



Australian Government

Department of Health

# Draft National Medicines Policy Consultation Draft

Consultation Draft

**The purpose of this consultation document is to seek stakeholder and community feedback on the draft of Australia's revised National Medicines Policy.**

**The diverse perspectives, experience, and knowledge of all stakeholders, including members of the community, are valued and will contribute to the final Policy.**

## Introduction

The National Medicines Policy (NMP) sets the direction and approach for the availability and use of medicines in Australia. It is applicable to medicines research, development, regulation, manufacture, evaluation, supply, and access. It promotes the quality use of medicines by focusing on the needs of people and the responsibilities of health professionals to support all communities in Australia to achieve optimal health outcomes.

The Policy's Pillars and Principles direct the identification, design, development, implementation and evaluation of policies, strategies, programs, and initiatives that advance equitable, safe, timely and affordable access to medicines. This improves the health of the whole community and contributes to a strong economy and society. It identifies key policy enablers and connects them to related health and industry policies.

The Policy's partners include individuals, families and carers, the Commonwealth, state and territory governments, non-government organisations, health practitioners, health educators and professional and consumer organisations, the private and public sectors, industry, researchers and academics, media, and the general community.

The Policy also outlines a governance and evaluation approach that acknowledges that success is dependent on all NMP partners playing their part in fostering a medicine policy environment geared to respond appropriately to current and new challenges.

This policy influences, and is also influenced by, related strategies, legislation, policies, programs, and initiatives of the wider health system.

This is the second edition of the policy which was first published in 2000.

## Australia's National Medicines Policy

### Aim

The aim of Australia's NMP is to create the environment in which appropriate structures, processes and accountabilities enable medicines and medicines-related services to be accessible in an equitable, safe, timely, and affordable way and to be used optimally according to the principles of person-centred care and the quality use of medicines, so that improved health, social and economic outcomes are secured for individuals and the broader community.

### Scope of the National Medicines Policy

The term 'medicine' covers a broad range of products that are used to prevent, treat, monitor, or cure a disease.<sup>1</sup> These products include prescription medicines, over-the-counter medicines and complementary/traditional medicines and encompass biologic and non-biologic medicines, including gene therapies, cell and tissue engineered products and vaccines.

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<sup>1</sup> Commonwealth of Australia Department of Health. Health topics: Medicines. Available at: <https://www.health.gov.au/health-topics/medicines>

This broad scope ensures the policy is adaptive and responsive to new and emerging treatment options. It also recognises that the definitions of medicines may vary across Commonwealth, state and territory legislation and regulation. Notwithstanding, the Policy's principles and pillars are applicable to all the above products and their clinical use, as well as being applicable to relevant future advanced therapies.

## Central Pillars

The NMP consists of four central Pillars. The function of these Pillars is to guide and focus collective actions to deliver the NMP's aim. These Pillars do not stand in isolation and their fulfilment is dependent on partners working collaboratively. The NMP documents these interdependencies and sets out the principles, enablers, responsibilities, and approaches to create the required medicines policy environment.

The Pillars of the NMP are:

- Timely, equitable and reliable access to medicines that are needed, at a cost that individuals and the community can afford;
- Medicines meet appropriate standards of quality, safety and efficacy.
- Quality use of medicines and medicines safety; and
- Responsive and sustainable medicines industry and research sector with the capability, capacity and expertise to meet current and future health challenges.

The NMP's Pillars are mutually supportive. One cannot be secured at the expense of another. For example, providing *access to medicines in a timely and equitable manner* is balanced with ensuring the *quality, safety, and efficacy of medicines*. It also acknowledges that access begins with research and a responsive and proactive medicines industry and culminates with the *quality use of medicines*.

The NMP also identifies the intended outcomes associated with realising the central Pillars. These concentrate policy efforts on outcomes rather than prescribing specific activities. This approach promotes flexibility in the development of policies, strategies, programs, and initiatives.

## Principles

The Principles of the NMP, outlined in Table 1, should be evident in the planning, design, evaluation and implementation of all policies, strategies, programs, and initiatives related to the Policy.

**Table 1 – Principles**

| <b>Principle</b>                       | <b>Principle in action</b>  |
|--|---|
| <b>Person-centred</b>                  | All partners deliver policies, strategies, programs, and initiatives that are respectful and responsive to the needs of Australia's diverse population. This includes a focus on building health literacy, so that individuals, carers, their families, and the broader community are supported to be informed and active participants in decision-making.  |
| <b>Equity</b>                          | All actions relating to the NMP focus on delivering positive health outcomes that matter most to people and their communities. All communities are supported to access safe, effective, high-quality, and affordable medicines and medicines information when needed, irrespective of diversity, background, age, location, or personal circumstance. This includes a focus on positive actions that strive to eliminate health inequities that are disproportionately experienced by groups within the community.<br><br>These groups include, but are not limited to, Aboriginal and Torres Strait Islander people, people from culturally and linguistically diverse backgrounds, those living in rural and remote areas, and other vulnerable groups. |
| <b>Partnership-based</b>               | Active, respectful, and collaborative partnerships are established and maintained across the health environment, which harness partners' skills, experience, and knowledge. Each Partner is aware of, and acts on, their contribution towards the achievement of the NMP's aim.   |
| <b>Accountability and transparency</b> | All partners are accountable for advancing the NMP's central pillars aligned to their role and contribution. This includes demonstrating the Policy's principles in action, measuring, and reporting outcomes, and always committing to act with respect and transparency.  |
| <b>Shared responsibility</b>           | All partners have a shared responsibility in working towards the achievement of the outcomes for each of the NMP's pillars in an equitable, efficient, and sustainable manner.  |
| <b>Innovation</b>                      | All partners support new and improved ways to respond to unmet needs and/or deliver greater value to individual health outcomes, the health system, or to broader society with a particular focus on medicines, medicines information and enabling technology.  |
| <b>Evidence-based</b>                  | All partners objectively apply rigorous, relevant, and current evidence to guide decision-making, related program design and appropriate communication. This should also include consideration of safety, efficacy, and effectiveness in real-world conditions.   |
| <b>Sustainability</b>                  | All partners consider the collective economic, environmental, and social impacts of the strategies, policies, programs, or initiatives they deliver to positively contribute towards the sustainability of the health system. This includes the efficient use of resources, to reduce the negative impact on the environment, without compromising the achievement of quality health outcomes.  |

