear goal for change a suite of strategies for large-scale change implementation principles that guide group behaviour evaluation approach. 	<ul style="list-style-type: none"> Support implementation in alignment with goals and strategy. Implement differentiated approaches coordinated through a joint action plan (strategic action framework).
Sector involvement	<ul style="list-style-type: none"> Facilitate broader sector involvement around an agreed goal. 	<ul style="list-style-type: none"> Continuing engagement with sector to seek buy-in and good will. Coordination of sector activities through the strategic action framework. 	<ul style="list-style-type: none"> Continue sector-wide engagement and advocacy. Share progress, impacts, outcomes and learnings.

<p>Evaluation and improvement</p>	<ul style="list-style-type: none"> • Analyse baseline data to identify key issues and gaps. • Identification of draft indicators for key QUM issues • Establish baseline data that forms a basis for change. 	<ul style="list-style-type: none"> • Establish a small but comprehensive set of shared metrics (indicators, measurement and approach). 	<ul style="list-style-type: none"> • Collect, track and report on progress. • Provide evaluation training and support to stakeholders as required. • Support process to learn and improve.
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APPENDIX 5: PARTNERING MODELS

NPS MedicineWise adopts a number of partnering models for delivery of QUM programs and services. These models may inform future collaborate models for partnership. to support the NMP.

1. QUM Partnership agreements: These agreements set out shared responsibilities between NPS MedicineWise and individual organisations with respect to driving the QUM agenda. Both organisations commit to continuous engagement, information sharing and collaboration on defined QUM activities. Governance is provided through regular meetings that monitor progress against an agreed action plan. Stakeholders with whom agreements have been established to date include:

- Australian Commission on Safety and Quality in Health Care
- Consumers Health Forum of Australia (this Working Together Agreement can be viewed [here](#).)
- National Aboriginal Community Controlled Health Organisation
- Pharmaceutical Society of Australia
- Primary Health Networks
- Society of Hospital Pharmacists of Australia
- Therapeutic Guidelines

2. Collaborative alliances: Bring together organisations in a collaborative activity to deliver QUM activities around a specific shared goal.

Example: Funded by the Australian Government Department of Health through the Value in Prescribing – Biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) Program Grant, the [Targeted Therapies Alliance](#) includes nine organisations representing specialists, pharmacists, consumers, and research experts. Led by NPS MedicineWise, the aim of the Alliance is to provide stewardship and direction about the safe and wise use of bDMARDs and other specialised medicines to ensure the best possible health and economic outcomes.

3. National collaborations: Example: Choosing Wisely Australia: This national initiative, facilitated by NPS MedicineWise, seeks to engage consumers and health professionals in conversations about unnecessary health care. The initiative has > 90 members (and growing) including 90% of medical colleges, consumer organisations and hospitals and health services, who have committed to upholding the core principles of Choosing Wisely and supports grassroots, locally contextualised implementation activities.

4. Program-specific partnerships – The NPS MedicineWise program: Heart Failure - taking an active role has been developed in collaboration with the National Heart Foundation of Australia, ensuring access to clinical expertise as well as relevant health professional and consumer resources.