## Enablers

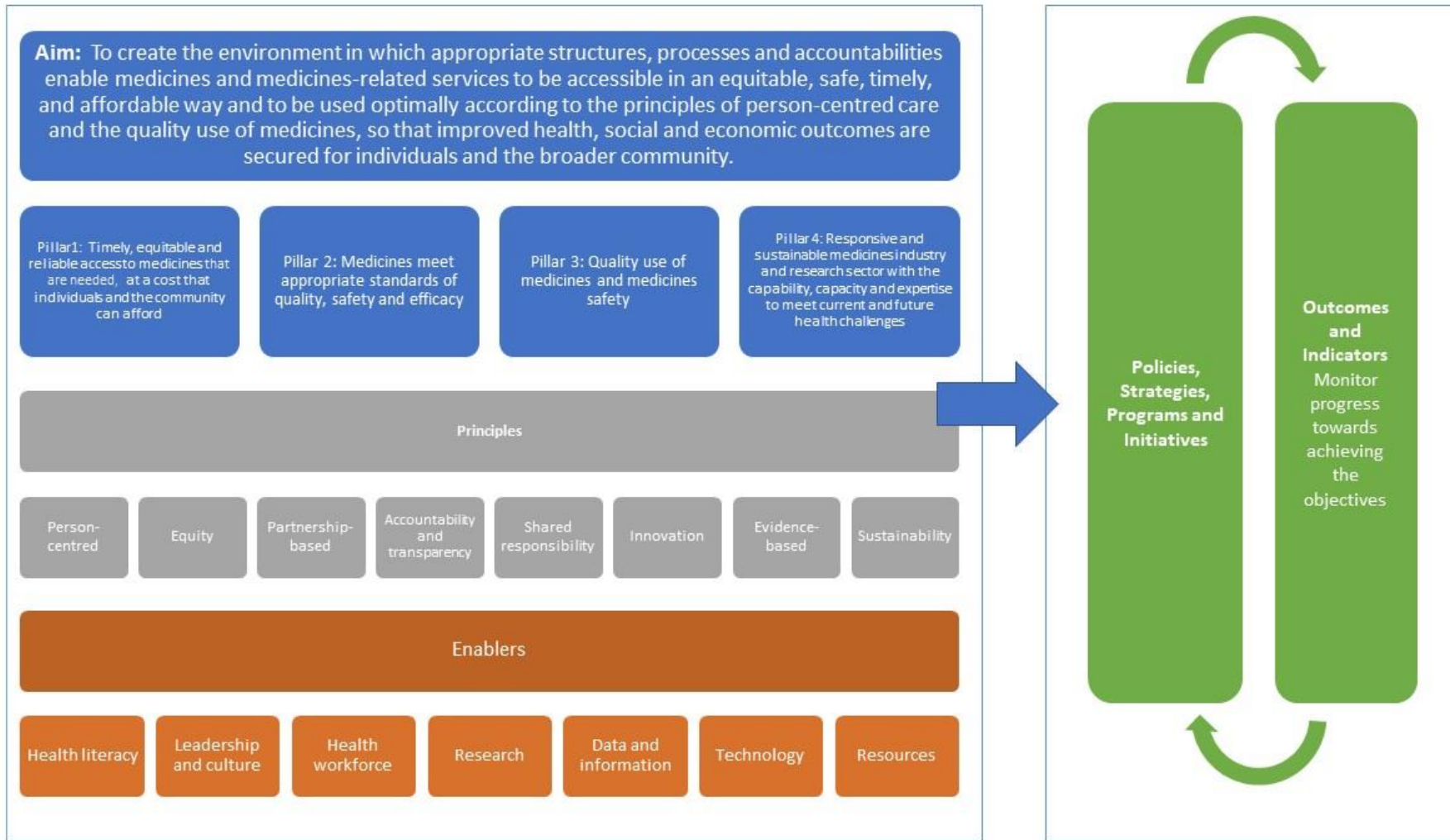
Seven enablers are critical to the success of the NMP. These include:

- **Health literacy** - that builds the skills, knowledge, motivation, and capacity of a person to access, understand, appraise, and apply information to make effective decisions about their health and health care and take appropriate action. The whole health system can respond to individuals' health literacy needs, through delivering person-centred health information, support, and services. The format and channel of delivery will be appropriate to each person's culture and language, health beliefs, accessibility, and information needs. Digital tools and technologies will be utilised to engage and support people in managing their health and wellbeing, connecting them in meaningful ways to their health teams and offering them choices for how, when, and where care is delivered.
- **Leadership and culture** - that supports innovation, cultivates efficient and aligned digital transformation, encourages the identification, pursuit, and communication of agreed strategic goals in a collaborative, respectful, flexible, adaptable, and transparent manner.
- **Health workforce** – a competent workforce that is accessible and resourced to provide co-ordinated and integrated care, working to their full scope of practice, across all health settings applying applicable and relevant best practice guidelines which are regularly updated to consider the clinical place of new technologies.
- **Research** - that deepens knowledge, generates innovations, discovers new and better medicines, reduces harms, and informs continuous improvements in the quality use of medicines and medicine safety.
- **Data and information** - that includes the responsible collection, and secure storage of appropriate data, the use and management of data that enables evidence-based decisions to improve health outcomes, quality of life, the quality use of medicines and effective value through data driven insights and digital integration.
- **Technology** - the capacity to embrace the opportunity of technology, such as digital information and technological systems and methods that are validated and interoperable to drive improvements in access, quality, safety, and efficiencies for all people across their health journey.
- **Resources** - equitable and adequate allocation, appropriate distribution, and efficient use of resources, including funding, within the medicines environment in recognition of the shared responsibility for sustainability within the broader health system.

By highlighting their importance, the NMP calls on all partners to proactively develop and promote these enablers.

Figure 1 illustrates the relationship between the components of the NMP and the essential elements that interact to guide policies, strategies, programs, and initiatives delivered in alignment with achieving the NMP's Aim.

**Figure 1 – A summary: Australia’s NMP**



## Governance

The NMP is a living document intended to guide and reinforce the behaviours of all partners, focus their efforts, and encourage greater dialogue and collaboration to achieve improvements. The NMP's governance is focused on co-ordination and shared problem solving and accountability.

Governance structures, including specific committees and working groups may be established for the policies, strategies, programs, and initiatives aligned with the NMP. These governance structures must adhere to the NMP's principles and prioritise their commitment to person-centred care by including appropriate consumer representation at all levels of governance. Mechanisms that support collaborative action and timely application of the efforts and expertise of relevant partners in setting shared priorities are vital to the Policy's success. Therefore, these structures should monitor the achievements against the Pillars of the NMP, including reporting on how the NMP's principles have been put into action.

In this context, the role of the Commonwealth is to lead and encourage collaboration between partners toward shared goals, to promote transparency in relation to accountability, reporting and communication. This includes facilitation of collaborative action on problems that cannot be solved by any one partner.

Each partner is responsible and accountable for achieving the NMP's aim and intended outcomes. Figure 2 illustrates the relationships between the NMP partners.

All partners, in line with the NMP's principles, should work collectively, collaboratively, and respectfully. All partners should also act transparently, through acknowledging and declaring conflicts of interest where they arise and engage in open communication. It is recognised that conflicts of interest will be present, and each aligned program or initiative should have processes in place to manage conflicts of interest.

This recognises that no single NMP partner can be completely responsible for achieving the NMP's aim. All partners should work together, by acknowledging and respecting the contributions of others to achieve the Policy's aim.

**Figure 2 – Partners of the NMP, with individuals, carers, families, and communities at the centre**



The following sections outline the intended outcomes for each of the Pillars, key considerations, and partners' responsibilities.



# Pillar 1: Timely, equitable and reliable access to medicines that are needed, at a cost that individuals and the community can afford

## Intended outcome

- **Medicines are affordable and accessible in an equitable and timely manner, leading to improved individual and community health outcomes and economic benefits.**

Ensuring access to medicines for all people and communities in Australia involves considering timeliness, equity, affordability, and value together with their impact on achieving improved health, social and economic benefits. The Pharmaceutical Benefits Scheme (PBS), Repatriation Pharmaceutical Benefits Scheme (RPBS), and the National Immunisation Program (NIP) are national health programs that provide subsidised access to medicines. Medicines are also accessed through public and private hospitals, clinical trials, compassionate access programs, or may be privately purchased.

## Timeliness

All communities in Australia, across geographies, population groups and specific clinical conditions, should have timely, equitable and reliable access to safe and affordable medicines required to maintain their health and/or wellbeing. Appropriate and efficient registration, health technology assessment and subsidisation processes support timely access. This includes the flexibility to rapidly respond to changing, emerging, and disruptive technologies, including innovative and highly specialised therapies and services. These processes and their outcomes need to be communicated to all stakeholders, including the public, to build and maintain the community's understanding and confidence in their application and rigour.

## Equity

Access is also an equity issue. Australia is a diverse nation and people can experience inequity of access to health care and to medicines because of their identity, background, or personal circumstance. Recognition and awareness of all factors (including quality of life, social-economic implications) that impact health outcomes are critical.

Australia's Aboriginal and Torres Strait Islander peoples can experience substantial access barriers, and partnerships to address these access issues should be progressed. Partnerships and shared decision-making that include Aboriginal and Torres Strait Islander self-determination and leadership is needed to identify and drive priorities and solutions.

Australia is also home to people with different migration experiences and diverse cultural and linguistic backgrounds. Ensuring equity of access to medicines means acknowledging that diverse health beliefs, shaped by interdependent social, economic, and cultural factors can influence a person's health.

Progression of science and medicine can lead to inequity in access to needed medicines for some people living with rare diseases including under-recognised conditions. These inequities can be caused by the technical complexities of generating the data and evidence required to assess treatments used for such rare conditions. The Policy supports the ongoing commitment by all Partners to work collaboratively together in addressing such inequities.

All communities in Australia, no matter their location, should have timely access to safe and affordable medicines and related services required to maintain their health and/or wellbeing. Health systems can further support this by recognising health literacy needs, education, skills,

and needs related to internet and telehealth access. Efficient and effective distribution and supply networks should exist, including to rural and remote communities. The location of care delivery should not affect 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.

## Affordability and value-based health care

Affordability is another dimension of this Pillar both for individuals and for the community. At the individual level, addressing cost barriers related to access to medicines or related services is critical.

At the community level, within the constraints of limited budgets, robust and transparent prioritisation of spending on medicines is critical for co-ordinated, equitable and efficient supply and use of medicines. Investment and disinvestment decisions are informed by health technology assessment processes. This ensures that subsidising new medicines is an economically considered investment that the whole community can afford. Following these assessments, financing, price, and supply arrangements must be secured. Where new therapies, or classes of therapies emerge, financing arrangements for medicines should be pre-determined between Governments and other stakeholders to avoid incentives for cost-shifting between levels of government or other funders, or other perverse financial incentives. A fair distribution of costs and savings between the partners should be achieved.

## Responsible partners

Access to medicines relies on all partners playing their role in the medicines lifecycle. All partners, in line with the NMP's principles, should not be limited by transactional interactions and work together collaboratively and respectfully. This involves each partner recognising interdependence with the others, respecting the expertise of others, and focusing on delivering a shared commitment to timely, equitable and affordable access to medicines.

In broad terms, the partners identified in Table 2 have prime carriage of work to advance the achievement of this Pillar.

**Table 2 – Partners and their broad responsibilities and functions to advance Pillar 1**

| Partner                                | Broad responsibilities and functions   | Intended outcomes   |
|--|--|---|
| Consumer organisations and peak bodies | To support consumer engagement and participation in the health sector at individual, service, and system levels.<br>To support the distribution of information, coordination, and advocacy for individuals and groups, particularly those who may experience inequity of access.   | Medicines are affordable and accessible for all people and communities in Australia, in an equitable and timely manner, leading to improved individual and community health outcomes and economic benefits. |
| Health practitioners                   | To recommend, prescribe or provide medicines applying a person-centred approach and promote the appropriate quality use of medicines and medicines safety.   |   |
| Commonwealth Government                | To deliver national health programs that facilitate affordable, equitable and timely access to medicines.<br>To be accountable for proactive engagement and alignment across partner jurisdictions including promoting interoperability.<br>To facilitate an active and progressive clinical trial sector through collaboration with state and territory governments and industry and by the facilitation of nationally consistent platforms, processes, and guidelines. |   |

|                                 |  |  |
|---------------------------------|--|--|
| State and territory governments | To deliver access to medicines through publicly funded services and being accountable for proactive engagement and alignment across partner jurisdictions, ensuring interoperability.  |  |
| Industry                        | To research, develop and supply medicines in a timely and sustainable way, at a cost which is sustainable, and supported by evidence and information.  |  |
| Researchers                     | To lead research and clinical trials that promote quality and safety, are conducted in accordance with national and international guidance and which support Australians in accessing new and better medicines and therapies. To carry out research into innovative and improved ways to use existing medicines. |  |
| Professional organisations      | To develop and support the use of systems and processes which promote timely, equitable and reliable access to medicines   |  |
| Media                           | To report responsibly on issues relating to timely, equitable reliable and affordability access.   |  |

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## Pillar 2: Medicines meet appropriate standards of quality, safety and efficacy

### Intended Outcomes:

- **Medicines are safe and effective, and their labelling and supporting information is readily available and supports the quality and safe use of medicines.**
- **Australia's medicines regulatory processes are efficient, protect health and safety, and are trusted by the community.**

The regulation of medicines in Australia is led by the Therapeutic Goods Administration (TGA), which assesses the quality, safety, and efficacy of specific medicines, and regulates the supply, manufacturing, and advertising of medicines.

There may be potential risks as well as benefits associated with the use of medicines, and the relative risks and benefits need to be considered prior prescribing or consuming a medicine. These risks, as well as the potential public health implications, are addressed through poisons scheduling or other controls. These controls may require intervention by suitably qualified health professionals to ensure appropriate use.

### Protecting the health and safety of the community

Ensuring quality, safety and efficacy is integral to the medicines lifecycle. Ongoing quality assurance processes guarantee that medicines continue to meet appropriate standards of quality, safety and efficacy for specified conditions or indications.

These processes include pre-market assessment and post-market surveillance, the outcomes of which should be available in the public domain. This promotes transparency in demonstrating how quality, safety and efficacy standards have been achieved.

In protecting the health and safety of the community through their use of medicines, all partners should strive to:

- Improve access to up-to-date, understandable, evidence-based information to assist all people in their health care decision-making;
- Build the knowledge of people about key aspects of medicines regulation, such as the reporting of adverse events, to support the quality use of medicines;
- Encourage active participation by all partners to assist in identifying and reporting potential problems with medicines use, quality, safety and efficacy;
- Ensure that all suppliers, including researchers and industry, understand and meet their requirements as outlined in relevant legislation.

### Effective, timely and risk-proportionate regulation

Australia's medicines regulatory system strives to protect the health and safety of the community by adopting an approach that is contemporary, adaptable and supports innovation.

This can be achieved through the:

- Presence of rational and transparent criteria and processes to support the evaluation and management of a nationally and internationally standardised approach to the regulation of medicines.

- Promotion and vigorous pursuit of collaborative opportunities to achieve regional and international harmonisation of regulatory requirements to reduce duplication and unnecessary restrictions, and to facilitate early availability of therapeutic advances.
- Regulation that ensures appropriate practices are followed in the research, development, production, supply, and disposal of medicines.
- Adoption of a risk/benefit-based approach to regulation.
- Clear and transparent processes that actively support reporting of and response to any regulatory problems or breaches with a prompt and proportionate response that is clearly and transparently communicated to all partners and affected individuals.
- Accurate and understandable information that supports prescribing, dispensing and quality use of a medicines by all users.
- Flexible and adaptable processes where appropriate in response to public health issues and/or high unmet clinical need.
- Maintenance of a positive and co-operative relationship between regulators and the medicines industry, with effective models for co-regulation used wherever appropriate.

## Responsible partners

Regulatory arrangements are primarily the responsibility of the TGA, in co-operation with state and territory governments and industry. These partners, together with health practitioners and consumers, work together to maintain an efficient, relevant registration and scheduling process. These partners, and examples of their broad responsibilities and functions, are outlined in Table 3.

**Table 3 – Partners and their broad responsibilities and functions to advance Pillar 2**

| Partner   | Broad responsibilities and functions   | Intended Outcomes   |
|---|--|---|
| Consumer organisations, individuals, carers, and families | To alert health practitioners and/ or health services and regulators to adverse events or product quality issues.<br>To engage with the Australian community and individuals to build health literacy, that promotes an understanding of medicines information and supports the safe and quality use of medicines.   | <ul style="list-style-type: none"> <li>• Medicines are safe and effective, and their labelling and supporting information is readily available and supports the quality and safe use of medicines.</li> <li>• Australia's medicines regulatory processes are efficient, protect health and safety, and are trusted by the community.</li> </ul> |
| Health practitioners                                      | To prescribe, supply or administer medicines in line with current and best practice guidelines, and in consultation with the person taking the medicine, carers, and families if appropriate.<br>To support patient engagement in clinical trials, where appropriate. To commit to undertaking coordinated pharmacovigilance including monitoring and reporting of adverse effects or any other medicine related events and medicines safety in clinical practice. |   |
| All governments and regulatory agencies                   | To work collaboratively and consistently to achieve a best practice, responsive, relevant regulatory environment, and system.<br>To encourage the use of best practice communication principles in the provision of medicines information, including labelling, Product Information (PI) and Consumer Medicines Information (CMI).   |   |

|                            |   |  |
|----------------------------|---|--|
| Industry and researchers   | To adhere to appropriate research and development, manufacturing, and regulatory standards, including coordinated post-marketing safety monitoring and reporting. |  |
| Professional Organisations | To promote best practice in reporting adverse effects or other medicines related issues to appropriate authorities.   |  |
| Media                      | To inform the public of issues regarding product safety and quality in a responsible and accurate manner.   |  |

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## Pillar 3: Quality use of medicines and medicines safety

### Intended Outcome:

- **Consumers and their carers actively participate in prevention, management and treatment of ill health and medicines use through shared decision making.**
- **When the use of medicines is appropriate, to make the best possible selection for an individual and to promote their use to optimise health outcomes and minimise harm.**

The community in Australia, of all ages and in all circumstances, deserve to have medicines which are the best and most appropriate for them, and to be supported to get the greatest benefit and the least harm. The quality use of medicines and medicines safety is a National Health Priority Area.

The quality use of medicines includes three elements:

- **Selecting medicines management options appropriately** – recognising that medicines are often appropriate in managing conditions and treating illnesses, but that they may not always be the most appropriate option. Therefore self-care, prevention, and other treatment or management options should be considered and be accessible, when required.
- **Choosing suitable medicines if a medicine is considered necessary** – by weighing up both clinical and non-clinical factors, such as the benefits and potential harms, the cost to the individual and community.
- **Using medicines safely and effectively to get the best possible results** – including monitoring outcomes, minimising misuse, overuse and underuse, and empowering people to have the knowledge and skills to make decisions to use medicines safely and effectively.

The quality use of medicines applies equally to decisions about medicine use by individuals and decisions that affect the health of the broader community.

### Person-centred care and shared decision making improves health outcomes and quality use of medicines

Person-centred care, including shared decision making, is essential to the quality use of medicines. Health literacy better enables people to actively participate in shared decision making with their health practitioner about whether or not to use a medicine. Health literacy involves people knowing how to access, process and use health information which is relevant and meaningful to them in a way that benefits their health, and includes the ability to access relevant and accurate information.

The NMP partners recognise that this relies on a collaborative effort in:

- Building culturally appropriate, person-centred, health environments for people to access appropriate health information, support, and services, including that which is digitally enabled.
- Actively developing the skills and confidence of individuals to self-care and manage their own health and medicines. This includes the support of digital technologies and engagement platforms, including when and where to seek help at an appropriate level in the health system.
- Engaging people to be active, empowered, and informed participants in their care.
- Actively encouraging people to ask for, and use objective, evidence-based information, resources, and services as part of a shared approach to informed decision-making.

- Providing prompt, appropriate, targeted, and tailored support to facilitate individuals' understanding of the risks and benefits of medicines and the role of non-medicines options to achieve optimal health outcomes.
- Building collective awareness of the place of medicines in the broader context of health and society.

The NMP recognises that people with low health literacy are likely to be less well equipped to take appropriate action to prevent and manage disease and ill health. The quality use of medicines therefore requires the prioritisation of hard-to-reach groups in the co-design, implementation and evaluation of health services and literacy interventions to address inequity in accessing care

All NMP partners recognise that focusing on health literacy is not limited to supporting the quality use of medicines but contributes towards broader positive outcomes for individuals' engagement with the health system, as they move between supports and services across their life.

## Promoting the quality use of medicines and medicines safety across the health system

Reducing harm and promoting the best possible use of medicines is a continuous process that requires health professionals to be up to date with the development and appropriate use of existing, new, and emerging medicines and health technologies available in Australia. Medicines whether prescribed, recommended, or self-selected should be used only when clinically appropriate, in the context of best practice and through informed decision-making about pharmacological and non-pharmacological treatment options.

Efforts by all partners to minimise the risk of harm from the overuse, underuse and misuse of medicines is crucial. This includes a particular focus on reducing antimicrobial resistance, monitoring, and responding to inappropriate polypharmacy and the deprescribing of unnecessary medicines, reducing harm from high-risk medicines and improving medication safety in all settings including at transitions of care.

The NMP partners should recognise that supporting health professionals and the health system in the quality use of medicines and medicines safety requires:

- Leadership that builds a culture of coordination and collaboration to collectively solve challenges associated with promoting the quality use of medicines and medicine safety.
- Policy development and implementation, such as guidelines, accreditation and clinical information systems that focus action and provide structure to guide the safe and quality use of medicines. This includes recognising the increasing effectiveness and interoperability of digital systems, digital therapeutics, and smart technologies on prescribing.
- Education, training, and awareness campaigns that promote best practice, and ensure that health professionals safely prescribe, dispense, and administer medicines, monitor their effects, deprescribe when necessary, and engage individuals in decision-making about their medicines use.
- Access to objective, credible, evidence-based, and current information curated for the Australian health system that spans the full life cycle of medicine availability, and to respond to misinformation and the unethical promotion of medicines.
- Research, evaluation, and data collection to enable timely and efficient monitoring, analysis and reporting of the experiences and outcomes of medicines use to investigate, communicate, and drive continuous improvements in medicines safety.



## Responsible partners

The quality use of medicines relies on purposeful effort by all partners. In broad terms, the following partners have prime carriage of work to advance the achievement of this Pillar. These partners, and examples of their broad responsibilities and functions in relation to this Pillar, are shown in Table 4.

**Table 4 – Partners and their broad responsibilities and functions to advance Pillar 3**

| Partner   | Broad responsibilities and functions  | Intended Outcomes  |
|---|---|--|
| Individuals, carers, and families                   | With support from other partners, to build their knowledge and understanding of medicines use, including the benefits and risks in order to ensure the safe and appropriate use of medicines.   | <ul style="list-style-type: none"> <li>• Consumers and their carers actively participate in prevention, management and treatment of ill health and medicines use through shared decision making.</li> <li>• When the use of medicines is appropriate, to make the best possible selection for an individual and to promote their use to optimise health outcomes and minimise harm.</li> </ul> |
| Consumer organisations                              | With support from other partners, to promote and build health literacy among the Australian community, to enable participation in shared decision-making about medicines. This includes increasing knowledge and skills in the interpretation and use of information about the risks and benefits of medicines, and ensuring this information is accessible and appropriate to an individuals' needs.   |  |
| Health practitioners and professional organisations | To adopt and implement the quality use of medicines and medicines safety into practice. This includes appropriate communication of risk and benefit information to support decision-making. To maintain compliance with up-to-date best practice guidance on prescribing, supply, administration and deprescribing of medicines and the use of effective and respectful communication to ensure better health outcomes. To use contemporary resources to support practice, such as digital health products and software, to seamlessly share health information with individuals and across the health system.  |  |
| All governments                                     | To coordinate and fund programs and processes that promote the quality use of medicines and medicines safety, including addressing misuse, overuse and harmful use of medicines, and raising awareness among the public and health professionals.   |  |
| Industry  | <p>To commit to and promote the quality use of medicines across the medicines lifecycle, including in the research, development, manufacture and supply stages.</p> <p>To commit to minimising the misuse and overuse of medicines, including transparent collaboration with other partners to identify and address misuse.</p> <p>To ensure evidence-based, up-to-date, balanced and understandable information is communicated to health professionals and consumers, including maintaining publicly available resources about the efficacy and safety of all medicines, aligned to the Medicines Australia Code of Conduct and to Australian and international standards and regulation.</p> |  |

|   |   |  |
|---|---|--|
| Health educators, including higher education and professional training bodies | To promote the quality use of medicines and medicines safety in educational curricula, including in undergraduate, postgraduate, and continuing professional development education.   |  |
| Media   | To responsibly report on medicines and issues associated with their use.<br>To monitor and ensure that digital platforms used to provide information, protect individuals against harm from online disinformation and misinformation. |  |

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## Pillar 4: Responsive and sustainable medicines industry and research sector with the capability, capacity and expertise to meet current and future health challenges

### Intended Outcomes:

- **Industry is proactively engaged and supported in meeting Australia's medicine needs, is recognised for its contribution to improving health outcomes, and operates within an environment of innovation.**
- **The research sector is supported to improve medicines and medicine services and the quality and safety of medicines, including support for commercialisation of innovations that improve health outcomes.**

The medicines industry and the medical and pharmaceutical research sectors significantly contribute to achieving positive health outcomes within the Australian communities and growth in economic development in Australia. A responsive, thriving, and sustainable medicines industry and research sectors are critical to the research, development, manufacture, and commercial supply of medicines, that Australians need. Further, there is a need to have a responsive and reliable supply chain network which enables a timely and equitable distribution of medicines throughout the country. The NMP commits all partners to a co-ordinated and aligned approach between health, research, and industry policy, to maintain a consistent and supportive environment for industry and researchers.

### Maintaining a consistent and supportive environment for industry and researchers

Partnerships between governments, industry and researchers are needed so that the Australian community can continue to access medicines that deliver health improvements and benefits to the Australian community, and to realise and promote the economic benefits of a thriving industry.

Driving scale, competitiveness, and resilience, while maintaining safety and quality, in medical product manufacturing is a focus of industry policy. This is achieved through increasing the volume of investment in commercialisation, encouraging translation of local research, building supply chain integration, and focusing on positive end-to-end collaboration.

Supporting this environment are contributions from Australia's and International science, research, and innovation capabilities. These capabilities can be harnessed by government and industry to transform and build on emerging opportunities. This includes embracing new technologies, processes, and practices.

Conditions that enable successful collaboration between governments, industry and researchers that can lead to economies of scale, knowledge exchange, and drive innovation should be supported.

International competitiveness will only be achieved if Australian industry can continue to operate in a global environment, where there is alignment of international intellectual property protection standards under relevant international instruments, and medical research and innovation is supported through Government investment and positive Industry policy.

Regulatory partners commit to continuing harmonisation of standards and/or mutual recognition, and to the promotion of a strong export culture consistent with standards and ethics endorsed by the World Health Organization. Industry is likewise committed to these objectives and recognises the need to be forward-looking and proactive.

## Responsible partners

All partners need to enact their part of progressing the NMP, in a manner that is both aware and respectful of the interdependence between, and expertise of, other partners.

In broad terms, the following partners have prime carriage of work to advance the achievement of this Pillar. These partners, and examples of their broad responsibilities and functions in relation to this Pillar, are shown in Table 5.

**Table 5 – Partners, and their broad responsibilities and functions to advance Pillar 4**

| Partner   | Broad responsibilities and functions   | Intended Outcomes  |
|---|--|--|
| Industry and researchers  | <p>To ensure that research, development, manufacturing and commercial supply practices follow international best practice processes and procedures to ensure quality, safety, and efficiency throughout the development and supply chains.</p> <p>To identify further opportunities to improve health outcomes, through the use of innovative research and technological advances.</p> | <ul style="list-style-type: none"> <li>• Industry is proactively engaged and supported in meeting Australia's medicine needs, is recognised for its contribution to improving health outcomes, and operates within an environment of innovation.</li> <li>• The research sector is supported to improve medicines and medicine services and the quality and safety of medicines, including support for commercialisation of innovations that improve health outcomes.</li> </ul> |
| All governments   | <p>To promote an efficient regulatory and reimbursement regime for medicines. To pursue international harmonisations and collaboration while maintaining world's best practice.</p> <p>To create and support a positive, stable and conducive business environment to encourage the growth of the industry and research.</p>   |  |
| Individuals, carers and their families  | <p>To recognise the health benefits of accessing high quality medicines and efforts to improve evidence-based, up-to-date information through participation in clinical research.</p>  |  |
| Health practitioners, Professional organisations, Health Educators, Consumer Organisations. | <p>To work constructively where appropriate with industry and researchers in new medicines development and in related educational initiatives to optimise the quality use of medicines.</p>  |  |

## Implementation

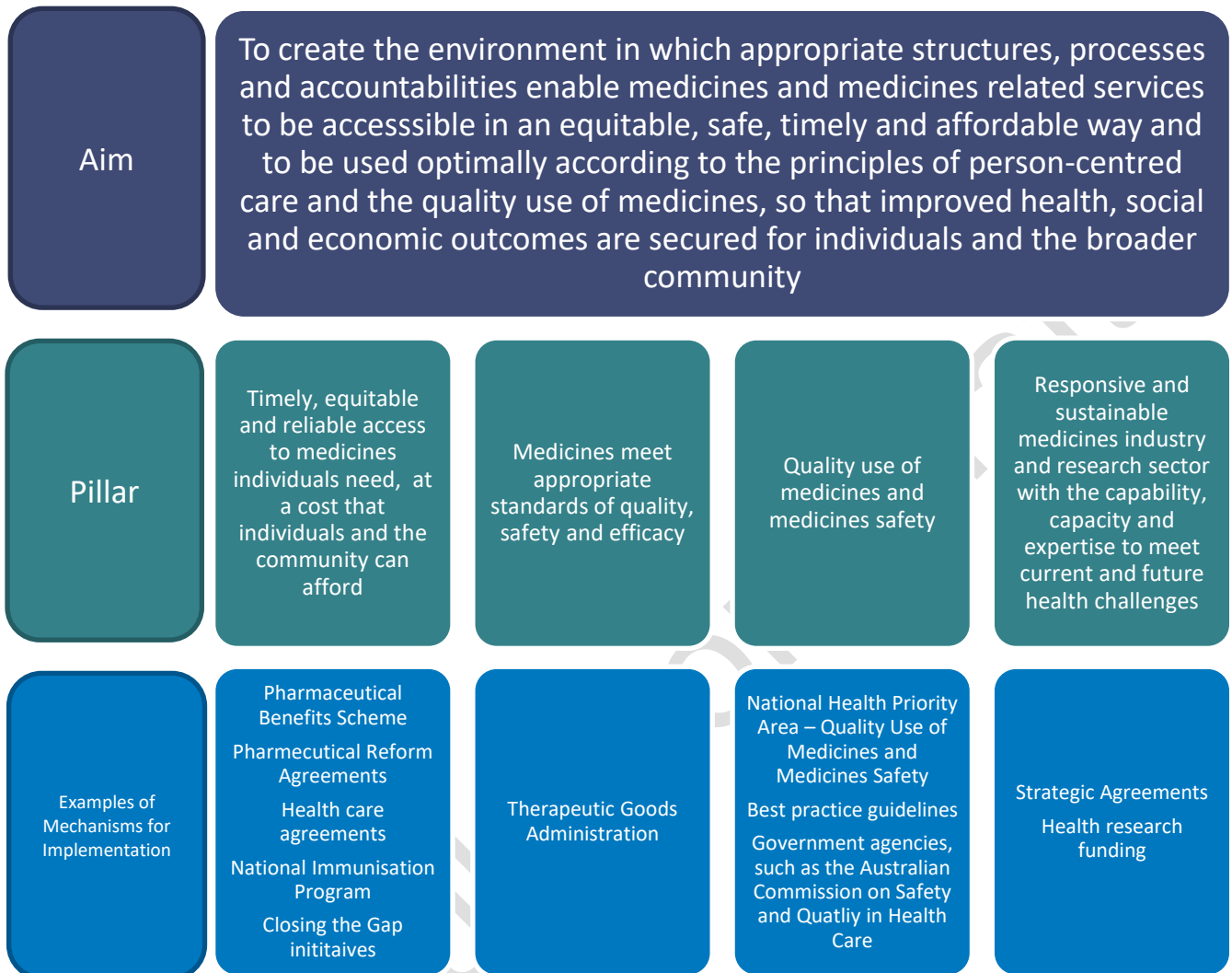
Australia's NMP functions as a co-ordinating framework that sets out the Pillars and intended outcomes for all partners to work towards. As no single partner can be completely responsible for achieving the policy's aim, its implementation is a collective responsibility appropriately defined and documented at the program level by each partner. The role of the Commonwealth will be to facilitate, coordinate and monitor the identification, engagement, and commitment of partners to achieving the Aim of the NMP, within an agreed transparent reporting structure.

Each partner should communicate the linkages between their actions, connection to the Pillars and the implementation of the NMP's Principles, to support collective understanding of what is being done to achieve the policy's aims and achieving the agreed outcomes. The development of policies, services, programs, and initiatives involving medicines should include a requirement to identify whether they are consistent with the Pillars and Principles of the NMP. This information should be meaningful to individuals, be accessible, and understood regardless of the mode by which the content is delivered. This is important in terms of governance and transparency. It ensures there is a shared understanding by the NMP partners of the strategies, activities, programs, and initiatives undertaken to implement the NMP.

As an example, the Commonwealth's responsibilities in contributing to the NMP's pillars and intended outcomes are illustrated in Figure 3. All partners are encouraged to map out the areas where they can deliver and/or influence action according to their remit. Achievement of the policy's aims and outcomes is the collective responsibility of all partners.

The aim of Australia's NMP is to create the environment in which appropriate structures, processes and accountabilities enable medicines and medicines-related services to be accessible in an equitable, safe, timely, and affordable way and to be used optimally according to the principles of person-centred care and the quality use of medicines, so that improved health, social and economic outcomes are secured for individuals and the broader community.

**Figure 3 – Examples of implementation mechanisms led by the Commonwealth under each of the NMP’s Pillars**



## Evaluation

Australia's NMP describes the intended outcomes that the partners should collectively strive to achieve. The monitoring and evaluation of the collective progress towards the intended outcomes will enable the acknowledgement of achievements and identification of emerging priorities.

Consistent with the Policy's principle of transparency and accountability, each partner is obliged to make publicly available the results of monitoring and evaluation activities associated with their NMP aligned programs. The sharing of information and learnings supports the collaborative and respectful approach to progressing the NMP.

Governance structures, including specific committees and working groups may be established for the policies, strategies, programs, and initiatives aligned with the NMP. These structures will monitor the achievement of the intended outcomes against the Pillars of the NMP including reporting on how the NMP's principles have been put into action. A partner, or group of partners can develop their own organisational reporting processes to monitor their progress and highlight how the NMP's principles have been achieved in an effective and efficient manner.

Figure 4 presents guidance for partners to consider when demonstrating their progress in achieving the NMP's pillars, including reporting in accountability documents, such as annual reports.

**Figure 4 – Guidance for components of an evaluation strategy aligned to the NMP**

|  |   |
|--|---|
| <p>What are the questions we are asking?</p>           | <ul style="list-style-type: none"> <li>• How have the NMP's principles been seen in the development and implementation of actions?</li> <li>• How have these actions contributed towards achievement of the aspirational outcomes of the policy's pillars?</li> </ul> |
| <p>What is being evaluated?</p>                        | <p>Policies, Strategies, Programs and Services</p>  |
| <p>How are we measuring progress?</p>                  | <p>Indicators<br/><i>National and program-level indicators</i></p>  |
| <p>Who is responsible for measuring and reporting?</p> | <p>Each policy partner delivering actions aligned to the policy's pillars</p>   |
| <p>How are we communicating the results?</p>           | <p>Annual Reports, Summaries, Conferences, Ministerial/Government statements</p>  |